NATIONAL QUALITY FORUM

Moderator: Andrew Lyzenga
July 14, 2014
2:00 p.m. ET

Operator: Welcome to the conference. Please note today's call is being recorded. Please stand by.

Andrew Lyzenga: Hi, everybody. This is Andrew Lyzenga from the National Quality Forum. This is the Patient Safety Standing Committee's Post Draft Report Comment Call. What we're going to be doing today is just taking a quick review over the comments that were submitted during the public comment period.

We are not going to be doing any voting on this call. We will be – for any voting necessary, we will be doing that online in a – at a point subsequent to this call. So just to let everybody know that. We won't be doing any voting today. We may be making some decisions on whether or not to reconsider take up reconsideration vote on some of these measures. Otherwise, we're just going to have discussion at this point and then we will use that to inform our voting within the next week or so, yes – an online survey.

With that, I'll just see if Dr. Septimus, do you have any introductory remarks or anything you want to say or should we just move into our review of the comments?

I'm not hearing Ed. I thought he was on here. But I guess …

Ed Septimus: That was – do you not hear me?

Andrew Lyzenga: Yes, I couldn't hear. I think you were on mute.

Ed Septimus: I may have been. Yes, that's perfectly good. I think we just want to jump in and listen to the comments. OK. Great.

Andrew Lyzenga: Let's do that and you all should have received a memo that gives a brief summary of some of the major comments and themes and we are just going – planning to sort of walk through that to address the comments. And I'll just briefly sort of describe what the – what the comments were on each measure. And we'll skip over some because there are – all of the comments, we didn't think required a formal response from the committee. But please do let us know if there is something that we skip over and we think that is more of discussion and you think the group should focus a bit of conversation around that. Just let us know. Otherwise, we may skip over some of the comments that don't really require a formal response from the committee.

So, let's see. There is a – I'll just note that there were a number of comments around the HAI measures, the CAUTI measure and the CLABSI measure just asking for, expressing a desired to be an outcome measure similar to this developed into the outpatient settings.

We figured that the steering committee largely agreed with that and we'll have that to our recommendations in the report on future measure development. But let just know if you object to that or if you have any particular thoughts that you'd like to share on that topic.

We did – so for measure 0464, this is Prevention of Catheter-Related Bloodstream Infections. This is an (AFA) measure and we did get a request from the developer themselves to hold some further discussion on this measure and to reconsider the decision not to recommend the measure.

Largely, the developer sited the reductions that have occurred in CLABSI rates since the measure has been endorsed and reported by an anesthesiologist. And noted that there is a remaining gap and adherence to the measure and just sort of express that they believe this measure remains very important and should not be retired from endorsement by the committee.

Do you think …

Lisa McGiffert: This is Lisa McGiffert. Can I ask you a question?

Andrew Lyzenga: Yes, go ahead.

Lisa McGiffert: This is the measure that's a process measure, correct?

Andrew Lyzenga: It is. This is a process measure, correct.

Lisa McGiffert: And who is the developer?

Andrew Lyzenga: The American Society of Anesthesiologist.

Lisa McGiffert: OK. OK, thank you.

Andrew Lyzenga: Yes. So are there any thoughts on that subject from the committee.

Female: OK.

Andrew Lyzenga: Is there any interest in reconsidering your decision on this measure considering the developers comments?

Lisa McGiffert: The developer is asking us to continue this measure and we recommend it to just discontinue it because there was a 90 some percent compliance or?

Andrew Lyzenga: Right. Yes.

Lisa McGiffert: Remind me.

Andrew Lyzenga: I believe that is correct (pull up) the report, yes.

Lisa McGiffert: And this is a …

Andrew Lyzenga: And I think one of the issues with this measure was that the evidence really linking use of it to (reduce) infections was not strong as the – you know I think that was a major point of contention, was that the evidence is not totally clear linking us to outcomes that we do have an outcome measure for this.

Laura Ardizzone: This is Laura Ardizzone. I just wanted to add too that the APIC are kind of, if we could prevent, present the balance kind of point here, they agreed with us

that we should get rid of this not continue to endorse this measure because it wasn't so reliable and valid.

Andrew Lyzenga: Yes, thanks Laura. We did give that comment in support of the committee's decision as well.

Any other thoughts or comments from the committee?

So we will, I think at least tentatively, it sounds like the committee does not want to reconsider their vote. But we'll follow up after this via e-mail and maybe get a more formal show of hands or vote on that question of whether to reconsider the measure. But it sounds like we're not leaning towards that.

Laura Ardizzone: Yes.

Andrew Lyzenga: So let's go ahead and – OK, let's go ahead and move on to the next measure. There's a variety of measures around the various radiation safety measures. A number of people thought that it was a very important area to begin measurement and we're concerned that the committee's recommendation to not endorsed the measures might send the signal to the field that radiation safety is not an important issue or that there is not a concern about radiation exposure levels. There were – I think I believe from supportive measure, it's on (comment) supportive of the committee's decision as well. But we just wanted to see if the committee had any thoughts about the comments and whether you'd like to consider re-voting on that measure either or the set of radiation safety measures.

Michelle Schreiber: Yes, this is – this is Michelle Schreiber …

Lisa McGiffert: This is Lisa McGiffert. I'd like to get in the queue.

Andrew Lyzenga: OK, go ahead. Michelle you can – go ahead Michelle.

Michelle Schreiber: Thank you. Yes, thanks for this opportunity to comment. I've been one of the people reviewing this and I think by the end of the session, many of us felt badly that none of the radiation measures had actually passed. This was the first one that was presented and it was voted down because it was an outcomes

measure and we really didn't go any further. In subsequent deliberations that we had, it became a parent that there was an exception that we could have moved forward and I wonder if we had applied that exception for this particular argument if there would have been more support at the time.

So I guess, I'm one who might be in favor of re-discussing it or at least some of the radiology measures, understanding full well that we didn't have a very good outcome for measure for it. But that this could be one that sell into that exception category.

Andrew Lyzenga: OK, thank …

Lisa McGiffert: This is Lisa McGiffert: I'd like to speak when I have a minute.

Andrew Lyzenga: Sure. Go ahead Lisa.

Lisa McGiffert: Yes. I think that it's really important that we, in our report that we address the importance of these, measuring this and the disappointment of the committee had that we did not have a good outcome measure. And it was my feeling that if the developers were pushed hard enough they would come up with a good outcome measure. And I'm very concerned that if we go with some of these process measures, they'll just slide along for years and years and years without an outcome measure and I just think that we could make it really for strong statement about why you know everybody thought was an important thing to measure. But that these did not (keep) asked the problem.

Andrew Lyzenga: OK. Thanks Lisa (inaudible) at this point and we would certainly – in any case, we will certainly (inaudible). Go ahead. Go ahead.

Kimberly Applegate: Yes, this is Kimberly Applegate and I hear what you're saying. I think that and someone's whose very (kind) to get that outcomes right now. The outcomes we have on the (sentinel) events that the joint commission requires for skin burn and those are very fair.

So, in terms of daily use, I think what we want to do is, I mean we have to think little differently about what we're trying to achieve here which is education in awareness which is what we're doing in a lot of safety culture

metrics. And I would argue that we are making huge steps if we have a process measure and I'm not sure that we want to climb the whole mountain right now and wait for an outcome session because right now, we cannot link medical radiations with cancer.

What we care to do is say that there might be a link and I think if you're careful about what you read and I can give everybody (quality) of information from the scientist who have spent their entire careers looking at this in the national (counsel) for radiation protections, there is no definitely link. I'm very concern there might be as a pediatric radiologist. And so we want to be very careful and we want to be more prudent that we've been especially in the United States as radiation.

So, I think, that's where we want to be if we want to be more careful than we've been about our use of radiation. And what we're doing is we're making it very, very easy to use these machines without being educated and how to use them well. So, I just want to put it out there as where our goal should be in terms of education and better use of these machines by people who have no training in them.

Stephen Lawless: This is Stephen Lawless, (inaudible) more than a comment and see if I could talk?

Andrew Lyzenga: Yes, absolutely.

Stephen Lawless: I agree with actually both of all the speakers so far with this. I think that from an NQF standpoint and the turndown of the some of the measures we're talking about that. I guess from an – maybe if my, I need guidance from the NQF in terms of where NQF is going. We have a lot to process measures which are very tactical measures versus the NQF want to be lock into 500 different measures on processes first and it be really (purist), thank people for all the things they're submitting. Not saying they gather (hit) the list of NQF, it's not using more.

But the way we think would want to go with that. That wanted to become here the overarching outcomes we want, all of our process, overarching

processes and be able to clear a success or that they want to have every step along the process be guided by a process measure.

You know and I would say that that's a debate that is certainly occurring across different committees quite often. And I think it's less you know the – I don't think we want to give you too much direction as sort of NQF. But as a standing committee with the amount – sort of the responsibility for stewarding this portfolio of measures and patient safety, I think you as the committee should be just giving up input on that whether you know you think we should be moving towards outcomes in an any given area. Or if there should be a balance the process outcome – process measures. That's something that we're certainly very eager to hear from you in terms of the feedback, we should just giving to developers and that we'll go in the report as guidance to developers and sort of feedback on feature measure development efforts.

Leslie Schultz: This is Leslie Schultz. To that end, we don't ask the radiation measure now. I think we feel the needs for having one and starting spot would be a process measure that could rally folks around the education and understanding and asking some better questions but has something in the portfolio that we can agree upon and build forth outcome measures. We have nothing right now.

Male: Right and just to comment on that. So you know one thing that's evolved over the years with NQF is the standard by which the measures are graded against that the various criteria you know the – that the threshold for getting through the NQF process for process measures is higher. You know certainly we want thing – processes that are clearly targeted outcomes.

So, just – as you think through this, I think that that was one of the discussion points for these measures and that's why you know they're certainly desire for outcome measures in this area or process measures that are clearly charged outcomes.

Martha Deed: Yes, this is Martha Deed.

Andrew Lyzenga: Yes, go ahead Martha.

Martha Deed: Yes, I've been very concerned about this particular measure, set of measures and how the voting went and I'm – I was quite struck by the commenter who made the point which I'm somewhat familiar with that a poor – you know an overdose reaction to radiation of any kind can take years to develop and that consequently having proof that of a cause and effect relationship could be you know it's easily could be a decade off and maybe further than that.

And meanwhile, what do we do to protect patients if we can do anything at all. And what came to me which may my naivete is that if we can take a closer look of what the other developed countries are doing and the European standards for this kind of issues. Maybe we can get a measure that way that would be workable at least for a few years.

Kimberly Applegate: I just want to tell you, this is Kimberly. This has been long required in off the United States. Yes, they have any ability to record this policy European standards and that's based on the international counsel for radiation protection, the basic safety standards they must record all the data, all the radiation data (inaudible).

Lisa McGiffert: So this is Lisa McGiffert again. I think we – it would be – I would recommend if this is revisited that needs to be revisited in another face-to-face with going through this, we went through this (pain) mistakenly and I do believe that it should be you know. the radiation level should be measured and that should be the measure. That they should be measured and they should be published not just measured and shown to the people who are using it but to show it to the patients too.

And so, if we are to revisit this and not go with the vote that we made face to face, I think we need to have another meetings and go over all the evidence and all the things we've discussed because we did discuss this quite thoroughly and there was a lot of disappointment in not having good measures and having measures that have a fee to them and all kinds of things that came up during the discussions needed to be revisited.

Andrew Lyzenga: All right, so we'll maybe follow up with the committee again to see whether there is what kind of interest there is and reconsidering the measure. I should

note that we actually have been gotten some communication from the American College of Radiology. They were one of the developers of the couple of radiation safety measures and they are – we're in discussions with them about some additional measures that they – or have in development. I believe, they have a number of outcome measures and of different types.

So they certainly are moving forward I think in response to the committee's guidance to them during the meeting. And those could be submitted for consideration in a subsequent project. So I just wanted to note that. But again, we'll follow up with the committee to see there is sufficient support for reconsidering the endorsement decisions on these measures.

Charlotte Alexander: Andrew, Charlotte Alexander here.

Andrew Lyzenga: Yes …

Charlotte Alexander: Just want to follow up on that. It would be more meaningful to me rather than just documenting the radiation type if there was a threshold that were acknowledge as a threshold that it would desirable to stay below because of an increase risk of injury.

If we could then have people report the amount of times they went over that threshold or some indication of harm. Kimberly maybe able to address that better.

Kimberly Applegate: Yes, yes. The issue is that if there are a lot of factors that go in to counseling that and there are some guidelines, some interventional or heavy user community both the European and American and we tried to harmonized those data from those communities through our guidelines. But it's based on the number of things including the size of the patient (inaudible) they are the patient, the more dose there is, the amount of digital runs there are, the amount of magnifications. So there are – unfortunately, there is no magic number but there is a 60 minute for our time that kind of visits the trigger. But there are different criteria for what to use for recording risk.

And we can – I'd be happy to talk about that as another meeting.

Andrew Lyzenga: All right, thanks Kimberly.

Ed Septimus: This is Ed. Let me ask if is there a measure that you can conceive that could be link to and ask that maybe the developer should go back and resubmit.

Kimberly Applegate: Well there are degrees of risk and you know what – you know is obviously using the links, the longer the (plural) time, the higher the risk there is of a skin burn. I mean that's an outcome and that's why we – that's why the international community wants people to track it.

And they not only want to track the time but they wanted to track the machine at those output. So anything that they can track depending on how old this (input) is, they want to put it in the patient record.

But I don't have a one dose unit that I can give you.

Ed Septimus: So you're saying it should be measured but in terms of being in the NQF criteria not tying it to an outcome, we may not be there.

Kimberly Applegate: Well you know we can set the art of the criteria's on the guideline that people used and we can get some criteria – like a thresholds for when to be worried. The problem is that because patients are different size then there's different you know positioning of the tube. It's not simple. It's a complicated …

Ed Septimus: I got that. Yes, I appreciate that.

Kimberly Applegate: Yes.

Andrew Lyzenga: All right, thanks everyone. So we – again, we'll follow up on that and we can move on at this point to maybe one of the larger discussions we'll have which on the Sepsis Ad Hoc Review.

And we have …

Stephen Lawless: How come we've guess that?

Andrew Lyzenga: Excuse me.

Stephen Lawless: How come we have not have guess that one?

Andrew Lyzenga: Yes, yes.

Female: OK.

Andrew Lyzenga: Of course. And I don't know if – (Jessie) do you want to give us a quick summary of what the comments were or if there were new issues that were raised?

(Jessie): Sure. So, just to remind everyone. What this refers to the Item F which is the requirement for invasive monitoring was central venous catheter for all patients with severe septic shock. There were several comments. As you can see that came in again sort of both sides of this from a lot of the similar people who were on the previous you know the previous (extensive) discussion that we had on this.

I think everyone has the summary here and also has the comments that were submitted. Also (Sean Thompson) who is on the call submitted a separately letter which you should have received, and in looking through everything. I'm not sure there was a whole lot of new information that came in this time around. But I'll let the committee in charge for themselves based on this summary and also based on the comments that came in.

Andrew Lyzenga: Thanks (Jessie). So yes, we had some comments that were requested a reconsideration of this decision and the number of comments that we're supportive of the committees decision as well. So, do we have any thoughts from the committee on whether you found anything new that might want a different decision or some discussion?

Martha Deed: Yes, Martha again.

Andrew Lyzenga: Yes.

Martha Deed: What I was wondering about is I really read very, very carefully all of the comments that came in and I was very concerned about some of the technical issues in terms of how we handle breaking down a composite measure. I

thought that was – I was squeamish about it at the time and I think its (Sean Thompson). His comments really based some concerns in my mind about the committee's process with dealing with that measure in terms of deconstructing a composite measure.

And I just wondered if somebody could just give us a briefing on you know what the technical side of that was and in terms of has that been done before? Is it legitimate? Because otherwise, I think we do need to revote for sure if we didn't follow NQF's own protocol. Thanks.

Andrew Lyzenga: Thanks Martha. I mean this was a different – a bit of a different situation because this is not a typical endorsement review. It is really an ad hoc review focus specifically on that that particular element of the measure. And I don't know if (Sean) had any specific comments about what the impact with that would have sort of the composite measure of the whole or the composite score. Are there – and does anybody on the committee have any thoughts about that?

(Jessie): Well and also, just to comment there. So there are specific NQF rules around composite measure. Mission of the composite measure would be one you know sort of similar to, like PSI 90 is a composite measure which is a whole bunch of separate measures that are put together into one measure. This is really a sort of a bundle more than necessarily a composite measure. You know and sort of similar to the 0464 which we noted down.

This is a theory of activities that, unless you have all of the activities together, you don't get credit for the measure. So, I think we want to talk about this and sort of a bundle that rather than necessarily a composite measure.

Andrew Lyzenga: Yes, that's a good point (Jessie) unlike the part PSI 90 composite measure, this has not have a similar kind of waiting scheme for each of the elements but rather is then all or none measure. You hit all of the items and you'd have or if you hit – if you don't get one or any of them and you don't have I believe. So that there are fewer concerns that I would think in terms of the effect it would have on measure scores. It doesn't, it wouldn't throw off any kind of waiting scheme or anything like that.

I believe we do have Dr. (Thompson) on the line and maybe we could …

Kimberly Applegate: Can I ask a question first before we go to Dr. (Thompson)?

Andrew Lyzenga: Yes. Yes, please.

Kimberly Applegate: Have we – has NQF ever dealt with this kind of process before about when new evidence comes out, you reexamine because Dr. (Thompson) made a pretty – saying that the NQF staff didn't prepare the committee for the rigor of the evaluation that we had done something that wasn't appropriate with the process. And I wanted to make sure that you know because we talked about this at length and debated very long time. So I want to make sure that if we really follow the process, if you – with that you followed before when you have reexamine when new evidence comes out that we really didn't do anything wrong by this measure.

Andrew Lyzenga: No. I think we have followed the process for an ad hoc review here. I don't think we've you know had a multiple levels of review internally in terms of the process that we put this through.

I mean I think that the committee you know had a pretty robust discussion about it. But you know if you feel like you did not get sufficient information, I mean that's something you can let us know. And if you feel again that it would worth re-voting on this measure and that – in quite of that, you have the – that's within your (per view) to do.

Lisa McGiffert: This is Lisa McGiffert. I think that you know the NQF staff prepares us to a certain extent. But in this particular measure, I thought like we got a front row seat to an active debate between scientists on several occasions. And I show that I learned a lot in the same to the discussions and it made me think of this much differently and frankly on some technical as the teams like what we've got this measure was probably better than any kind of analysis sort of preparation with the NQF staff because we've gotten – we got the preparation from the scientist involved.

Andrew Lyzenga: All right, thanks Lisa. Thanks (inaudible). Any other thoughts, and either the process or on the measure itself whether they were – whether there was any new information that would prompt the re-considerations?

(Sean Thompson): You would ask me to wait. Andrew, it's (Sean) (inaudible).

Andrew Lyzenga: Hi (Sean).

(Sean Thompson): If you want me to speak I would.

Andrew Lyzenga: Yes, it sounds like we don't have any comments at this particular moment. Maybe you could just take a – just a few minutes (inaudible).

(Crosstalk)

(Sean Thompson): I'll be very brief.

Andrew Lyzenga: Yes.

(Sean Thompson): I think, my major concern is the issue with the composite. I had wished the committee had taken the comprehensive meta-analysis that Dr. (Rivers) has provided into consideration which shows even after process, there's no – still a positive effect for really (inaudible) that did therapy.

But mine is that, one scientific comment criticism. The thing I'm mainly concern about is that in order to get a process measure like this has the standard for validity and reliability requires a comprehensive statistical analysis for composite measure. And that process is very careful divided by NQF. And I was required at the time we build this to take all of our data for 200 hospitals across the country and to analyze that in that very rigorous format to prove that it was valid meaning that if you did this, here are some things together. You achieve the same effects reliably that ultimately, we had an effect on outcomes and the same thing for reliability that the measure was reproducible.

The concern I have is if you dismantle this composite measure, you've untested development. We don't know what the composite does. And I'll keep a very specific example and I'll let you discuss it some. But if you

remove element have, you've taken out the requirements monitor ongoing blood of only the issues in perfusion adequacy. And what you've left in places, you give a fluid bolus, you put patients on vasopressors and then you tell the clinician good luck. And that's exactly what we had prior to the (Rivers) trial.

So this new manager actually has a potential from harmed patients, a true harmed patients because vasopressors without monitoring volume status in perfusion issues alone can meet the tissue ischemia, digital ischemia and loss of one's (limbs). And this is totally untested territory now.

So you know I understand the drive in potentially removing on this based on process, but what you've left us with is something we know nothing about. And that's about the bulk of my concern.

Andrew Lyzenga: Thank you (Sean). Go ahead (Jessie).

(Jessie): I think also down the line with us, Dr. (Don Yealy).

Male: (Inaudible).

(Jessie): Were you there (Dr. Yealy). I thought I heard …

(Don Yealy): Can you hear me? Yes, yes. Can you hear me?

(Jessie): Yes, we can hear you.

(Don Yealy): OK. Thanks again for the opportunity.

The measure that sits now without the F component does not return us back to 1999 in any way shaper form. It measure before 2012 which is where most of the benefit that we scribe to all of this did not have the lowest – added in recently was the central venous catheter. And we now have large scale randomized data that's suggest that that's not mandatory in all patients. The question isn't whether it's harmful. Is it mandatory in order to get the good outcomes. And what we're going to do is to ask people to do an intervention and it – and almost half the folks that they can really benefit from. That has not sound like a quality measure to me.

All of the meta-analysis data comes from trials of different levels of grade – different grades of quality may have whom didn't fully subscribe to the entire goal directive therapy process including the central venous catheter.

So in my view, the meta-analysis section makes the point that the proximal steps, A3 are much more important. And that evening when you can't follow the entire thing, you get a traumatic benefit and that's what we're seeking here right now. So, I think it's a mischaracterization of the data and whereas – no one is asking to go back to 1999. You're measure without F will not take us back to 1999.

(Sean Thompson): It can only give remark that it's not testing. Dr. (Don Yealy) can hypothesize that's true. But when people are forced under measurement scheme to give people a simple fluid bolus and place in the (venous pressure) and do nothing else. He does not know what will happen.

(Don Yealy): We do know that. We know that from the extra – exceptionally large trial that we just published. We know exactly what happens with that.

(Sean Thompson): We actually don't know what happens with that. We have no idea about these affect to those patients would be if there are under measurement scheme endorsed by the government. Your trial was not a test of measure. It was rather a clinical trial.

Andrew Lyzenga: I'm going to have to see if we have any thoughts from the committee at this point, if there's any discussion from any of our committee members.

(Sean Thompson): And just to make one remark Andrew before I don't make any further remarks.

Andrew Lyzenga: Yes.

(Sean Thompson): We've talked about this substantially and we are prepared to withdraw the entire measure, if the element had tested your (mood) because we can't be responsible for the possible patient harm that could occur.

Andrew Lyzenga: Thank you (Sean) and thank you for both Dr. (Thompson) and Dr. (Yealy) for joining us. Again, does the committee have any questions for either for those …

Stephen Lawless: This is Steve Lawless and I – this is Stephen Lawless and I am in (inaudible) and I've heard all the arguments and we'd be talking about this remark. But I just want to remind everybody, we're not the Supreme Court and this is not a closing arguments and this is not a who's right, who's wrong. We're trying to make an informed decision and then guidance. But I know everyone is very passionate about this. And it almost like it's going to be there's going to be a winner and there's going to be a loser. And it's not – it should not be that way. It should begin on what the outcome is guys, the survival have their shocking got better. People are refining things and not in judging it. I think that the two of you guys, your team is getting together and as a team work it out and give us a recommendation rather than having taking sides on them.

Because my – quite honestly, my patients level is kind of run out a little bit with it hearing it and I think that as new guys getting together and then informing us in a uniform way was due to this, would be probably the best approach in long term.

Andrew Lyzenga: Thanks Dr. Lawless. Any other comments and questions from the committee?

Jason Adelman: All right, this is Jason Adelman. I have one comment.

Andrew Lyzenga: Yes.

Jason Adelman: First of all, I appreciate the last comments and I just wanted to add that in you know accessing this measure, I tried really hard to understand all the research that underlies it and there is hundreds of articles with them are you know very well done. Randomized controlled trials, some of them are observational studies but there's so much information and the experts on the phone are so far ahead of the rest of us even if we're you know general patient safety experts. We're not – we don't have enough of a little expertise in sepsis that these guys have. And if we are going to all look at this further, it will be helpful to me if they could help us narrow down which of all the articles that are out there, we should focused on.

How much of that that we're going to be continuing on. But if we are, it just very, very difficult I think and they're like surviving sepsis campaign if you look at all the references there. Just so many had just founded very, very difficult.

I just want to say that.

Andrew Lyzenga: Thank you Jason. All right, well I don't think we want to make decision quite yet right now on the phone on this. So again, we will follow up. We'll be sending you a memo with a number of issues in follow up to this call. We just kind of wanted to have a bit of discussion while we have the time.

But again, we'll be voting subsequent to this and I am actually voting on whether to reconsider some of these measures as well. Any final thoughts on the sepsis bundle ad hoc review?

(Sean Thompson): I would just comment. I'd be happy to sit with Dr. (Yealy) and try to workout a compromise position. I have no problem with that.

(Don Yealy): I'm happy to do the same.

Andrew Lyzenga: Thank you both.

All right, I'm just going to skip over a few of the measures here. Some of them are (inaudible) is related to the radiation safety measures – issue that we've already discussed. Let's go to – there was – we thought maybe we should discuss measure 2337, Antipsychotic Use in Children Under 5 Years Old. There were still – we have some facing discussion about this issue at the meeting. There were some, still thought it maybe commenter's who thought it maybe inappropriate to have this is a quality measure given that it maybe appropriate in some instances to provide antipsychotic to children under 5 years.

I think most of the comments were supportive, more supportive of the committee decision but we wanted to just bring that up and see if there are any further thoughts from the committee on this issue.

Lisa McGiffert: This is Lisa McGiffert. I would just say that that point of view was brought up in the committee and we heard it and discussed it.

Andrew Lyzenga: It was. Yes. OK.

All right. So beyond that, the major thing that I think we wanted to address on this call in addition to those two comments from discussion on the Sepsis Ad Hoc was the AHRQs measure number 0531, PSI 90. This is the Patient Safety Composite and as you may recall, we – the committee had requested that the developers go back and add three additional components to the measure that had been actually included in the measure previously.

They did not include them in the measure that was submitted in the version that was submitted for your review but they added those three components back in and re-weighted the composite based on that which again was one of the major concerns of the committee was the weighting scheme for that measure. And I know we are actually weighting on Dr. (Romano) to join us at 3:00. We're running a little bit of ahead of time here. But I wondered if (Pam) – if (Owen) is on the line if she might be able to just give us a bit of a summary of the changes that were made to the measure and what the implications of that or and what the – and maybe some of the new information on the new weighting scheme.

(Pam) are you on?

(Pam): I am and thank you. Can you all hear me?

Female: Yes.

Andrew Lyzenga: Yes.

(Pam): OK. Great

Female: Yes.

(Pam): First of all, thank you so much Andrew for trying to weight for (Patrick). (Patrick) actually is in court this morning and he knows that at 3:00 he will be

able to join us and so I will try the best they can in the next 15 minutes but (Owen) surprise me if our conversation takes longer than 5 minutes.

I also very much appreciate your willingness to receive AHRQ the submission of the re-weighted PSI 90. For those of you who don't know when it originally went to NQF for submission. It did actually include all 11 indicators. And then the steering committee in 2009 wanted three indicators removed. We did not actually remove the NQF endorsed version of the indicator. Going into this was only an eight item indicator and that's why it was presented as it was presented.

But in terms of maintaining it in RQI software et cetera, we actually maintain those three additional indicators and then gave the option for people to change the weighting if they wanted to so that (they) weren't zero weights for those three indicators but in fact, they could calculate something different.

But the NQF endorsed version going into it was an eight item indicator composite and what I submitted to you is back to the 11 item composite. We feel like there's revised weighting them this of course more consistent with the original conception and design of the PSIs that was (embedded) through several technical panels in terms of how to come up with the composite and which indicators to include in that composites.

The revised weighting does continue to account for reliability of the indicator and the prevalence of the patient safety event. We'd actually did here taking to account and other components in terms of weighting and that is with – in terms of this, this measure related to the burden of cause of some other component of that. However, that was beyond – we had one month to work on this and that would have required bringing a bit together, a committee to really that's how – what additional weighting factors we might want to consider and it's putting on the tables going into the new contract here which we're hoping to have a new contract this summer to really analyze whether that weighting should also included. But to go back to the original which was 11 items. That's what we submitted here.

We feel that the revised weighting balances the total weights more equitably and fairly across the 11 different hospitals associated in safety related events. No one single indicator comprises more than 32 percent of the total weight. I think this related composites (can) declare in more consistent signal to users about safety related events and performance across all hospitals and the re-weighted composite retains and improves the desirable properties of the previous ones including consistencies and repeatability and the ability to discriminate across hospitals.

And I will tell you, I had originally put in the memory. You know may have previously received that we weren't given the time and we're able to calculate reliability overall for the re-weighted PSI 90. We were able to accomplish it between the time that I originally submitted the memo to NQF and then on Friday, I did actually get the revised document.

So, in the memo you received over the weekend, that would have included the re-weighted PSI 90 reliability estimates and those are the average hospital signal to (noise) ratio.

If you use all payer data, that's 0.785. If you were to use one year of Medicare fee for service data, that's 0.689, and if you were to use two years of Medicare fee for service data, that's 0.7674.

The thing that we were also able to do – I know several of you at least in the committee mentioned, well, how do you take all payer discharge data and how does that relate to you know if used in terms of using it with Medicare fee for service data. So we were able to show you the reliability and the validity using both the all payers set data as well as the Medicare fee for service data.

So we hope that that addresses some of those concerns there and I felt like you know it gets in more complete picture. I think that's for the most part addressing most of the comments other then thank you again for letting us resubmit. The other thing I guess I should say is I try to – I knew it came up in the committee towards the end of our discussion. The two – it would have been great to walkthrough the methodology at the beginning of the presentation.

And I think I apologize for not having done that. I didn't realize that didn't connect. And so if the memo also details the methodology which is first, we've calculate the risk adjusted rates in the confidence intervals for each of the components. Then you create a uniform indirect standardization of them, smoothing them for their reliability adjusted. Then you select your component weights. We do use numerator weights that are based on the prevalence of the condition and they are combined. So on page four of the memo, you can see those weights and then how they're combined.

So if anyone has any question?

Andrew Lyzenga: Thank you so much (Pam).

(Pam): Welcome.

Andrew Lyzenga: I know will this – just – no, we'll send you – resend you all of this information. You should have gotten (that are) have access to it. But wait, just to give you a little bit more time with that and you know the revised submission and the revised reliability estimates will have you sort of review some documents related to that in the memo related to that before you – after you vote. So we will again, be voting on that on this call but, does anybody have any questions for (Pam) or comments on the revised and re-weighted patient safety composites?

Ed Septimus: Yes. This is Ed. First of all, a question of a procedure. Since we point out (they do), we weighted, recalculated measure, this just (begin) based on NQF procedure. It's OK to reconsider with the revision?

Andrew Lyzenga: Yes. I believe. So we've had some discussion on this and we think it would be appropriate. We think we may go through each of the criteria again voting on each of the criteria because it has changed a bit. We'll do that again via an online surveys. But we think it's appropriate in a sense than to go ahead and take another look at this and since the committee had specifically requested that our return with a revise measure and that they wanted to take another look at it at that point.

Ed Septimus: And then second, there's something I should know but I'm just sort of blocking on this right now where it says, PSI 07 as an example, central venous catheter-related bloodstream infection rate that that is based on administrative data?

(Pam): That's correct. All of these indicators are based on …

Ed Septimus: Right.

(Pam): … data from the health cost and utilization project.

Ed Septimus: Thank you. So, again, I'm assuming that based on our prior discussion, this is of course this is different in the other publicly reported measure which is also part of evaluating (inaudible). Correct?

(Pam): That's correct. Yes.

Ed Septimus: OK. And so then the next question I have and following up on that is that what is the validation of let's say PSI 07 compared to CLABSI rates as the developer from CDC in this (risk) adjustment? How do they correlate?

(Pam): Excellent question. I personally do not have the information (inaudible) ready. I certainly could send that to NQF and (Patrick) may actually have that information in his head. I know that we actually have looked at this. Unfortunately it proceeded when I went on the project. So I can't speak to it directly.

Andrew Lyzenga: Well call me back, because I think that's – we always wanted to – actually the problems concerns about administrative data and risk adjustment versus other data which is also still currently being reported. That's being my concern with this composite measure. Anything is how you …

Lisa McGiffert: This is – OK.

Andrew Lyzenga: Go ahead.

Lisa McGiffert: This is Lisa McGiffert. I think that probably one of the few, I mean – I think we can all admit that this data, none of this data is perfect and the consumers

(union) that's a big advocates for more rigorous validation for data on the administrative data sides specially but also the infection reporting side. But health affairs published the piece (about) very four years ago about medical errors and I can provide it to the committee where they, researchers actually look at the reliability of reporting. And I think the administrative data was right alongside this self reporting data as not the best report, but you know way of report but it's all we have right now. And so, I think that while we all wanted to strive for something better, this is the best we have at this time.

(Pat): This is (Pat) quickly. I would like to comment Andrew.

Andrew Lyzenga: Yes go ahead (Pat).

(Pat): Thank you so much and I would – you know I don't know lot of the evidence surrounding all of these indicators but you know my comment during our meeting is that I thought that there were better measures that should be included if there was a going to be a composite measure. I do have issues with one score being used to rate one hospital with another realizing that really we're not adjusting for age. We're not adjusting for co-morbidities of the patient population, and that we have an aging population on hospitals.

So that being said, just to focus on post-op hip fractures to me is not the best measure that's to be use as related to any fall related injury. You know when you look a the nine adverse condition, hospital adverse conditions that the affordable healthcare act partnership for patient is going after in a very robust way, it is any injury that occurs and will fall for anyone who falls in our care. So you know that's really my issue was that you know I think some of these measures really should be reevaluated before they're use in today's world.

So that's my comment.

(Pam): So (Pat) – all right, I just want to make sure the committee understands that each one of these indicators are actually risk adjusted for age, and gender and co-morbidities. So that if you were to look and each one is a separate model. And if you were to look at the risk adjusted model and I apologize that our documentation on this is – it's in very statistical presentation which does not

make it user friendly to interpret or to see that in fact it's done. But each of the co-morbidities in particular adjust or adjusted force.

So for instance trauma or cancer that if in total you can see that hospital's actually are credited for the severity and the sickness of the patients.

(Pat): Thank you so much for your comments but I would just like to share to may colleague is that there are many more hip fractures that occur in our hospitals that are not post-op hip fractures.

So you know I just wanted to say that limit it to post-op hip fractures, and this is only one variable. I know that there are other people in our committee that could speak to others that if you were going to try and use something to get to one score to rate all patients, I just think it would be better to rate the hospitals – excuse me, the hospitals on each of these measures and see where they stand. But I think that this one could – should have been changed to all you know all serious injuries that occur from falls not just the post-op hip fracture.

So thank you for the opportunity to comment Andrew.

Jason Adelman: And can I have – this is Jason. Can I follow up in …

Andrew Lyzenga: Yes.

Jason Adelman: One of the issues that I had when we discussed this last time I still have, which is a find that people are very confused by this measure because it's a composite patient safety indicators that the weight of for each measure is dictated by the data that they have which I understand is base on the prevalence.

But many people don't completely understand the weight and so like to (Pat's) point of post operative hip fracture represents, I think its 0.07 percent of everything there. It's so close to zero. Yet it's in there as if it's some meaningful part of all this. And if we would a priori decide what is a meaningful patient safety composite it would look nothing like these are the (weights) that distributed like …

(Pat): Exactly.

Jason Adelman: If you recall, I made the point that accidental puncture or laceration rate is nowhere near the top 10 preventable things hospitals are working on. Dr. (Romano) you know had mentioned one article that said maybe if we better credentials providers or have you know perhaps. But the things most hospitals are working on that represent really where there's any as a patient safety are. As (Pat) said, falls, we're working on falls. We're working on pressure ulcers. Pressure ulcers represent 1.4 percent.

So, all hospitals across our country are not being rated on the AHRQ PSI 90 composite as if it's a reflection of the work we're doing to work on this preventable patient safety things. But it's not really. If it was, a priori would be focusing on falls, pressure ulcers, CAUTIs, CLABS and this is just not a representative of that. And by adding in these three measures, it didn't really change that big picture issue that I had and still have with this measure.

(Pam): Hi this is …

Female: Hi.

(Pam): Can I add something?

Andrew Lyzenga: Yes. Sure.

(Pam): Yes. So, with just a couple of things, I have – I guess a question for (Pat) on her comment about this one measure being used to rate off hospitals. For my understanding, if we're talking just strictly about how the measure is currently in uses, it's one of a number of measures that's being used to rate hospitals. So, in addition to this measure that appears on for example the hospital compared Web site, it is also I think that this point (six) infection measures an individual PSI which is PSI for complications from hip and knee replacements.

So, this is one particular patient safety measure that is a composite among host of measures that are being used to compare hospitals and I think from my (personal) and consumer point of view, I think when the (benefits) (inaudible)

have ever tried to go on hospital comparing care hospital on it. It really is a lot of information that can be quite intimidating. I think one of the really advantages of a composite is that it brings together a lot of different important patient safety indicators and allows typical look at them you know without trying to compare a single hospital on 20 different things and then deciding you know how one might be best in the other.

I think that a lot of the things that everyone has been talking about like falls which sort of ironic is that they're actually used to be measures that CMS had it part of the inpatient quality reporting program that measured more broadly falls in trauma and those measures have been removed.

And so frankly you know …

Andrew Lyzenga: Considered they were unreliable.

(Pam): This hip fracture rate you know certainly doesn't encompass all falls. But you know today, it's all we have because those other measures have been removed. I hope people will be really thoughtful about that when they consider this.

Andrew Lyzenga: I think those measures removed because there were claims data and they were unreliable and I even thought AHRQ PSI 90 was removed. I mean if I go to hospital (for cure) right now, I don't think it's there.

(Pam): Well …

Female: Can we all look at that together because I'm trying to look at the slide two and I'm not talking about the …

Kimberly Applegate: And this is Kimberly Applegate. Since you responded to me, I'm so sorry I missed your name but my point is that you know the measures of today's – of yesterdays (world) and creating those composite are not necessarily that that's measures for today's world in 2014 going forward. But we do have nine adverse conditions that hospitals are going after reducing on a very robust way.

So, I just think that there's other measures that out there and I do think if you go out there saying that your hospitals you know five star hospital, that's not as informative to the public. I mean it's not the same thing well you know I won't reduce to that. But you know I'm trying to just think of there was just recently an article that was published and some was going to be with this and look at where the harm was occurring.

And it might in the Dr. (John James) article that re-estimated the estimates of pay and harm in hospitals which is now with the major teaching hospitals that did much worse in community rural hospitals.

So you know I was just – I have such issue with reducing everything to one score and I do think people are going to hang their hats on it. And I just think that the hip fracture it should be falls with injury or major injury because you know a (colleague), minor injury and all people can be grave. It's not just the hip fracture. I think that there're just other measures.

Lisa McGiffert: Hi. This is Lisa McGiffert I have a question for AHRQ when it's appropriate. I don't want to stop the flow of the conversation. OK, OK. Are – Is AHRQ developing a new composite measure? Thinking about some of the things that people have been raised inside – is their work going on now to develop or improve upon this composite measure.

Female: So, the question is yes, and – but let me explain what I mean by a yes. We – RQI contract ended at the end of November so we unfortunately have not had a contractor who's been able to help us to refine, to continue to refine and develop measures, but it is our mission to continue to refine and develop measures and we hope to have a contract in place this summer. It is certainly within the contract's scope of work to be looking at this in particular to look at the waiting strategy which I talked about at the very beginning to not only account for prevalence but also account in some way for importance.

I think in that same vein we need to be taking a look at the measures, these were all of the indicators in 2008 and 2009 that were considered by technical experts and clinical experts to be the ones that are – were most relevant. And so the waiting here in terms of prevalence is not based on the prevalence of

one hospital but rather the prevalence across the entire country for all community non-rehab hospitals in 46 states, that's the near universe. It does not include hospitals in Delaware, hospitals in Idaho, or hospitals in Alabama and that's it everyone else is in here.

And so it suggests that in fact …

Lisa McGiffert: I don't think the V.A. is in there, isn't that right? Do you have the V.A. …

Female: Right. No, it's community non-rehab …

Lisa McGiffert: Right.

Female: … not the V.A., not Department of Defense, that's right.

Lisa McGiffert: Yes.

Female: I'm sorry. Didn't mean to imply that, I meant …

Lisa McGiffert: Right. That's …

Female: … outside of the military system. And so, yes, the answer is we will continue to develop it and to look at them you know in terms of do we need to add this notion of importance to the waiting strategy, we have reliability and we have prevalence in the waiting schemes. But now, what came up in the last Steering Committee meeting was that we look at importance. And so that's what we'll be doing.

In terms of whether or not PSI90 is in-hospital compare, I believe (Alex Ball) or (Sam Stailey) maybe on the call and can comment on what's in-hospital compare.

Female: I (still can't) …

(Alex Ball): Oh, sorry to interrupt, this is (Alex Ball) from (Mathematika), yes, PSI is in-hospital compare. If you were to go to hospital compare and you go to the tab for readmissions, complications, and deaths, there is a dropdown tab under

surgical complications at – is – it says surgical complications is in the measure and that's where it puts on in-hospital compare.

Female: Right. And its listed a serious complication by its technical name.

Andrew Lyzenga: Now just – this is Andrew, just to remind the committee again we're sort of treading into a little bit of shaky territory here with – as an endorsement committee giving into the questions of implementation and use. Again, not that they're entirely a relevant but to some degree that is the sort of purview of the measure's application partnerships in that and is sort of intended to be left while this committee is revealed than more sort of scientific review of the measure's merit on their own. Just wanted to add that in there, but go ahead with your conversation.

Laura Ardizzone: May I make another comment this is Laura Ardizzone. I'm – Thank you for coming back and putting some news things in there because that was sort of our discussion but I'm still hearing the same concern from some of the committee members, is yes this is a composite measure but it's not a good composite measure. And that's what we're really concerned about. You know even again this accidental puncture, laceration, right, just really came up a lot in our conversation and it's still 31 percent of the score. I think that's really what we're still concerned about yes in what we agreed that we need a composite measures.

I'm so sorry. It's helpful for a patient, it's helpful for consumers, absolutely. But it needs to be the right measure and not just a number. Because people are going to use this number some way and we need to make sure it means – it's meaningful.

Female: I believe (Patrick Romano) may have joined us that he can speak to the inclusion of which indicator. (Patrick)?

(Patrick Romano): Ah, yes. This is Dr. (Romano) I'm on the line now.

Female: So (Patrick) there's been some concern about which indicators are included in the composite as a whole in terms of its clinical relevance which is you know

what the committee needs to assess on. And as to whether these are the 11 best clinical elements for the composite. If you can speak to that.

(Patrick Romano): Right. Well, I think so as people probably know this composite will develop through a two-stage process and the first stage was really identifying the individual patient safety indicators. Those indicators have to go through a complex two-stage expert panel review process based on review of the evidence.

So as part of a previous contract, our team with investigators at Stanford University actually proposed a much larger site of potential patient safety indicators and provided reasons through the process of evidence gathering and discussion, the final set as we know as the PSI was arrived upon a number of other indicators postoperative heart attacks for example, postoperative pneumonia were considered add to score too low to be included in the final set of patient safety indicators.

This composite was developed through a second stage process in which the idea was to bring together all of the approved individual measures that included these safety related complication into a single composite. So we didn't – through this process we didn't have the ability to go and throw for additional events because those e events had been considered and scored lower by previous panels. And of course going forward or would have the ability to potentially consider other patient safety indicators that could be added to the composite. But it's important to understand that this was the end result of this two-stage process of the indicators have – has to be the original review process as individual measures and then go into the composite. Did that address the question?

Female: I think that helped.

Kimberly Applegate: This is Kimberly, I have one observation to make from having us go and look on the left side of hospital compare and it's a question for actually (Patrick) and Pam. It seems to me that something I've learned from this discussion is that this composite measure is really maybe nicknamed or it's confusing to those of us that are new to the committee that this is actually a –

what consequently on the hospital compare site at a post-surgical composite measure. So it's listed on the left side as a surgical complication measure and not a hospital-wide measure.

So I think that if isn't were renamed as such it might clarify for some of us what the goal really is. It still doesn't address the waiting that some of us still are struggling with in terms of you know the puncture and laceration were aiming to be 31 percent that's tolerable but had for some of us to get our heads around and understand. And it may need some discussions, but I think that at least for what it is or what it is you're trying to measure and assess for the public and for those of us trying to see what we're trying to do. I think it's a – now that a surgical complication measure and not a hospital life measure. Is that – Am I correct in that?

Jason Adelman: Hi, this is …

(Patrick Romano): Well …

Jason Adelman: Go ahead.

(Patrick Romano): Sorry, please.

Jason Adelman: No, no, you go ahead.

(Patrick Romano): What I was going to say is that obviously how AHRQ labels the measure is not necessarily how CMS labels the measure on hospital compare, but having said that, this measure does include for some indicators medical patients as well as surgical patients. But it is true that it is dominated by measures of postoperative complications. And so mathematically it's more of a surgical measure than a medical measure. But some of these events iatrogenic pneumothorax stage for example do occur in medical patients who are having central lines inserted or endorsed in (thesis) for medical reasons.

Jason Adelman: This is Jason Adelman, my issue is similar but not exactly that. I think – and we discussed it when we met in person, to me it's more the issue of preventability versus currently not really preventable you know if it's not really preventable it's an adverse event and usually we just de-consent and

explain the risk, benefits preventable it becomes a major patient safety program. So the big patient safety programs that are out there right now are preventing pressure ulcers and falls and (clamps) and (codif).

And at the meeting I remember Dr. (Romano) I had said that for accidental puncture and lacerations, I didn't recall and (AHRQ) bundle around that while there's many, many bundles and high-(H.I.) initiatives around fall preventions and I recall you mentioned an article about credential and making sure the right doctor was there, something like that. But I just don't think that this patient safety composite is anywhere a reflection of the current you know patient safety movement that's going on where many of us are working on falls and pressure ulcers and the way is in fact dictated not by an – a priori thoughtfulness even though you described the process of like patient safety officers that are working on preventable things but more dictated by the prevalence and the data.

And so there I would consider all of the not really major patient safety data in their noise. So the real – so pressure ulcers is something many of us are working on, but it's 1.4 percent and accidental puncture and laceration although your point is taken that there maybe a way to be careful about credentialing, it is not an IHI or AHRQ bundle right now. And it's mostly noise and this is – these indicators most are noise, but it's being interpreted both publicly and with financial penalties as a real measure of patient safety. I just don't think that's what it really is. That's my $0.2.

(Missy): Hi this is (Missy). I think that through the criteria that we're asked to evaluate the measure again, I'm a little confused, I guess about some of the comments from the direction – the direction of the conversation. So, in terms of the developers responding to our feedback and coming back I think they've done a really fantastic job in terms of the committee members being more clearer about how we should've evaluated the measure and gone through the evaluation criteria at the in-person meeting. I think that we can still use some clarification on that.

But in terms in general of having what hospitals are working on today dictate the direction of endorsed measure. I don't agree with that and I don't even

know that the conversation for this committee. I think you know hospitals are certainly working on lots of patient safety initiatives you know thank God. But in terms of limiting endorsed measures, the thing the hospitals are working on today, I think is not helpful and not necessarily going to move the patient safety movement forward. I think that you know we we're just talking today about the need for these new radiation measures and I – there are a lot of folks in the phone saying, but you know geez we really need some radiation measures and you know that's based on the fact that we know that there is a problem and maybe hospitals aren't doing enough for it.

So to say that these things are happening but hospitals aren't working on them today so we shouldn't be measuring them as – to me is not necessarily you know the kind of conversation we should be having at the committee level, but I mean …

Jason Adelman: Can I just – this Jason because I think that was directed to me when I said it's not that hospitals are working on it. I meant to make the point but maybe I didn't make it clearer. I was trying to differentiate preventable versus non-preventable like it used to be that ventilator-associated pneumonias were considered adverse events and before you put someone in a vent you get them to sign a consent and then (Peter Pronovost) did all this work showing if you hold – keep the bed at 45 degrees and use suction you can now prevent it and the rate went significantly down. And now there's something we can do about it and if your hospital isn't doing it and your rate is high then that's considered a patient safety issue.

It's not – So I didn't mean that like if you're working on it, it's important I mean that this is a patient safety indicator, something that hospitals shouldn't let happen to their patients because it's preventable, but we can't have every surgery go perfect. Sometimes there's going to be a complication and unfortunately there's nothing we can do about it except explain the risk very clearly, the patients. We should certainly track it so that maybe eventually 10 years from now or 20 years from now we will prevent them, but right now there are adverse events and not much we can do about it.

So I didn't mean to say we should only track stuff we're working on, I mean that patient safety is usually the work of what's preventable. That was my point.

(Pam): And this is (Pam), quickly and my point is to clarify is that there is a better measure specific to falls in post-op hip fracture. And that measure is injury of fall that is sponsored by and hosted by the American Nurses Association and collected in the NDNQI database. And you know AHRQ know about it and CMS knows about it there's over 2,000 hospitals reporting that data, the NDNQI and they're the stewards of that, it's an NQF endorsed measure.

So you know when you look at what is the best measure and that's my comment as I do then that there's better measures that have been out there for some time that could have been integrated into this as a – as the measure that you want to use related to falls. It would be a fall with injury if that's what you wanted about falls. But, again I'll just say that you know when you're looking at an aging population and that is who we care for that a minor injury in an old person can be grave. So I just think that there's a better measure.

So, I still thank you (Patrick) for all you've done as I said in the meeting but I just you know I just don't support this. So, thank you.

Lisa McGiffert: This is Lisa McGiffert, I just want to address the last of your comment because I really believe strongly that preventability changes over time and I don't think it necessarily have to take 10 years and, but 10 years ago there were a lot fewer events in sections and errors that people thought as preventable and now they see them as profound because of the work – the kind of work that Jason was referring to. So I think we really have to push the envelope on preventability.

And to address (Pat's) comment, I mean I agree with you. You've got an NQF measure for falls and I think that you know hospitals should be using it, it should probably be measuring them. But that's a different measure. This is an AHRQ measure that was developed by AHRQ and what you're asking them to do is take a different measure and substitute it for their measure. When we

could have actually both of those measures and give a fuller picture about falls for example.

So I don't think it's an either/or, I think all of this is you know putting all these things together to get a picture of what's happening in the hospital.

Kimberly Applegate: Oh, this is Kimberly Applegate and I'll just go back to the question for clarity's sake, I'd really like to ask the developers to rename this in some way can make this a procedural (complication) composite measure. This is not a hospital-wide and just relate it to procedures.

And I think that that's really what (Pat) is struggling with. These are all procedure related except for pressure output. Every single thing in here is related to a procedure, am I right? So if there are some willingness to define this in a different way.

Lisa McGiffert: Well, I think on those definitions are – have been in the – with the measure all along if you look at what it is it's connected mostly to procedures. So you're thinking that rather than (pulling that up) because …

Kimberly Applegate: Yes. It's not a hospital-wide measure. It's a procedure complication composite measure.

Lisa McGiffert: Right.

Joshua Rising: Hi, this is Josh Rising, I think they clarified earlier that it's not just with procedures. That be like the iatrogenic pneumothorax for example could – and for any hospitalized …

Kimberly Applegate: That's a procedure.

Joshua Rising: … patient. No, it's not for a procedure specifically, I don't believe. Not according to what they said earlier.

Kimberly Applegate: Well the iatrogenic is a – I mean, what would you consider this? I mean, that's what I'm saying. (Procedure to say).

Joshua Rising: That is procedure but don't like pressure ulcers are really procedure, but …

Kimberly Applegate: That's not …

Joshua Rising: … you know right, but the waiting of it is very you know it's heavily weighted towards procedures. Or maybe it …

Kimberly Applegate: Everything – If you touch – but what I'm saying is, if you took out pressure ulcer which is – could be a separate measure in terms of safety, you'd have a composite measure that would be all procedure-related.

Joshua Rising: Right. That's not the point.

Kimberly Applegate: That's my point. That's my point. And so I think it's a very confusing composite measure for everyone to get their head around without redefining what it is you're trying to present here.

(Patrick Romano): This is (Patrick), if I could just address one point there or a number of questions and comments related to PSI15 and just to clarify that PSI15, accidental puncture and laceration is separately endorsed NQF measure. It was reviewed by executive committee through a detailed review process. The evidence was presented to that committee including the studies that were commissioned by AHRQ as well as V.A. funded studies. That measure went through two expert panels that were convened by AHRQ.

So the measure has separate endorsements. So to the extent that 31 percent of this composite that is relatively small component versus having it as a free standard measure by which it's also endorsed. So I just want to clarify that. With respect to the naming or the contextualization of the composite, I'll have to defer to (Pam) on that question.

(Pam): So I apologize for some reason my line went dead. And yes, we could certainly talk about changing the name of it. I mean it really – that would be fine if it makes more sense and provides more context. It's a learning experience. The more feedback we get, the more I see where we can improve and often times it's just a naming or preventing information.

The other thing that I'd like to just point you to if there was any concern about preventability for PSI15 and accidental puncture. 49, so we did in the previous initial submission showed that 49.3 percent of the events were considered preventable and showed that in some of the materials that we presented prior to the initial meeting.

Male: Thanks, (Pam). That's a very good point. It's – because that's – it's very much how I feel about this measure. It's like a mix of you know complications and patient to – like medical errors and unfortunate adverse events. It's just a mix of it. And it's confusing by the title because patient safety to me is usually we're focusing on what's preventable right now. I agree with some of the other comments. We should always keep pushing the envelope and converting what's not preventable to preventable. But it's just right now a mixture of it. And maybe the name can somehow reflect it. I don't know how, but …

Lisa McGiffert: This is Lisa. I mean the PSI is a title for all the patient safety indicators that AHRQ has produced. And as (Patrick) said, not all of these are individually endorsed. And so, I'm not sure what it is that you're asking (Serena) and not that patient safety indicator but you title it differently, right? Because they are all patient safety event.

(Serena): Well, I think the title for PSI 90 is Patient Safety for Selected Indicators. And perhaps that selected indicators and perhaps that selected indicators could be better defined.

Lisa McGiffert: Got it. Got it. OK, thanks.

Andrew Lyzenga: All right. Thanks everyone. Any more thoughts, comments, or questions for the developers on this issue?

Ed Septimus: This is Ed and from completely different side of the issue.

Andrew Lyzenga: Sure.

Ed Septimus: Are there any other unintended consequences of these composite measures?

Andrew Lyzenga: Is that for the developer?

Ed Septimus: Sure. Anybody else who's had experience with these composite measures.

Female: So you know AHRQ is not actually aware of any unintended consequences other than the part that's not part of this meeting which is, is it used appropriately and you know and that piece of it. So that – but in terms of overall, no. (Patrick) can you speak to this more?

(Patrick Romano): I'm sorry. I got bounced off for a second. What are the elements or the consequences that you're referring to?

Female: Well, do you know of any unintended consequences for PSI90 – for the implementation of PSI90?

(Patrick Romano): I am not aware of any unintended consequences. Obviously there's a number of questions that have been raised about whether it's clear, potentially discouraged operations on high risk patients. And we respond to those questions by pointing out all the factors that are in the risk model and how all of the patient characteristics that people express concern about like trauma, and cancer, and so forth are usually built into the risk adjustment model.

So given that, I'm not aware if anyone has actually has actually discriminated against high risk patients.

Male: Let me just say that again, let me ask in a slightly different way by holding these composite measures out versus other patient's safety, things that we might work on. Is there anything that says that we're diverting resources away from other potential opportunities?

Michelle Schreiber: This is Michelle Schreiber from Henry Ford. And let me just side what Dr. Adelman on this you know I think one of the questions has to be why teaching hospitals in particular seemed to be very penalized by the third hospital acquired condition program that you know be ticking in in October and I think part of the reasons that is around the lacerations and accidental punctures. That's going to force our organization quite honestly to divert resources around this.

And I know it sounds a little bit you know like sour grapes to say that we're one of those institutions who is going to be negatively affected. But the reality is, it will probably prevent us from doing so, excuse me, certain surgeries. We have surgeries where we have to have vascular surgeons and now they're surgeons in the O.R. because we know it's a complication of the surgery that's being done. And so, the answer I think is, yes, we're going to have to divert resources. And I'm not sure it's a true reflection of patient safety because of the heavy weight of lacerations and accidental punctures.

Leslie Schultz: This is Leslie Schultz. To that point if one reads the (operational) of the measures, there are ways to account for something that's incident to its – we're exploring, trying to get a tumor out of a deep seated location, there may be things that happen but they're intrinsic with this case, with this patient but it's how we do our documentation that is in our favor.

Michelle Schreiber: Yes. And I absolutely understand that. But to the question are we going to have to divert resources to do this, the answer is yes.

Leslie Schultz: So I would like to speak to that a little bit and going back to something Andrew said at the very beginning which is I think that stepping beyond the bounds, its AHRQ's understanding of that stepping beyond the bounds of what this committee is supposed to be reviewing on. And in that sense, that would be a question for the measure's application process or partnership because that's a meeting we can talk about how it's used in conjunction with somebody – something else regarding a composite that is not – I could not tell you that that measure itself in combination with other measures is what's driving your rate. You would all have to be disaggregated. And it's beyond the scope of this particular review because that combination is not actually that straight forward.

Michelle Schreiber: And I agree with you. I'm just trying to support some of the conversation that is going on of – are there adverse consequences to this? Yes, I believe there are. Are we going to be diverting resources that we would have used for other safety events? Yes.

And it does get actually to the point of this committee and that we're looking at the most appropriate measures and it's come up you know now over and over about the appropriate waiting and is that actually correct. So I didn't actually want to blabber it because again I don't want to sound like sour grapes from our organization. But I do think there are some negative consequences that you have to think of.

Lisa McGiffert: Well, this is Lisa, I just want to point out that about half of the teaching hospitals are going to be – are on the list to be penalized but about half of them are not on the list to be penalized. So I think that we are getting into the territory of that's in you know at a certain point in time, some hospitals are going to score more poorly than others and maybe they do need to divert some attention to the issues that put them on that list.

And you know I probably somebody who was harmed by one of these events would say absolutely. We want and for them to be on the list and someone who was harmed by another event would want something else to be on the list. And you know I personally hope that someday, everything will be on this list, that we will be measuring every event and that every event will be documented so that the public can really see how safe the hospital is. But I don't think anybody should want to go there right now.

Female: My one question and I understand what all of you're are saying and obviously we all want the same kind of outcome, to NQF who's hosting this meeting, what are our next steps around this particular measure? What is it that you're asking us to do at this point?

Andrew Lyzenga: Well, we will be sending again – resending the revised measure and comments and explanations about it. And then we will be asking you to revote again an online survey and to evaluate it against each of the criteria and that will be the final – the committee's final recommendation on the measure. Does that make sense?

Male: Yes.

Female: Yes, thank you.

Andrew Lyzenga: Any other comments or questions?

(Lucy): No, this is (Lucy). Just that thought like there is some confusion during the voting in the in-person meeting about at each stage of the criteria review whether we're supposed to evaluate the measure as a composite or the individual.

Andrew Lyzenga: Yes. So, yes.

(Lucy): Is there going to be some additional materials around how to do the evaluation for composite measure?

Andrew Lyzenga: There will. We will send out some additional materials around specifically around composite evaluation where you should be looking at the components, where you should be looking at the overall score and so on.

All right, well hearing no other comments, maybe we could go ahead and open the lines up for public comments. I know we've gotten a couple of request to make comments. Dr. (Rivers), Dr. (Emmanuel Rivers) was on the line earlier and I think wanted to make a comment. Could we have Dr. (Rivers) line opened up?

Operator: Yes, just one moment. I'm not showing if Dr. (Rivers') in the main conference at this time.

Andrew Lyzenga: OK, we may have lost him. Well then, could you just open it up for public comment generally? And prompt the audience members to submit comments. I think we have at least one who is waiting.

Operator: Yes sir. At this time if you would like to make a comment, please press star one on your telephone keypad.

You have a comment from Iona Thraen.

Iona Thraen: Yes.

Andrew Lyzenga: Oh, Iona, you should have been on the call all along.

Iona Thraen: Well, when I joined I realized she put me on listening, so I just had a quick comment and I hesitate to say it but I'm going to say it anyway. So back in the day when infections were first being identified, there was a standard rate of infection that were expected as being normal and then there were some work done here locally with IHC that demonstrated with prophylactic antibiotics. You were able to actually impact that infection rate tremendously.

So that is a metaphor parallel to the conversation related to lacerations. I get all the conversations that's been made about that but these are risks, these are complications et cetera, et cetera, you're in a teaching hospital, you got unskilled folks learning how to do it. There's all those issues and complexities associated with that. But I just use the infection rate as an example of how at one time, point in time and this point was made earlier, one point in time, we accepted the status quo as being OK and we've been able to demonstrate that with focused measurement and attention, we actually can improve that status quo and maybe the laceration is our next challenge in terms of being able to do a better job and that in a surgical procedural area. That's it.

Andrew Lyzenga: Thank you (Iona). I'm (sorry) to have left you off the rest of the call.

Operator: Your next comment comes from the line of (Kim Duncan).

Andrew Lyzenga: OK.

(Kim Duncan): Hi, yes. I'd like to comment on the radiation safety measures and I think it really sort of act as what was just said is that you know the first step is measuring and I think the measures for radiation safety, they are not perfect but I agree with (George Box) that all models are flawed but some are useful. I think all measures are flawed but some can drive improvement. And we're getting there. It's a long road but progress is being made. Yes there are improvements driven by process measures. It's going to be very, very difficult to come up with outcome measures for radiation safety.

Andrew Lyzenga: Thank you.

Operator: Your next comment comes from the line of (Michael Falen).

Andrew Lyzenga: Hi Dr. (Falen). Go ahead.

(Michael Falen): Hello. Fascinating conversation. I'm an emergency medical physician and I have some concerns about the NQF by target measure, I'm kind of concern about how we got to where we are today and the actual NQF process for measure re-endorsement or maintenance. And my big question is, can a measure be altered substantially from its original form if they considered a maintenance issue or is it a completely new measure.

The original NQF (such as) 500 was endorsed in 2007 and then it went significant modification from the original measure that was submitted. And during their process, a huge number like they currently have now of elements that we – on the technical expert panel really felt that they were going to be difficult to implement and we didn't like some of the science behind it, some of the elements and the feasibility of using it.

The original measure submitted four years ago have multiple elements and we worked with the measure developer at the time and came to our (inaudible) agreement about you know getting it done to like four reasonable elements that could be utilized probably as a quality measure, cultures, antibiotics, lactating fluids.

These are ones that we really felt had an impact on the outcome and because it could be translated either with a manually abstracted record or from clinical data from the EHR at that time and routine. And so when this measure came up for maintenance and re-endorsement the (voice) of elements that were eliminated by the first technical expert panel, it kind of brought back to life and (freed) – put into the measure.

So I guess for the documents for viewing is and NQF itself, is how much can a measure be materially altered from the originally submitted and still be considered a maintenance versus sufficient of a new measure. I couldn't imagine just looking into this conversation the PSI measure being that material altered and not considered a full new measure versus the news division.

And just a couple other points, this was also from what we heard before, I was terribly enlightened to hear some of the challenges of converting some of this medical research into a utilizable, (tear use), nationally recognized, quality metric and I think there is a lot of work that could be done and supported you know through either brands or measure development foundations or something to take this translation that the teams like there's a big gap between you know the medical research and how to translate that into a usable quality metric. And I'll just thank you for letting me have to tell you (these three).

Andrew Lyzenga: Thanks Dr. (Falen). This is a response to a couple of your comments. I think that is a fair question about when a measure should be considered completely a new measure or remain a maintenance measure. I think that's something we can have some discussion about internally. I know measure 500, the sepsis bundle did actually go – undergo a maintenance review just two years ago I believe. And again, this is not a maintenance review of that measure, this is an ad hoc review of that specific element of the measure. But I think that is worth having some discussion here when a measure is resubmitted for maintenance and has changed significantly, a lot of that should be considered a new measure or indeed a maintenance measure.

But I think based on our discussions and deliberations here today, I think we feel comfortable taking in the AHRQ composite measure and reviewing it again at this time. But we will have some further discussion on that and it's you know we can think about it for future reference as well.

Are there any other public comments? Sorry go ahead.

Operator: For public comments, please press star ONE. You next comment comes from the line of (Matthew Davis).

Andrew Lyzenga: OK.

(Matthew Davis): Hello?

Andrew Lyzenga: Yes, hello.

(Matthew Davis): Hi, this is (Matt Davis) I'm calling from TIRR Memorial Hermann Rehab Hospital in Houston. You guys may remember me I was – I attended the April face to face meetings and I was talking about the quality measure as it relates to spinal cord injury patient.

Anyway, I just wanted to kind of report today with these measures are tied to public (appraisal) financial accountability. You definitely do see a change to response supposed being done. I'm seeing that I'm having you know most of my patients are coming to me from facilities that are pulling catheters in spinal cord patients.

I think that you know a lot of things that I see here is we have two different sets of guidelines that are kind of at odds with each other, we have the guidelines and eventually (code) that was put by the CDC written in 2009. And you have a clinical practice guidelines for neurogenic bladder (with the) Consortium Of Spinal Cord Medicine. I just you know want to get into this kind of a small sub specialty that we're talking about here. The irony is that both steps of these guidelines will agree to the evidence supporting in and out (cathing) over indwelling in terms of UTI risk is very weak.

So you know I mean that a lot of (studies and inputs) they will not find the (simplicity) and significant difference in UTI risk between those to rather mentioned methods which I think is one reason why the CDC had recommended that you consider removing indwelling catheters it was considered the category two recommendation with the rigorous recommendation. It said that before you know it's a public policy makers should you know only consider enforcing this particular measure you know this particular portion of the measure after a substantial debate.

I think when you look at the clinical practice guidelines that were put forth by the Consortium Of Spinal Cord Medicine I mean these guideline are essentially being ignored, I mean not well publicized and they're being – they're not being followed. There's kind of widespread kind of non-compliance with these guidelines because people are more focused on the quality guidelines. And I think this thing it seems you know concerns me the most is the Consortium For Spinal Cord Medicine guidelines look at the entire

patients. So you look at much as the UTI risk if you look at issues such you know concerns about renal failure, hydronephrosis, quality of life for the patient can take this all in sort of account.

It's a literature of (it) that was done by neuro-urologists not just general urologists but neuro-urologist and spinal cord injury specialist. And when you look at the quality measure, most of the you know people list it on a sheet or epidemiology is infectious disease (dot) it is one general urologist who was involved in it.

And so you know this is really you know continuous sort of frustrations and I'm presenting on this topic. There are national meeting on September. We're working on a petition that would now circulate to the American Spinal Injury Association, but I kind of get the sense of the folks at the CDC or seems like to me (grinding their feet) on this. And I'm wondering if there're something that the NQF can do to help you know move this forward. It seems like a very small thing to me to exclude this very small portion of patients.

Andrew Lyzenga: Well, I think the Standing Committee was very supportive of your comments and potentially excluding that population from the measure. I have gathered you've been in communication with the CDC. Is that correct (because) I guess half things have not been proceeding a (proposed) help?

(Matthew Davis): Well, the thing that I'm concerned about is that institutional habits are being formed here. So policies are being written. You know hospital policies are being written to take into account, these you know this – the (priority) measure and you know people are not you know if we come potentially to make exclusion for spinal cord patient six months on the line, all these hospital policies are going to be written, people's practice patterns are going to be changed and there's a lot that needs to be undone at that point.

And kind of selfish and reluctant and that CDC's put – I'm not sure exactly (what the generic is). It's kind of epidemiologist. They want to track you know UTIs and they want to keep tracking UTIs in spinal cord patients, they do not report them which I guess its fine except their definition of UTI is not

even definition that it would be accepted and it you know if you're going to publish it on article on UTI in spinal cord patients.

And so I you know I'd like to got to fast forward button a little bit because yes. It's simply – the longer we wait to get this done the more undoing there will be and the more work it's going to be to undo some of these hospital (tossing) to be with. And I've had patients who've told me that you know such and such you know (LTAC) would not accepts me as a patient until my Foley was removed. That bothers me.

Ed Septimus: This is Ed. Great comment. I know that the CDC was very open to further discussions with you regarding this area. So – do I hear that you and Dr. (Pallet) is not perhaps hooked up since the meeting.

(Matthew Davis): We've hooked up. We've had a couple of e-mails that has gone forward and my last e-mail was about two weeks ago and it wasn't ever responded to me. It brought up some kind of interesting logistical challenges would exclude the spinal cord patients, (it's my conclusion with that). And I know that they were very busy and have a lot of other stuff that they're working on.

Female: So are you planning to go to the (HicTac) meeting next – wait was this week?

(Matthew Davis): I've realize – I didn't – yes. I would love to do that and actually going to be at a different conference at that time and not be able to attend.

Female: Because that would be the body that might be a good one for you to bring this up …

(Matthew Davis): I know. I just realized that last week I was going to call in the (Rosebowl) middle to the end and a (plane flight) at that time unfortunately.

Andrew Lyzenga: Yes, well they all considering a change in definition of UTI again, so.

(Matthew Davis): Yes. OK.

Andrew Lyzenga: But that's a little separate from I think the original issue you brought up and as a you know if I can help facilitate conversation with Dr. (Pallate) and the folks

at (CECM) I'm more than happy too but I know that he really thought, you did bring up some very good issues but …

(Matthew Davis): OK.

Andrew Lyzenga: … like many things on the federal level as you just mentioned, there's a lot of – they've a lot on their plate. It's not an excuse.

(Matthew Davis): Yes. OK. Well, I will reach out for them again but I just wanted to you know yes. Yes, I didn't want people to be pacifying me and trying to break it and then hoping I would go away. I mean that's you know I want people to take this seriously and I guess it's OK with me if it does take a while but I'd like to keep raising this issue because it's you know I am seeing this in patient care.

Andrew Lyzenga: Well, I think that's why we have these (issue to be) open and comments like yours are taken very seriously. So keep on as if we're not responsive.

(Matthew Davis): Well, thank you so much for you know having these comments open and I you know appreciate meeting you guys last April. And you know I'll reach out to (Dan Pallate) again and you know see if we can (keeps) the process forward you know one more step.

Andrew Lyzenga: And we can certainly emphasize that point again, the committee is feeling on this and that they have urged the developer to make this change as well.

(Matthew Davis): Yes. I appreciate it. OK.

Andrew Lyzenga: All right. Thank you. Are there any public comments?

Operator: No sir. There are no further public comments at this time.

Andrew Lyzenga: All right.

Female: Actually it was like we have (Katherine Allen) who raised her hand on the Webinar. You'd like to make a comment?

Andrew Lyzenga: Could we have (Katherine Allen's) line opened up?

(Katherine Allen): No. Hello?

Operator: Her line is open.

Andrew Lyzenga: Hello? Are you on

(Katherine Allen): Hi? Yes. I am. Can you hear?

Andrew Lyzenga: Yes. We can. Go ahead.

(Katherine Allen): Hi. Actually was trying to get in on the conversation and I'm representing the CDC today. And I want to make sure that the committee is aware that this is not something that we are trying to brag or state on. It's not anything that we're trying to push of, it is something that we are definitely taking into consideration but we do have other considerations that come into this. I think that it's important to point out that the guidelines that are put out by (HicTac) for (cardia) prevention are very clear on that. For all clinical assessment should be made before any catheters are withdrawn from patients including especially those spinal cord injury.

So the (cardi) measure does not in and of itself suggest that indwelling Foley catheter should be removed from all patients. And we think it's very important that there'd be some education as these measures are put forward for proper clinical assessment to be made. One of the issues that we are trying to do is that we are, one, we are collecting information working with rehab facilities on our annual assessment for (NHSN). We are collecting information about the portion of patients that have spinal cord injuries so that we can make some educated decisions about how we move forward with this group.

We do not feel at this point in time that the proper management is to simply exclude this population. This population is at risk for (our body). And as a result, we want to include them but we do want to possibly stratify rates of infections based on this element of risk. And we have talked with Dr. (Davis) a few times. We also have the other individual from rehab facilities and so I do want to make sure that the committee does not leave here thinking that this is something that we haven't addressed or that we're not continuing to address.

Andrew Lyzenga: And thank you for that comment. Any other public comments on the line?

Operator: No sir. There are no further comments at the time.

Andrew Lyzenga: All right. Well, I think we can wrap up then at this point. Just to remind you again, we will be sending the committee members some additional materials. We'll layout exactly what the decisions are before you and the process for voting on the measure if it should what the committee decides to do. We'll probably have sort of a stage voting first on whether or would not you would like to reconsider your decision on a couple of these measures and then if you do, we'll hold the vote after that on the actual measure. But again, we'll follow up with more information both on what we're asking you to decide on and some additional background on some – and context for the decisions as well.

(Katie) did you have anything to add in terms of the next step?

(Katie): No, just that you know what you said we'll be sending the information and the voting links and then we're looking to post the report for NQF member voting by next Friday the 25th so we will have somewhat of a quick turn around with asking for your responses but as of right now we're looking to open voting on next Friday.

Andrew Lyzenga: Thanks (Katie). All right. Well, with that we'll let you all …

Female: Can I ask a question real quick about the …

Andrew Lyzenga: Yes.

Female: … turnaround you're going to post them on Friday and expect us to vote on Friday?

Andrew Lyzenga: Well, no. We'll give you the materials before then.

Female: OK.

Andrew Lyzenga: I think we want – (Katie) was talking about ex-NQF member vote actually. So our report will be posted on our Web site for a member vote once we – the committee has made a final recommendations which is …

Female: OK. Sorry.

Andrew Lyzenga: No problem. No problem. Right. Well, I think we'll let you go with that. Thank you all so much for joining us taking the time to come on this call and having a robust discussion again. We appreciate your time and we will be in touch soon.

Female: Thank you.

Female: Thank you…

Female: OK. Bye-bye everybody.

Female: Bye-bye.

Female: Thank you.

Male: Bye-bye.

END