NATIONAL QUALITY FORUM

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

Reva Winkler: Good afternoon, everybody. This is Reva Winkler along with Alexis Morgan and Adeela Khan at NQF. Thank you all for joining us this afternoon for the conference call of the last workgroup for this Infectious Disease Project.

Today, we're going to be looking at seven measures. We have our committee members with us. We've got Tom File, Rekha Murthy, Curtis Collins, Mohamad Fakih, Mary Blank. And has Tiffany Osborn joined us yet? Not quite yet. We also have with us one of our co-chairs, Dr. Septimus is with us. Do we have any other committee members? You're all – everyone is invited to join in any of these calls and thank you, Dr. Septimus for joining us.

We also have the major developers with us. We have folks from NCQA and we have folks from PCPI on the line. Has anyone from IHI or Henry Ford joined us yet? OK. Hopefully, they will join us as we get going.

The purpose of today's call is to give the workgroup members an opportunity to share your initial spots and evaluations of the measures in your workgroup. You should have received a summary document that pulls together all of the ratings and the comments that you submitted via the SurveyMonkey tool earlier last week. This was – this is summarized by measure through the evaluation criteria. So, this will be an important document to look at as you discuss each measure.

And what we've done successfully on the other calls is have the presenter go through their thoughts about the measure as well as the information submitted by their colleagues as we go through each of the criteria in order. So, the first measure.

Emanuel Rivers: Hi. This is Manny Rivers.

Reva Winkler: Oh great, Dr. Rivers. Thank you for joining us.

Emanuel Rivers: Yes.

Reva Winkler: Before we get started, there may have been questions about what we're going to be doing? OK, let's get started.

The first measure is Measure 0058 Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis. This is the percentage of adults 18 to 64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.

The level of analysis for this measure is a health plan or integrated delivery system. And Dr. File, I do believe this is your measure.

Thomas File: Yes. Thank a lot Reva. And let me just review again that this is a maintenance endorsement. So this has already been endorsed earlier – the process of care measure. And as you indicated, it's for acute bronchitis, for which, I think there's great consensus that antibiotics are way overused in this particular diagnosis. It's stewarded by NCQA and there is a representative from NCQA, correct?

Reva Winkler: Yes.

Thomas File: Because I do have some questions. The first question is – I mean, actually I'm in a numerator statement. I just want to be clear because it says patients who were dispensed antibiotic medication on or three days after. I assume that means on or within three days after outpatient or ED encounters. Is that correct?

Male: Yes, that is correct.

Thomas File: OK, fine. So, let me just review here – I mean, you can see that the bottom line is that there was a consensus for continued endorsement although it appears that one of us did not vote for final assessment criteria being met or not. I think there was consensus that this has a very high impact, it's a very common diagnosis for which we've already said there's a lot of unnecessary antimicrobials prescribed.

However, I think there are some issues that we need to discuss. Some of us and one particularly even for the performance gap brought up a very good point about the implementation measure that was presented within the application by NCQA.

And so I want to ask our representatives from NCQA so that I'm clear on this because I was trying to go over this to make sure that I interpret this correctly but basically this is – as I interpreted a negative measure, that is we're not to do something. So that if you're not in compliance with these measures, you're not – not doing something. So it's almost like a double negative.

And then when you look at the measure as it is actually measured, it's an inverted rate so that it's supposed to reflect the number of people in health plans that were not dispensed an antibiotic.

So my question is, when we look at the summary of the data that demonstrates the performance gap, this is brought up by a couple of the comments. When it goes from 2009 to 2005 and I'm just going to go look at the results for the commercial database, it goes from a mean of 25.48 to a mean of 22.03.

Could the representatives please clarify for me what that means? That does mean that in 2011, in this particular database that 22 percent did not receive an antibiotic or did not comply with the measure?

Male: Yes. Thank you. That is a very common question with these measures that they are reported as an inverted rate. So there's the numerator compliance of people who did not receive the antibiotic and then we invert that to a higher rate that's better. So, the rates you are seeing there are the actual performance rates for people who were appropriately not prescribed an antibiotic; however,

the rates are extremely low for this measure. There's been a continued quality gap here in the dispensing of the antibiotic used for people with acute bronchitis.

Thomas File: And what you're telling me is that only 22 percent met the measure?

Male: That is correct.

Thomas File: OK. So that basically, 80 percent of the patients were receiving an antibiotic for this or for 466 – ICD-9 code 466.

Male: Yes. That is correct.

Thomas File: OK. So it's a little bit discouraging and it's worse. I mean, there's less…

Male: Yes.

Thomas File: I mean there's less compliance now than there was in 2009, correct?

Male: Right. But we – this is another measure that we have seen year-to-year that the turning doesn't necessarily always go towards the, you know and written in the right direction and we have several theories but no absolute data to prove why that is the case.

Thomas File: Well, let's me just ask along those lines. What is the incentive for prescribers to comply with this measure? I mean it's a bit different than pay for performance, I would assume.

Male: Right. I mean for these measures HEDIS Health Plan Model and so the – you know, the plans to report us every year, to NCQA and it's really –and the PQRS as well I (inaudible) and it's a Meaningful Use. So, that the incentive is really to – just to encourage the providers to really avoid using antibiotics.

Thomas File: All right. As we get into the EMR with Meaningful Use, this may have somewhat more sort of authority if you will.

Male: That'd be it.

Male: I might – could be I'm correct? OK.

Male: Right. So through the public reporting of these results, we're hoping that it will – it will incentivize people to do better.

Thomas File: Well, the other concern that's brought up by a couple of us was this report that I'm sure you're familiar with, that was reported a couple of months ago in the American Journal of Managed Care, showing what I sort of interpreted as unintended consequence here where there was at least in this database of a healthcare system and of course, it's different timeframes. But it was 2006 to 2009, there's a significant drop in the use of antibiotics for 466 but there was a significant increase in 499 or 490 or whatever it was, you know, which was a bronchitis not otherwise specified, such as if you look at the overall rate, if you combine those two, there was just a marginal drop in antibiotics.

So, to me it appears that at least in that particular healthcare system that they utilize, there was an attempt at least in those years to reduce the use of 466 but a corresponding increase in 490. So, I'm wondering what the response is from NCQA on that observation.

Male: Right. So, the initial choice of 466 was to really target acute bronchitis and the reason we, you know, are only looking for avoidance for the episode or the few days after is because, you know, for persistent bronchitis or other bronchitis as specified, you know, the evidence that we're getting perhaps the – and reassessment for persistent bronchitis that, you know, antibiotics may or may not be appropriate as a per clinician judgment.

For the bronchitis codes that are unspecified, we attempt to avoid those as much as possible because of the fact that they aren't specified, as we're looking to convert our measures. ICD-9 to ICD-10, obviously, we have a great, you know, more specificity that we can include more specific codes and we're again, however, not including ICD-10 codes for unspecified diagnosis that they don't – they would just basically increase noise in the data and we can't be exacting to that, you know, this in fact where acute bronchitis and for which the measure really is targeting.

Thomas File: I really don't have any other specific comments. I'll be happy to open it up to the other panel members.

Mohamad Fakih: This is Mohamad Fakih. You know, I had the same issue about the coding in the codes 466 and 490, you know, that study in the managed care – American Journal of Managed Care. You know, I've done – a few years ago, I have done quite a bit of work on upper respiratory infection.

One of the things we always worried about is shifting diagnosis by physicians, so you do an intervention and you look at coding. So, whether it's bronchitis, none otherwise specified or another, you know, another diagnosis just to be compliant with whatever we're asking them to do and that's my may concern.

The other thing that I have of major concern also is that we have not shown market improvement in reducing antibiotic utilization with acute bronchitis. So, these are the two issues that I have. I mean, is there a way that NCQA can consider looking at – at least a, you know, not just one code, multiple codes and look at the change over time rather than having one code and then you know, physician groups if they have some incentive or disincentive, they can just switch diagnosis to another code.

Male: Sure, sir. And I think one of the things we can do is that we can look in some large database and do a similar look to see, you know, the use of the different codes. One of the things that we do to all of the data that comes to NCQA for HEDIS it is audited. And one of the things that the auditors look for across all measures and particularly for measures like this is, you know, if there is one plan that shifts from year-to-year, the notice will shift in one direction or the other.

One thing is they will go back and do is they will look and see which codes are meeting the numerator compliance. So if there is a plan that's basically shifting our coding to try and meet numerator compliance, the auditors will pick up on that and they will be go and report that and they will – they will probably invalidate the rate because of that factor.

So they're – you know – it's not – it's not a perfect process but there is – there is a way to look for the – you know, for trying to get in the system by shifting codes to a different diagnosis not included in the measure.

Male: Again …

Male: But I agree and I think, we can – we can try and look across other different diagnosis codes for bronchitis and which one are appearing very frequently and try and consider which ones might be more appropriate to include in the measure.

Thomas File: This is Tom. When I discussed this measure with some of my primary care physicians or colleagues, one of the comments they made is that oftentimes, they're being called or the patients are calling their offices with descriptions that sounds like acute bronchitis and they instruct them, well, it's probably viral, just don't do anything, call me back in two or three or four or five days or if we have to see you, then we will. But then I see them, so it's already been like three or four days and then they may prescribe an antibiotic.

And I'm wondering if there's any way to capture that course on – with EMRs. I think at least telephone contacts will be – should be able to be captured. Would that be considered in variance to the measure, if let's say a physician has documented a phone contact about a patient with symptoms consistent with acute bronchitis on day one and then day seven, they're first seen in the office and now, they are prescribed an antibiotic.

Male: Yes. This is one issue that we've looked at several times over the years as measure because we have heard this scenario before. Unfortunately, you know, up to this point those telephonic communications were not appearing in the administrative claims code and we weren't able to document that. I do agree that I think in the EHR measures that will be coming, we can look at it.

The other scenario that we found is that you know, people come into the office with, you know, bronchitis. And if there is no regular prescription but they, you know, don't fill this for a week, you know, unless you don't get better. Unfortunately, the patients have been going and filling it right away.

You know, we try to capture the dispensing dates for the prescription and so you know, there's that – so those are two things we're looking at.

But yes, the previous – the first scenario you said is – we haven't been able to capture up to now but I think as we move forward, increasing those telephonic and those other encounters if you will, if I can define them as such, we're certainly interested in trying to capture the measure algorithm as soon as they're consistently appearing.

Thomas File: Well, you know Reva, if you look at the final analysis, I mean, it was five to zero to accept or to continue the endorsement, I agree with that quite honestly. Certainly given the discussion points that we just mentioned, do we need to do further analysis?

Reva Winkler: At this point, I think this – at the meeting next week, what we'll do is a little bit more structured go through the criteria and the committee will vote on each of the ratings for the importance and reliability validity. But if you feel that – if anyone in the workgroup feels that you've discussed the issues that no one has any outstanding questions, I don't think we need to have that degree of details today.

And the question I would like to ask then about the measure, though, is the measure before is strictly to health plan level HEDIS measure used with administrative data. When do you think an EHR measure might be available?

Male: I believe we expect the stage 2 rule will be published this week – next week. So, I mean as soon as it's public, you know – as soon as it's published, we plan on including our meaningful use measure alongside our plan measures. We're just – we're waiting until that is published first.

Reva Winkler: OK. That's an interesting thing we'll have to think about how to manage. OK.

Male: Yes. You know, again because it's a bit of a shift. Some of the calculation algorithms may be different with the data, identifications may be different. So we have to think about that.

Reva Winkler: OK.

Edward Septimus: This is Ed. I want to let also people know a very nice article was published in the last month about the relationship between antibiotics and upper respiratory illnesses and antibiotic resistance. Tom may have seen that in CID.

Male: That's correct.

Edward Septimus: And I think that leaves more urgency to adopt or re-endorsing this measure but it would really be nice if we have a little bit more accountability on the provider side.

Male: Yes. That's from CDC.

Edward Septimus: Yes. And it's – and it's – well it's – (inaudible). But the point is that there's ample literature to show the collateral damage of the – of this practice and little improvement.

Reva Winkler: All right. OK. So, that sounds like everybody is pretty much on the same page with that one. So we move on to another measure that's sort of in a similar vein also from NCQA. Pardon me.

Measure 69, appropriate treatment for children with upper respiratory infection. And this is the percentage of children 3 months to 18 years of age with the diagnosis of URI who were not dispensed an antibiotic medication. And so, Rekha Murthy, I think this one is yours.

Rekha Murthy,: Hi. Yes. Thank you.

And yes, the discussion we just had with Dr. File, on the first measure, almost all of that applies onto the second one and I'm glad that Dr. Septimus has mentioned the CID article that was really timely as well in terms of our discussion.

And so certainly, I think there was consensus that this is an important topic and it looks like five people voted yes and one – just one person didn't but I think it almost (held out). The only thing, I have a little bit of – a little bit of

trouble at first honestly was trying to reconcile why the numbers look different if the measure is almost identical.

So if one looks that the actual – it's an inverted rate just as it is for adult and supposedly, these are reflecting people who did not – were not dispensed an antibiotic for an upper respiratory infected children.

And from looks at the data, it looks like from 2009 to 2011, here, they seem to be an improvement, a small improvement and very marginal. And assuming that's – presuming that 84 percent of children who presented with URI did not receive an antibiotic. Am I interpreting that correctly?

Male: Yes, that's correct.

Rekha Murthy: Great. So it's certainly – I think it's a good sign. I guess the question is that should be pushed even further, higher and while there seem to be a small shift and whether it's reflective of just the general plans or any specific change in factors. I think it's certainly important to know.

And I think all of the other elements of the discussion almost identical with what we've just discussed on the prior measure, I just wanted to see if there were any other comments.

Edward Septimus: This is Ed. It has been known that pediatricians outperform adult physicians on this measure.

Female: Right.

Male: Right. There's a – there's two points to that actually. We have found out that in the pediatric population that people pay are much more selective when prescribing antibiotics. This measure also has a longer list of comorbid conditions or other competing diagnosis that, you know, their children might have that would allow them to be excluded from the measure.

So there's two – I think with these two factors, they can try those differences.

Female: There is more exclusion in this measure.

Male: Exactly.

Female: And I would agree the pediatricians in general are much more – much more, I guess, attentive and are attuned to educating parents about the lack of need for antibiotics.

Thomas File: This is Tom. Again, I think this comment about the delayed prescription or we – or we call it delayed observation or whatever probably applies here more as well, because I think the pediatricians have been used to that much more than adult physicians.

Male: And let me also address that. I've been thinking that's a– as an excellent comment but there's one other aspect. If we're looking at rate of improvement rather than a high compliance rate, in this measure I think the rate of improvement probably would be very helpful and there's going to be a few people that they may have had symptoms for three or four days but I think if we see a significant improvement then we know we're making progress. So I look at it at each, either delta was being more important than the absolute number.

Reva Winkler: Any other thoughts from any other committee members? Like you know, it looks like the preliminary evaluation to this measure, everybody in the workgroup was comfortable with the reliability and validity of the measure and the usability feasibility. Then I just want to check, is this one also another one that's soon to be for EHRs?

Male: (Inaudible) as well.

Female: OK.

Male: And PQRS?

Female: Yes.

Male: And PQRS.

Rekha Murthy: And this is Rekha again. I think just to echo Dr. File's comments earlier, again this – with the issue of whether they were delayed prescription, there's a

way to capture that. I think that would probably help with reliability and the validity.

Male: You know, and to Ed's point, you know, it's interesting because I mean, there's such a dramatic difference between the first measure as far as compliance in this measure. And I certainly agree that our pediatric colleagues are much better at controlling this and we need to do better ourselves.

But you know, I guess it comes to – you know, because with the delta now, it's going to be, you know, we already have 82 percent that are complying, you know, the delta is going to be more difficult I think to change. But then there's come to a point we'll – at what point do we even consider retiring the measure but I don't think I'd ever want to retire that measure even if it got over 90 percent but – because I think it's all important to maintain the appropriate use of antibiotics in this setting.

Mary Blank: This is Mary Blank. Can I ask a question about where the pharmacy data is coming from – the information about whether or not an antibiotic was dispensed?

Male: Right. So it's in the dispensed information of the administrator claims related to health plan.

Mary Blank: OK. So, would there be some bias in regard to how that's processed, the antibiotics because, you know, I think a lot of people, they have pharmacies that they can go to and get (inaudible) prescription for an antibiotic. Is that information being sent back into the health plan?

Male: In some cases it is and in some cases it isn't. You know, we were – we write the requirements and we sort of expect the plans to comply then use our auditors to validate, you know, the source of information and reliability of it. So, I believe that the EHR management will offer more opportunities for us to be more sensitive to the different dispensing practices for antibiotics.

Mary Blank: Thank you.

Reva Winkler: Any other thoughts or comments from the workgroup members on these two measures before we move into a different topic area? And besides, the next week at the meeting, we will go through these in details. So for each of the presenters, we will want to talk about the specific issues around the various subcriteria to the entire committee of the benefit of your in-depth analysis.

Thomas File: Reva, this is Tom. Now, once we present this, does the whole committee then vote?

Reva Winkler: Yes, correct.

Thomas File: Do the – does each member vote on each aspect that is usability feasibility impact, et cetera, et cetera?

Reva Winkler: Correct.

Edward Septimus: Yes Tom, there's a very nice cascade that it will become obvious after the first or two votes.

Reva Winkler: Yes. And that's why sharing your preliminary thoughts in the workgroup to kind of pull together a few people's thoughts can help that to be very robust presentation to bring all the rest of the folks on the committee onboard about the measure.

Thomas File: OK. Now, let me just ask for logistics. This is a sequential vote or we all vote at the same time?

Reva Winkler: We all vote at the same time.

Thomas File: OK.

Reva Winkler: We have a new little voting software.

Thomas File: Oh, so good.

Reva Winkler: Where you have your little voting pad.

Thomas File: Oh, good, good, good, good, good.

Reva Winkler: That you'll punch your button then the votes come up.

Thomas File: Well, I think that's the best way.

Rekha Murthy: I'm sorry. This is Rekha. Just to add to that, so are we voting then as we're going through the measure and the discussion phase?

Reva Winkler: Yes.

Rekha Murthy: OK.

Reva Winkler: (Two hours) at each date.

Edward Septimus: But just to tell the committees, we haven't been through this. If we get to a point there are certain things that have to be met for us to go on and you'll see the way they operate nicely, it's also in your packet but if you can't meet certain criteria, you stop and you may not vote on the rest of the usability, et cetera.

Reva Winkler: OK?

Edward Septimus: Yes, yes. Does that make sense? You'll see that – you can provide a handout form as to (inaudible).

Reva Winkler: Yes. And we'll – and we'll talk – well, the first measure, you know, we talked through becomes a little bit longer discussion and demonstration but everybody picks it up very quickly.

Edward Septimus: So is it – is it possible – if the committee members like to see there's a very nice handout that they provided us in my previous experience. It was very helpful in showing how the vote would occur and where there are certain stop points.

Reva Winkler: Oh yes, that's the quick guide to the evaluation.

Edward Septimus: Right.

Reva Winkler: Yes. Actually, I think we have shared that with you. If not, we can do it again and you'll also have one at your table at your …

Edward Septimus: OK. I personally would like to see them have it ahead of time so.

Reva Winkler: Yes, yes. We can get that.

Edward Septimus: Unless everyone want to see it ahead of time but I think it's very useful to see the quick guide.

Reva Winkler: Not a problem, we can do that.

Thomas File: Let me clarify that. Because when I was looking for that, for example, when I was looking at mine where, at least for performance gaps, there was one that was measured low. And now – so, do the majority have to say low before it would be not to go on or?

Reva Winkler: Correct.

Thomas File: OK, And I can't remember how many are on the total committee but – so all right, fine. So, there just has to be a majority that allows to be passed.

Reva Winkler: Correct.

Thomas File: Thank you.

Edward Septimus: So, anything that Tom File recommends, we're going to turn down.

Thomas File: That's quite fine.

Reva Winkler: All right. So we're ready to go on to a couple of more measures.

So next step are three measures around hepatitis C (inaudible) are brought to us from PCPI. These are three majors in addition to seven hepatitis measures that Workgroup C looked at yesterday. There's just a larger number than one workgroup could cope with.

So the first one is the first of a paired set of measures for hepatitis A vaccination in patients with hep C and Curtis Collins, I think this one's yours.

Curtis Collins: Yes, thanks. I think you started out pretty good as far as kind of the introduction that everybody has been through the documents there. Like Tom did, I will point out that this is – has been endorsed previous (looks like a lifetime) it was 2008. So we are – looks like we're endorsing – re-endorsing a previous product that has been approved in the past.

I will point out that this is this is a process measure that again looks that the percent of patient with hep C who have received one injection of the hep A vaccine or who have documented immunity to hep A.

s far as our workgroup preliminary evaluation both on importance, acceptability, usability and then feasibility looks like it all rated pretty highly with the majority on rating is it high or moderately high for most measures and the overall summary was a recommendation for endorsement again, with a vote of five to one and you know, maybe the first who gave the one can – as far as the reason for no vote, but overall, high votes and – I'll open it up for discussion. I think – I would imagine that at least this workgroup is pretty comfortable with re-endorsing this measure.

Reva Winkler: Comments from any other committee members?

Mohamad Fakih: This is Mohamad Fakih. I just – I fully agree with what was said. It's just comparing this measure to – let's say the antibiotic measure. You can see that this is either documented immunity versus the documentation of giving the vaccine.

So, we know that, you know, the person has received it or has this immunity versus the other measure was weaker measure, you know, the antibiotic one which at most would tell us that the person has received the prescriptions for the, you know, has filled the prescription for antibiotics and it's based on coding, the initial although both are based on coding but the other one, the coding may not be really reflective of the clinical symptoms versus this one. It really tells you that this is – this is a vaccine, was given to a person and the only reason for that vaccine would really be to get immunity for the person.

So, I think it's a very valuable measure, the hepatitis A vaccinations for those who would have hepatitis C.

Reva Winkler: This is Reva. And in looking to this, I have two questions for the workgroup members. In looking at the information presented for the evidence to support the measure, they reference the clinical practice guideline and the guidelines are rated as a Class 2-A level C recommendation and level of evidence. And the level of evidence of level C is only consensus opinion of experts' case studies or standard of care rather than based on a specific either randomized trials or observation trials.

And so, I want to ask the workgroup because really we're looking, in order to meet the criteria, we're looking for a body of evidence that is founded in at least some, you know, observational studies or better. Do you disagree with the way this evidence is rated?

Edward Septimus: You know, I think I quoted one article for the hepatitis B vaccination versus the, you know, in the hepatitis C population, which shows how important it is to vaccinate these people and there's an issue with the – and I may be jumping here but there's an – there's an issue also with certain populations.

There was a VA study – I mean I don't want to be the one who's opposite to everyone else but I truly believe there's much more help with this measure versus when you look at the acute bronchitis measure antibiotics based on coding, which I don't' think the slides were done on the coding itself. I mean we know, we should not give antibiotics for acute bronchitis but we're using coding, we're not using the clinical diagnosis, we use the coded diagnosis.

Reva Winkler: OK. So, anybody else is still on the evidence based for this?

Thomas File: Well, you know it's – I mean when we look at our guidelines, it's really interesting. We can have strong recommendations based on weak evidence. I mean that may be the case here and I guess my rationale was that I thought additional resource is unlikely to change a conclusion but …

Reva Winkler: OK.

Thomas File: But I still consider this an important process of care.

Reva Winkler: Right. The committee has the option to invoke an exception to the evidence, but it has to be crystal clear why that exists. But I guess my first question is, do you really agree that the evidence is only consensus?

Thomas File: It's not that there was one study that showed benefit and outcomes that they presented, but I'm going to have to look through this more carefully.

Reva Winkler: OK. Well, that's something just to raise because it is important that, you know, we really look at the requirements of the criteria in terms of the levels of evidence that supports the measures or if you decide to invoke the exception to it, we really have to have it crystal clear rationale to explain to the stakeholders and public at large.

So yes, I'd really ask members of workgroup to consider that a little bit further before the meeting.

Thomas File: Well, since this is a maintenance endorsement, do we have access to the evidence from the initial endorsement?

Reva Winkler: You know, it was a long enough ago that the requirements then were a lot less than they are now.

Male: OK.

Reva Winkler: I can take a look and see what I've got but I bet it's not a lot.

Edward Septimus: Yes and this is Ed. That may be the case where it makes sense for good medical practice that there may not be any good randomized control trials on this area or even any good quasi-experimental trials on that.

Thomas File: Yes. Actually, I'm looking now at the application here and they do quote a single report and this is indirect evidence obviously, it's not direct evidence. But they do quote a report that show that super-imposed hepatitis A was in patients with chronic liver disease, which patients who have hepatitis C would have are associated with the form of that hepatitis.

So, at least there's a bad result that they get hepatitis A. So indirectly, you could say that it's important to prevent hepatitis A. It doesn't say that getting hepatitis A vaccine provides a better outcome.

Edward Septimus: Yes and that's my point, you know. Are we ever going to get that data?

Mohamad Fakih: And it's not going to be data in the United States, you know. It's not an endemic virus.

Tiffany Osborn: But even if you had – this is Tiffany, sorry. Even if you had international data, at least you should have some data, I mean, right? I mean, I'm new to this but what I'm hearing is we're talking about creating something that is health for pay for performance in national reporting but we don't really have any data to say that it makes any – I mean clinically, you think yes, it makes difference but if we're talking about holding the entire country accountable, do you think it needs more than that?

Male: Well.

Tiffany Osborn: And I guess that was a challenge that I had because all the data that was supplied was not – it didn't really hit – the data that was supplied supported information for hepatitis C but it didn't really support any coinspection with hepatitis A or B.

Female: And does it make a difference to anyone because I just see that they're referencing one and the same article, one of the same references, and yes, there's this measure that I'm responsible for reviewing that. We'll try to open up the link to the World Health Organization, if not, I'm not able to get access to it. I mean does that – so I'm not sure of that matter is either.

Female: Yes. But we're not making fool decisions now. We're just bringing points of interest of anyway so …

Male: Well, let me just speak the devil's advocate here. Let's look at the wonderful British medical journal article on the use of parachutes, people who jump out of airplanes.

Never been a randomized control trial to prove that that's effective.

Female: Right. But they're not being held for pay for performance or public accounting, because if they jump out of a plane with a parachute then they held their souls accountable. You know what I'm saying?

Male: But I'm just saying are we going to let perfectly the enemy of good here. We know that if you get another liver injury on top of chronic liver disease, as you can have a bad outcome, we may never have a category I study that shows effectiveness but yet logic tells you it's good medical practice and risk of giving hepatitis A vaccine is minimal.

And the question is when we're going to have a study to prove to the level of category I and so the question is it's just (neurological) with patient care and always getting adults up to date on adult immunizations in general.

Tiffany Osborn: Well, I hear – I hear what you're saying. I'm not – I'm not I have no dog in the fight either way. I'm just saying, you know, maybe that's the difference between guidelines and something that we're the entire nation is being held accountable.

Male: Oh, I think Tiffany makes a big point. I mean, we can make recommendations based on low-level evidence that's what I mentioned before. But, you know, making it a quality measure that, you know, may significantly impact, you know, (reimbursement) I do think we have to think and I think or think about that. Reva's point is well taken.

Now let me ask, I mean, is a representative from PCPI on the…

Female: Yes, it is.

Male: … that can descend this then from their standpoint?

Female: (Dr. Wang), are you on the line?

(Dr. Wang): I am.

Female: Would you like to respond?

(Dr. Wang): Yes. I think you all raised very important issues. And I was around when the first measure was evaluated. And I can say that the question about half of evidence I thing is changed from the first time I attended NQF to this one.

When I think about evidence-based medication, I think about it in two ways. One is what the cloud of the evidence and then the other is what is the benefit versus the risk. And in this instance, as you all heard, hepatitis A acutely can be (formatted) and can (inaudible) mortality. So it clearly – vaccination would clearly percent some of those death should somebody with hepatitis C contract hepatitis A. And the risk of the vaccine is minuscule.

Now, in terms of what level of evidence you would deem sufficient for something that is somewhat that came to the parachute example for you to make that a quality measure. You know, some people would view that as being sufficient that the vaccine has known efficacy and that the acute hepatitis A could be formatted. Some would say that's efficient, others might want additional evidence and I can understand that.

Thomas File: Hello, this is Tom. There's got to be evidence though for the immunogenicity of the vaccine in patients with hepatitis C. I mean people who gotten hepatitis A who have had hepatitis C, I mean, to me that would be even better evident. I mean, if you showed good immunogenicity on patients with hepatitis C that does correlate well with protection …

Male: (Inaudible).

Male: … I thought you were looking for a harder outcome. But if you're looking for that then yes, there is evidence for that.

Thomas File: At least put that in …

Male: It can provide that if you wish.

Thomas File: I mean, yes. Again, it's not direct evidence of clinical outcome, but there is good correlation with that, with immunogenicity and protection, protection against that particular pathogen whatever it is.

(Dr. Wang): Yes. Again, absolutely there is the – and again that speaks to the benefit versus – the benefit of the vaccination versus the risk. And the level of evidence would be as you noted indirect and it wouldn't be on a hard outcome, which I got sense of what some people are asking about and understandably so.

Thomas File: But we're looking for any evidence to support …

(Dr. Wang): There is – there is evidence to support it.

Thomas File: I mean to me it's like mother with an apple pie. We want to support this but we need some meat.

Steve Brotman: Hi. This is Steve Brotman, one of the co-chairs. I'm in – we're group C. Can I speak for a second?

Female: Oh, Dr. Brotman welcome. Yes, please. You're a member of the committee, join us.

Steve Brotman: Thank you so much. So I guess some of you, (Dr. Wang) and Ed and Reva and the rest of you, a lot of you has been on the workgroup C yesterday and we were challenged with the same sort of issue, a number of PCPI measures that were up for maintenance and looking at the evidence they referred to clinical guidelines which – clinical practice guidelines which in the past in 2008 may have changed or not.

But that was the only evidence that was presented to we're not presented with quality, quantity or consistency in any of the regard. And the conversation you're having here is pretty robust and I just wanted to jump in and say any type of evidence, you know, again immunogenicity that sort of thing is very, very hopeful to sort of make their case.

I saw the look of this; I guess I have a little bit of different background. I look at this as almost a trial. This is the purest type of thing. You're presenting this measure for endorsement approval one of you want to consider it.

But it's like a trial and you need to present your evidence or the evidence that's out there to make your case. And just by saying I refer to a clinical guidance and that's enough for, you know, just because it's maybe a credible or what you perceive to be a credible source with sources within it, I think that's not enough for the people that are presented with the hard task of going through a ton of these measures and making decisions in a relatively short period of time.

So I think, you know, it's really the burden of the measure steward to be able to provide as much as evidence as possible even more so than (inaudible) so that we can actually decide what's important and what's not important. But that's my point of view.

Female: One other – one other thing to consider is it might be helpful if there were any kind of epidemiology that is available as well. I mean, how many – because I don't remember showing how many people were infected with the two either. I mean, doing that I would assume that we have that information, do we not or …

Male: Hepatitis A is a self limiting infection as opposed to hepatitis B. So if you've already been infected once with hepatitis A you'll develop antibodies and you would not need to be vaccinated in that case.

Female: What I meant was this is about colon infection. So how many people with hepatitis C get A or B better? That's the epidemiology, because we're talking about giving an …

Male: No, I …

Female: … immunization for some who already has hepatitis B to immunize him against A, right …

Male: Yes.

Female: … and B, so I'm just wondering, you know, the epidemiology – I mean, how – what percentage of the population this is – situation impact?

Female: It depends on the effect. It depends on lifestyle and exposure.

Female: Yes.

Female: So, you know, so I'm going to give you an example, both of my kids, you know, I'm Lebanese in origin so they go to my country of origin, they both got hepatitis A vaccination when they were in their infancy. So, there are certain populations that are high risk. The question with hepatitis B is you get even at the risk and I don't – I don't think we are evaluating what the risk would be unless the even the risk is one in ten, you know, one in thousand that the person would be exposed to hepatitis A when they are hepatitis B infected.

And you know, the impact on their hepatitis – liver status, this is where it's a problem. I think hepatitis B is much more of an issue than A but both are, you know, early preventable viral illnesses if we get vaccination. I'm very sure that the (inaudible) study that look at least that hepatitis B immunity and those that are – hepatitis B immunity and those that are hepatitis C positive within the last, you know, within the last 10 years but I reviewed that topic. A lot of these studies have been done looking at both immunity to hepatitis A and B also because the vaccine comes in together, you know, they can come as one shot together. So…

(John Wayne): This is (John Wayne), you know, I'll also add that there is evidence to support that if you have hepatitis C and you get super infected with hepatitis A, that's the outcome from the hepatitis A are worse than in patients who are noninfected with hepatitis C. I don't know at the top of my head what the co-infection incidence rates are for those – in those who have hepatitis C.

Female: Is that referenced in the submission that study?

(John Wayne): Yes, that study – I mean, that's what I mentioned earlier that, you know, for indirect evidence.

Edward Septimus: This is Ed. Just to let you know the overall incidence of hepatitis A in this country has gone down dramatically with the universal recommendation to immunize children against influenza A. So, the exposure to A in general in this country is going to be less.

Male: As far as I know, hepatitis A is not recommended yet, you know, as form, you know, form – I think it's – I am not a pediatrician but I think B is for every single newborn …

Male: Right.

Male: … gets it. For A, it's not mandatory so far. I may be wrong. They may have –something may have changed.

Male: But you are correct.

Male: You know…

Male: I think it would be beneficial for it to be universal as well…

Male: Yes.

Male: … but that's my personal bias.

Male: So, it has become universal? They changed recommendation.

Male: No, it has.

Male: For hepatitis A?

Male: Yes.

Male: So then you know, I mean, it' s another (inaudible) point because, you know, we know – well, follow with the other think but it's going to end up being everyone is going to get that vaccine (inaudible) to be.

Female: All right.

Male: So, I mean, I don't know where that leads us. It seems like a commonsense preventive measure and I – the other thing it's tricky with adults who have chronic hep C, B which are the majority were talking about that children who get it are often and frequently asymptomatic and then will transmit to adults.

Male: But what would…

Reva Winkler: In terms of where it leads you, in terms of the evidence, what I would say is it is important to take a look to see what the requirements to quality and quantity and consistency are to, you know, for NQF criteria. However, if it doesn't measure up to those criteria to pass, the committee has the option to invoke an exception to it when they can explain very clearly why and the rationale behind it, and perhaps at least one of those cases. So, it's – you do have an option there, but I think it is important to really evaluate what reviewers don't know about the evidence for each of the measures. Again, for the external audiences who look to us or for that kind of evaluation.

Male: Well, Reva, there's a time – is it fair to ask the stewards from PCPI to try to accumulate some of that additional evidence before next week or at the time so we have that either (inaudible) at you data or I would think there's got to be some observational data that looks at that. I mean, you're never going to do a randomized clinical trial, but I would hope that there might be some observational trial over to patients, you know, in big databases who received the vaccine or did not receive the vaccine who had hepatitis C: found out what happen to him.

Reva Winkler: The question to PCPI.

Female: You know, hepatitis A vaccine recommendations by CDC is for people with chronic liver disease. Now, can we use that or we still have to – I mean, this is a national's recommendation.

Male: You know, my point is – I mean, I don't even know if (it where) – you defined this, but there's got to be at his databases. I mean, where, you know, patients, I don't know – have hepatitis C, you can go back into the records see if they received hepatitis A vaccine or not and see if there is a difference in, you know, liver outcomes sir.

Well, I guess it's not fair to ask you to do that between now and a week from now, but I think it should be able to accumulate immunogenicity data that's got to be published.

Edward Septimus: This is Ed. I want to make a slide correction. They strengthened the hepatitis A recommendation, but it's not mandatory. I stand corrected.

Male: I didn't think it wasn't. But I think it should.

Edward Septimus: No, I stand corrected. They strengthened that it's still not mandatory but the immunization rates for A have gone up significantly and the incidence has gone down.

Female: OK.

(Catherine): This is (Catherine) and we do plan to submit some additional evidence before next week.

Female: Thank you. One other question I had for the committee was the measure specifications thus – and this is true for both measures around hepatitis A or B is patient are – gets credit if the patient has received at least one injection…

Male: Mm-hmm.

Female: … not necessarily the entire (series).

Male: Correct.

Female: Does that…

Female: Hepatitis A is two injections, isn't it?

Male: Correct.

Male: But you know, with hepatitis A, I think it's about 80 percent seroconversion in our – antibody formation with first injection. I mean the same thing was done for hepatitis B. I think it's mostly related to (ease) of recommendation but, you know, it didn't provide that a significant immunity for hepatitis A for B it's not the same, you know, they need much more, you know, they need three shots. But this is how the measure is written, you know.

Male: I agree. To me, I mean, it's a measure or at least a feasibility issue.

Male: Mm-hmm.

Male: I mean, if he has at least got one, that you are more likely to have received the whole series than if you got the – if you had the document – no documentation of any.

Male: Right.

Male: So, I would accept that.

Female: Any other comments or question from any other work group members for the measure on hepatitis A vaccine – vaccination, because we can then look at measure 400, which is essentially the same thing for hepatitis B, is there anything additional? Anybody wants to contribute.

Female: Well I think the comment about the one injection being noted for hepatitis B also is I think you need more than one injection and if there are studies that they – how much immunity you acquire with one injection, I think should be part of this discussion.

Reva Winkler: Some any other workgroup members?

Edward Septimus: And I agree that would be the, you know, antibody formation needs more than one shot. The question is (inaudible) again and whether it will fail a measure versus, you know, I see these – you know, as an effort from health care workers to evaluate for immunity status and vaccinate those that need to be vaccinated. So it's like a marker for us. I mean this is how I'm reading it because this is a process measure.

Thomas File: I agree. This is Tom. I agree with Ed. I agree that one dose of hepatitis B vaccine is inadequate for protection. At least it's a marker, it's a more likely to come protected and usability from the standpoint of documentation.

Reva Winkler: All right. Any other comments on the vaccination measure before we move on? All right, it doesn't sound like it.

So the next measure, the last hepatitis C measure is measure 401, which is counseling regarding risk of alcohol consumption. So Mary, I think this one is yours.

Mary Blank: It is, Reva and thank you.

This is also a maintenance measure is a process measure that describes the percentage of patients age 18 years and older with hep C who were counseled regarding the risk of alcohol consumption at least within once in the 12 months' reporting period. Going through to the importance to the measure and to the report from the committee that voted that there were yeses and two nos, I think some of the biggest concerns that need to be addressed for the fact that the quantity, quality, and consistency of the measures and I know that in the one – in the guideline that's presented in the developer's documentation, they're quoting something verbatim from the document that is a Class 2B, level C recommendation, which means that the usefulness and efficacy is less well established by evidence and opinion and C is only consensus opinion of expert case studies for standard of care.

So I'm not sure – and then others on the community raised concerns about the measure – of course, everybody agrees with the high impact of hep C on patient's health. It's a measure that addresses counseling for alcohol consumption and that is not necessarily a way to cessation.

Let's see here. Any other comments from the committee that you want to bring out or address or Reva, anything else that I should address?

Reva Winkler: Any comments from anybody?

Male: I wasn't sure how much is – I mean, is it just documenting? You know, I counseled the patients, so what does this mean? You know, versus – is there a method to counsel – I mean – how much of an impact is just documentation of counseling alcohol cessation. You know, this again – it's just the documentation issue with the EMR, which can be one click but doesn't mean that it really impacted in any way the patient that's coming there.

Rekha Murthy: This is Rekha. This is very similar to the smoking cessation issues, right?

Male: Yes.

Rekha Murthy: Pneumonia, and I agree with you. It's really documentation piece I guess. But if there's a process measure and sort of in question, is there a way to demonstrate the improved attention to documenting kind of a truer selection of the practice and changing behavior and I (inaudible) the same way to really know that from this measure.

Reva Winkler: Any other thoughts?

Female: Well, I can say that there are certainly that we share from stakeholders that simple documentation measures are not particularly well thought of for exactly the issues you raised. You don't know really what was the quality of the counseling or the content or the overall impact on the patients themselves.

Any thoughts about the scientific acceptability of the measure, the reliability, and validity?

Female: What's the highest possible rating for the reliability as moderate – let's me see which workgroup recommended here – reliability 3, high 3, moderate validity the same scoring. Usability required manual inspection of the medical record and I believe that there was – for the validity that there was a cap score of 0.47. I'm not sure if that – how that stands in regard to demonstrating efficient reliability and validity.

Does anybody else in the committee have any comments on that?

Male: I mean – I'm going to ask the same question we asked about vaccination. Is there any study that shows if we counsel for alcohol cessation for hepatitis C to stop drinking – if we document counseling?

Female: The measure developer for TTPI on the (inaudible) – I mean – that's from the developers?

Female: Yes.

(John Long): So this is (John Long) again. I looked for the specific evidence regarding hepatitis C patients. There are some studies that have been done. The vast majority of studies, just looking at a brief alcohol intervention over there suggest reduction in alcohol use and it has been quantified in a (inaudible) analysis across multiple studies.

So the impact of a brief alcohol intervention has been demonstrated across multiple studies in – not necessarily the hepatitis C population. There are some isolated smaller studies that suggest some reduction in alcohol use in hepatitis C patients but there are nearly as many studies done in the particular hepatitis C population.

Reva Winkle: Any other thoughts or comments from committee members on this measure particularly around usability or feasibility?

Mohamad Fakih: You know again, it's an important measure because they have to address whether patient will be treated for hepatitis C or not and part of their evaluation for that – they need to evaluate for alcohol use. They need to tell them stop drinking before they can be treated. But the issue is how it is framed. So you know, if just that kind of thing with counseling going to help the health care provider or we need to figure our something, you know, better. That's where I'm really having trouble.

Reva Winkler: Anybody else? Mary, do you need anything from your colleagues to prepare your presentation for next week?

Mary Blank: I do not think so but could I just ask the comment I made before about one of the reference that are listed in there – in the submission – it's not asterisked. Is that (inaudible)? (Inaudible) reference to the World Health Organization site.

Reva Winkler: What is it that you want to say about it? I just – whenever you try to open up the link, it's not accessible by – at least through my computer. And I wasn't sure if the developers had a different site to reference or not.

Reva Winkler: Anybody form PCPI?

Female: We could look into it.

Reva Winkler: Thank you.

Male: This may not be exactly the same as alcohol but obviously people have more advanced renal disease. Do we caution them against eating raw shellfish?

Female: I don't know the answer to that.

Reva Winkler: All right, I'll just ask all of you to think about the issues you've discussed, and compare them to the criteria NQF has for endorsing measures for each of the different areas. And see if what you know about the measure and have shares meets those criteria or not. Because that's going to be the fundamental questions we're going to ask you over and over next week.

So if there's no other points of discussion for this measure, looks like we've finished the three hepatitis measure and we're going to move on to sepsis. Is that OK with everybody? OK.

The next measure is the Severe Sepsis and Septic Shock Management Bundle. This comes to us form Henry Ford Hospital and Dr. Rivers is on the line as the measure developer.

Tiffany, I think this one is your measure?

Tiffany Osborn: Yes.

Reva Winkler: Do you want to go ahead and start sharing your thoughts?

Tiffany Osborn: Sure. And it's great to have Dr. Rivers on the line as well.

Emanuel Rivers: Thank you, Tiffany.

Tiffany Osborn: Yes, sir. So there are two things and I'm going to try to present this because the committee has to make a decision based on different views of the data. And I'm going to try – what I'm going to try to provide to you are the different sentiments so that you understand where, you know, different groups would be coming from in their opinions about how the data is assessed.

And this can basically be divided into two different areas. One is clinical and one is implementation. And so from the clinical aspect, I don't think that there's very much controversy that early goal-directed therapy or some form of quantitative resuscitation saves lives. So every study that has been done to date either demonstrated that there was a mortality benefit or showed no difference. And the ones that showed no difference state within the study that they were underpowered to show a difference in mortality.

So you have that positive component. Now, those who would argue a different viewpoint would say, "Yes, but really only one or two of those studies were randomized control trials, the rest were all observational bundle completion not completion studies before after studies. You know, do we really know that it was the bundle or the increased attention to this patient population that created the improved mortality?"

Additionally, there is a strong contingent either way on the use of central venous pressure. So there is a group of people that feel that central venous pressure is not a good indicator of intravascular volume and others who would say that it is. Either way, the point is that you want to measure intravascular volume before giving vasopressors. And there are multiple ways of doing that. And there would be a contingent that would state, "Why would you say we have to do it with CVP when there are other ways in which we could measure intravascular volume before we gave vasopressors?"

So if I said we all need to meet at the Hilton Hotel and I say we all needed to drive a car, and someone says, "Well, I'm going to take a plane or a bus." "Well, no we have to take a car." So that's just the way one group would argue. The way the other group would argue would be to say, "You can CVP provides a number and that number does not – it doesn't – there's not a lot of room for variation of the number. You see the number, you understand the number. You don't have to train somebody how to read the number, you just understand what the number means.

Now that – there is enough controversy one way or the other on that, that there are three ongoing international trials, one is here in the U.S., one is in England and one is in Australia. And they're all looking at implementation of early

goal-directed therapy. And at the – when they finish, there will be a patient level MAT analysis. So some could argue we should wait for something that implements something containing CVP and Scv02 until we have this data that reaffirms.

And then you have another contingent that would say." We've only got close to 60 studies although the majority of them are observational, there's a lot of data there that would support moving forward with this."

Now the next component when you talk about the challenge is the implementation. So, one of the things to consider would be the fact that at this point in time there is no risk adjustment for the patient population. Additionally we would have to figure out what the time window is or when does time zero start. So that's easy if they present to the emergency department – you know, the hospital – if they present in severe sepsis or septic shock, that's not as difficult.

What's difficult is when they present and they're not in severe sepsis or septic shock, and then they develop it during the admission. How do you determine what that time zero is to start the clock? So that would be one – not that it's not doable, it's just that that's a challenge that hasn't yet been addressed.

And then the additional thing that would need to be worked out would need to be the ICD-9 validation data. So how – for the denominator, what ICD-9 would actually be used. And I know we would stay severe sepsis or septic shock but the question then would be – you know, basically to ensure – well is it – when they have – is it a hospital diagnosis? Is it the ED diagnosis? When would you use one versus the other and how would you maintain the consistency?

So but – I guess the bottom line is that this protocol or variations of this protocol have been (seen) to save lives. Question is, how to implement it on a national scale for, you know, accountability.

Do you – Dr. Rivers, I'm sure you have some thoughts on that.

Emanuel Rivers: Oh, yes.

Female: I hope that I provided a balanced view of the thoughts on it.

Emanuel Rivers: Yes. Well, what we have to understand is we have a disease that is (inaudible) evolution to acute myocardial infarction stroke and trauma is that they are currently – they was subject by this (inaudible) and back as far as 1067, (inaudible) this recommendation as a protocol was (inaudible) …

Male: I'm having trouble hearing (Dr. Rivers') …

Emanuel Rivers: Can you hear me now?

Female: Yes. You were going out a little bit there.

Emanuel Rivers: Oh, I'm sorry. Well I just want to let people know that the description of a protocol is that goes back since 1967. And when you look at the components – the components again, has been around for 50 years. And the key point to that is it is a protocol in general. It is not a single item. It is a protocolization and basically connects some dynamic endpoints in a continuum, not as separate pieces.

So you look at CVP in isolation, it's not to be treated as one number. It is used to be treated as a continuum of a manipulation of other variables. And its meaning actually is interpreted in view of other variables. And so I think the great tragedy is, number one, is that it's not a new protocol. It's just a reaffirmation of what (Robert Wolf) and (Max Halliwel) (inaudible) decades ago.

But when you apply this just like a stroke and MI or trauma patient, the mortality reduction is a very similar one that we've seen with other diseases. The novelty was brought about by a study in 2001 which has been validated in over 20,000 patients – 50 publications. Now you may argue what these publications mean. They are basically a confirmation that replication of this protocol translates into meaningful mortality (inaudible).

And if you look at all the measures we discussed today, we're talking about mortality reduction going from an average of 45 to 47 percent down in to the

25 percent range. So we're talking about a huge mortality reduction which is really unheard of in terms of modern medicine. There is not a few diseases where you can affect change like that.

So with that becomes implementation and if you take – the same way with an MI 20 years ago, you had to get an EKG, you had to call the cardiologist, you had to give him – TPA was the treatment of choice. But as (it evolved), you take them to the (cap lab). Now that requires a huge amount of coordination and implementation obstacle but it's been overcome.

And so what we have to do is kind of look at it in relationship to other diseases and understand that we're part of a continuum of developing a concept that can change both health care resources and (at the same time) maintains lives.

So I think we have to look at it in that context because we can argue the details. And again, aspirin was not part of acute myocardial infarction therapy. Thrombolytics have come and gone or are still in place but when you look at the current evidence and you look at the current recommendations that's there, obviously a year or two year proposition. So what you have to act on is what we have now – what we know now and what we can recommend in terms of providing the best care for our patient.

Thomas File: This is Tom File and Tiffany , that was a great overview of the issues I think involving his measure. I will have to say at the onset that as a disclosure, I voted "No" not because I don't think this is important. I think it's very important to follow these recommendations. I just think the implementation part right now, I'm just not clear on how this could be totally implemented.

And you bring up the plan about ICD-9 code but when I looked at what the application says as far as the denominator is, it's all on clinical criteria. They don't even list an ICD-9 code. So I think that that's an issue. One of the criteria is administering in a timely fashion which we know is important for reducing mortality affected antibiotics and they say they have activity against all likely pathogens. Well, I don't know what that means. I mean, I had an antibiotic that was effective against all likely pathogens.

Tiffany Osborn: But just as an FYI on that, I think it's divided into two components. So within the three hours, it's administration of broad spectrum antibiotics. And I think that, to be fair, I think that that was what was being referred to. But also I think it's important to note – if I'm correct and perhaps, you know, one of our NQF colleague can assist me to make sure that I'm reporting this appropriately – that a bundle that's similar to three-hour component, would that not passed recently?

Reva Winkler: We look at these measures, you know, as a type of composite measure. And because they have different components that have to be met often or none. So we do have other measures similarly constructed.

Tiffany Osborn: But wasn't there another one recently just as to understand what's there already as either (inaudible) we're currently doing. But if we're about to do, there was one recently passed not long ago from this second – the second phase, I guess, of the NQF process that contained, you know, IV fluids, antibiotics before cultures or broad spectrum – something along those lines in severe sepsis and septic shock. Is that not right?

Reva Winkler: I would have to go back and check and their patient – they give it. But Dr. Rivers probably knows.

Emanuel Rivers: Yes. In 2007, it was submitted as a bundle very similarly. And because of logistical reasons that was met and the first three elements of the bundle was endorsed by NQF. So you have antibiotics in a timely fashion, fluid challenges and of the lactate measurement were all endorsed by NQF. What was the issues was again, was outpatient versus inpatient, what we call endorsement, and now was the key element that was on the NQF that wasn't sorted out.

So I think the committee itself was comprised of representation from the outpatient. And then the hospital measure was not represented so they approved the measure as an outpatient measure. But when you look at the continuum of care especially in the septic shock version of the bundle and Tiffany is correct that there's two portions – there's early detection antibiotics and then fluid administration.

Once you have an illness severity, i.e. hypotension or lactate – and again, that's very important because what this does is it doesn't rely on ICD-9 code. It relies on the clinical definition. So if you have chest pains and you got (inaudible) elevation, it doesn't matter what – that is a diagnosis of acute MI. Forget the ICD-9 code. So what this does is it breaks it down to allow the clinician to make the clinical decision in respect of the definition of severe sepsis and septic shock.

So as long as you have an infection but appropriate risk stratification, you fall into a mortality of more than 50 percent. And that's the most important thing for a clinician, not whether or not somebody puts the ICD-9 later. And so I want to – that's my understanding of this.

But nevertheless, what we call the initial resuscitation bundle was endorsed and the secondary bundle which is also endorsed by the Surviving Sepsis Campaign and also the Infectious Disease Society is the resuscitation bundle, which turns out to actually be the most strongest – or the strongest piece of the Surviving Sepsis Campaign recommendation, although as what probably – is it, Tiffany , 12 years?

Tiffany Osborn: Yes, it's been 10 or 12 years now.

Emanuel Rivers: Yes, so what (inaudible) did is an observation that this is – and actually they get rid of the (inaudible) maintenance bundle simply because the evidence fell apart. So if you look at this aspect of the bundle, over 12 years, you've seen the national mortality reduction of 12 percent in severe sepsis and septic shock.

Mohamad Fakih: Yes, this is Mohamad . You know, I really admire what you've done at Ford Center – from your paper to submitting this measure. One of the things that I worried about when I reviewed the submission is how we extract the data.

You know, I think if we have a full EHR Incentive Program then it will be wonderful. But I thought that there will be a lot of chart review, you know, not that the (inaudible), you know, like it's going to be quite tough as far as feasibility to get that measure. That was one of the concerns I had. I don't know what the others thought about that.

Emanuel Rivers: Yes, but if you look at current methodologies, there are easy chart (expansion) for hypotension, fluid challenges and lactate. So if you make those measurements initially, the (notes) can be extracted quite readily and that's how we do it at Ford. It's done by major health care centers and University of Kansas is one that's really put their EHR and superimposed them with the early detection software. But they have real-time notification of patients who meet these criteria.

So I think you take it – look at what we call risk stratification, i.e. hypotension, (inaudible) IV fluids or lactate measurements that is part of your screening. And that is one of the (inaudible) products of the actual bundle – they have the screening portion that allows you to become a high risk patient because of currently required therapy. So I would liken it to just like chest pains. If somebody comes into the ER or have chest pains, there are 10 – 20 different causes. But when you do an EKG and you see a certain pattern, then that patient fall into a risk stratification that requires therapy. And that's really what should you kind of do with an infection.

There are common infections that don't require anything but antibiotics or maybe a quick source control. But the key point is you want to identify those patients with high risk of illness severity and a magnitude of 40 to 50 percent.

Mohamad Fakih: Can I ask you and Dr. Osborn this question? You know, my understanding from what (inaudible) often has said is that, you know, there are two different – at least two different trends of thoughts right now as far as management of severe sepsis and septic shock in the ED.

And, you know, one of them is what you're suggesting which is part of it is having a central line placed in. And some others may not put that central line in. And this is where – I mean, you know, maybe what you have is the best thing right now that we have. But there may be some alternatives that would be trumped if this comes in as the measure of choice and then they're forced to abide to that measure and not other methods of taking care of these patients in the ED that may be – and I don't know the answer but I'm just, you know, rephrasing what I'm hearing.

Is there a possibility that we can look at this measure as far as what is in common and what should be on every single patient that comes in to the ED without having that measure biasing towards one component that would force everyone else to follow how they address severe sepsis and all the points that you raised?

Female: So …

Emanuel Rivers: Tiffany , did you want me to address that or…

Tiffany Osborn How about if I start and then you – I'll allow you to finish so you can address anything that I might say because I'm going to try again to, you know, provide two viewpoints from either side of the spectrum.

OK, so on the one hand, if you have septic shock, there shouldn't be a lot of questions because you need to give vasopressor and those really should be given through a central line unless you're giving phenylephrine. The rest of the vasopressors such as norepinephrine or epinephrine – anything like that should all really be given through a central line. And, you know, phenylephrine is really is more of a third line agent that's recommended.

So in septic shock, it should be less of an issue although it still is. With severe sepsis, it depends. So that's where somebody might say on the con side, where they might say, "Look, you know, I've measured my lactate and I've, you know, I've given my fluids and my lactate has cleared and yes, they should still be measuring Scv02." But a lot of people don't – or depending on which side of the (inaudible) you are when you read the data, right, or when you interpret the data.

There will be a group of people that will say, "Yes, you need to measure Scv02 as another biomarker to make sure that you have actually completed your resuscitation because your vital signs are not enough." You have another group of people who say, "Yes, but I've used a biomarker, I've used lactate." You have another group of people who will say, "Yes, but lactate is not always positive in all patients so you can't just go on that. You need an additional biomarker." And then another group that will say, "Yes, but there's some data that shows that maybe Scv02 is not that biomarker."

I'm not saying that it is or that it isn't. I'm just trying to explain to you, you know, the differences of opinion. So additionally, when you're talking about CVP and putting in a central line, like I said previously, you know, you have a group who will say, "CVP is the way to go because it's something that's easily done within the emergency department and it provides numbers and trends that are easy for someone to interpret. And where you're working in a potentially very busy department, CVP is the thing to use.

You have another group of individuals or another segment of the ED and critical care population that will say, "There are other things that potentially measure intravascular volume more reliably and I shouldn't be forced to use CVP if I prefer to use something else. So you shouldn't force my hand.

The other thing to consider on this is that about 25 – when you look at the Surviving Sepsis Campaign data, about 25 percent of people had Scv02 and CVP measure – two of them, that's 25 percent. So on the one hand, that shows a great gap analysis that there is a lot of room for improvement. On the other hand, someone could argue that feasibility is, you know, a potential issue.

So and I'm going to let – I know that Dr. Rivers has got, you know, a point that he'd like to make on that. I'm just, like I said, I'm just trying to provide, you know, alternate views on the topics so you can sort of see where different groups would be coming from.

So Dr. Rivers, I'll pass it to you please.

Emanuel Rivers: Well, the evolution of this whole concept is in 1997, we felt that 50 percent morality was unacceptable for septic shock or severe sepsis at our institution. So we went and got guidelines that said (inaudible) is the best evidence. So in 1999, American College of Critical Care Medicine, which is a combination of the Society of Critical Care Medicine as well as American College of Chest Physicians, had standards of septic shock management and that's no different back then in 1997 as it is today.

This is expert opinion. This is not Manny Rivers or Henry Ford. But that is where our protocol came from. And if you look at the Surviving Sepsis Campaign which is comprised of 59 international experts as well as 30 to 40 professional societies that have endorsed this ended up here, that has allowed us to (inaudible), well there's maybe individual patient variation or either clinicians, but the consensus of experts said that this is the standard of care to provide the best outcome for your patient today.

So if you take ACLS – ACLS is not a 100 percent class level 1A recommendation all the way from chest compressions to epinephrines to all the different components. That is arguably a committee that gets together just like Surviving Sepsis Campaign with (procedures) and guidelines and says, "This is how to do CPR." And so what you got to understand is that you'll never get consensus with every simple element.

So therefore, what you have to do is take the best evidence at the time, put it under a recommendation which is basically not from me or in report. It is from the largest collection of international experts that tells us what to do with septic patients.

And so I think that we should take it in that context because we'll have a continuous argument about CVP which has been around for over 60 years, lactate, Sv02 – all these elements are basically a continuum of care. And that's what I think is very important. Now whether you can implement this care is the same for any other disease as well. If you don't have a cardiologist, then you can't provide the best care for an MI patient. If you don't have a trauma surgeon, you can't provide the best care for that trauma patient.

That is something that we have to grapple with as a health care system in general. But what we have is a therapy, a clinical (disease) that needs to be operative in care and management. And I think that's the big picture. I think the individual components may change two years from now. When I presented this to the NQF in 2007, these were the same issues. But now you have five years of data, 40,000 more patients which basically says this was the right thing to do back in 2007.

So what I'm trying to …

Female: (Inaudible).

Emanuel Rivers: Yes, go ahead.

Female: Go ahead, (inaudible). I didn't mean to interrupt you. Go ahead.

Emanuel Rivers: Yes. So, what I'm trying to say is that we have the blessings and backings of two major professional society – and remember, this is not an emergency department disease. This is a hospital-wide disease. These patients come to the ED, they come from your clinic, they come from the general floors, the operating rooms. There is a continuum of care that's required as a hospital to make sure that you provide the best care.

And so patient comes into an ICU with septic shock, there's no question this patient gets a central line and gets all these elements. It's just that when they present in a location outside the ICU, implementation keep becoming an issue. And I think we should take in consideration that there's two bundle element components and if we (one) aside and say, well that most of (advanced) care can only be done in the ICU, that should be basically an ICU-based bundle element.

But I think we need to understand this is a hospital disease and it's not simply an emergency department disease. Fifty percent of the patients – 52 percent come from the ED, 48 percent of these patients come from the general medical floors, surgical floors and also originate in your ICU.

Female: And just as a point of information, since we were talking about (grading) and you brought up the Surviving Sepsis Campaign, I should probably let you know that the committee knows. So they use the GRADE system – the GRADE groups system for measuring quality of evidence. And it was – early goal-directed therapy was ranked a 1C and the C is for low quality of evidence but the 1 is a strong recommendation. There was a strong recommendation on a low quality of evidence per the Surviving Sepsis Campaign.

Edward Septimus: This is Ed. I've thought a lot about this and we have a very big initiative in my organization involving 55 hospitals using similar measures. We are actually collecting these measures and I just – there are levels here in what Manny has proposed. There's things that every patient ought to get and then there are additional interventions based on certain factor. One would be the lactate, the second would be persistent hypotension. That's when you would think about using certain lines and measuring Sv02 but not every patient that comes in with severe sepsis.

Emanuel Rivers: And I think that's the intent. I think if you step back and say, well, there's two components and one happens to be most applicable for ED patients, I think that the key is to understand the intent of what you're trying to accomplish whether you can get consensus that everybody want to do that, this is one thing. But there is a two component bundle to this which is different from the previous endorsement in 2007.

Edward Septimus: So, because they are different levels, not everybody – I guess what I'm trying to say is not everybody has to have a central line or an Sv02.

Emanuel Rivers: Exactly, exactly.

Edward Septimus: So just to let people know. And I think since we've been measuring this, it turns out – and I haven't seen the most recent numbers but it's probably less than 50/50 because people are – people who have lactates of 2 and are mildly hypotensive, they rapidly respond to fluid resuscitation and that's where that stops. So we're not putting central lines and preset catheters in every line. (Inaudible).

Emanuel Rivers: But what I think is important and novel is that you're bridging emergency positions and ICU positions together for the first time for disease (empathy) that's never been done before. We've done it for strokes MIs and trauma but we've never did it for sepsis. And I think the struggle we likely feel is that we have a new disease then we have a (fallow) mentality that these patients have been sitting in the ED for 10-to 12 hours and nothing's done until I go to an ICU – if they make it to an ICU. And I think that part of the challenge is to

understand that we're actually being novelly going against (inertia) and prior paradigms of how we manage these patients.

Female: So maybe we should ask the committee if they have – I know that it's an awful lot of information to be presented with at one time especially comparatively speaking. And you might want some time to sort of process a lot of what we discuss but do you have any thoughts or questions or …

Thomas File: Well, this is Tom again, and again I really appreciate that, Tiffany , you and Dr. Rivers have had there. And I guess I'm just going back to what, you know, my interest is which is, obviously the section on the use of antibiotics.

It's just a matter of implementation – who interprets quote "broad spectrum antibiotics." I mean, one of the more common causes of sepsis that we see is – you know, meningococcus or pneumococcus or staph. And oftentimes with rapid diagnostic test, we know that fairly quickly. And, you know, you can have passage interactive therapy so you really don't need to give empiric broad spectrum antibiotics.

And then the other thing is in some settings, ceftriaxone is considered broad spectrum. In other settings you've got to use four drugs including colistin. So, you know, it's just a manner of, I guess interpretation of how you implement that. When I've been involved in measures, for example, for the pneumonia where we've actually listed the antibiotics that are considered appropriate to be used for a certain type of infection – you've been pneumonia-required ICU admission, which, you know, obviously being a potential – well it could be in this category. Because as you know, pneumonia was one of the most common infections associated with sepsis.

So it's just a matter of – I mean I really appreciate what you're doing Dr. Rivers and I think it needs to be looked at carefully. I am just concerned about implementation. And then the other thing that I wanted to bring up and maybe, Reva, you can comment on this because I think this is a bit of a conflict of measures. Because it was my understanding that recently the respiratory panel or committee voted to remove blood cultures before severe

pneumonia require an ICU admission as a measure and this would almost go against this.

I mean, I would disagree with that but I think that, you know, recommendation or removal of a measure from that committee almost conflicts this. (Inaudible).

Reva Winkler: Dr. File, let me just you an update on that. Actually that's still under discussion.

Thomas File: No – right, I knew that there was a (inaudible).

Reva Winkler: And so there has not – the final decision has not been made on that.

Thomas File: No, no, I understand that.

Reva Winkler: Again, it's another one of these very controversial …

Thomas File: Right, OK.

Emanuel Rivers: And Tom , you know, the reason for the controversy in CAP has to do with the low percentage of bactoremia offsetting the contamination rate.

Thomas File: No, no, no – that's for patients submitted to a general ward. That's not the case for patients submitted to the ICU. The real pathogen rate is much higher than a contaminant for that group of patients. And I'm only talking about patients required admission to the ICU.

Emanuel Rivers: Yes, well, I think it is important to look at the data. If you look at most major sepsis outcome studies, 70 percent of the patients enrolled in these studies are pneumonia. And if you look at bactoremia rate, they range from 30 to 50 percent in these patient populations.

Thomas File: Correct, and …

Emanuel Rivers: If you look at the most recent study by (CAR) – this was published in text just a month ago – so that in the examined 44,000 cardiac arrests on general medical floors, 10 percent of the patients who came in had a cardiac arrest on

an average of 18 to 24 hours after who are (admitted) were pneumonia diagnosis (inaudible).

Thomas File: No, no, no – don't get me wrong – I agree exactly with this measure. I'm just saying that there's a potential for a conflict and I just know that the committee voted against – Reva, you're right. I mean, you know, NQF has to decide whether they're going to accept that, I guess. Is that correct?

Reva Winkler: No, what's going on is actually an ongoing discussion because we had several comments submitted against that measure form some professional society. It's an ongoing discussion.

Thomas File: (Inaudible) including what I wrote for my (inaudible) probably but …

Reva Winkler: No, I think that was – Tom, that's part of the new ones – new discussion.

Female: (Inaudible).

Emanuel Rivers: But one other thing to note is if you look at the implementation studies done out there 50/50 and you look at what you call antibiotic correctness, you left it up to the clinician and you gave him an infectious diagnosis, they got it right 85 to 90 percent of the time with an empiric antibiotic.

So if you look at culture sensitivities and then you look at – comparing that to initial antibiotic choice, it was 85 to 90 percent correct. And so if you look at (controversy) and say, "Well, if you're that good with your first dose of antibiotics, it's not much of a controversy." And actually (Kumar) is working (inaudible) this was done three years ago. If your first antibiotic choice was not correct, you have a fivefold increase in mortality.

Male: Right. Correct.

Male: (Inaudible).

Reva Winkler: So I think as fun as this conversation is, we do have just a limited amount of time left and we do have one more measure.

Mary Blank: Reva, it's Mary. Can I just mention one more comment about this sepsis bundle in that we at the Highmark Blue Cross Blue Shield, we actually have that as one of our indicators in our hospital – excuse me – (inaudible) performance program. So it's been very valuable to our hospital.

Reva Winkler: Mary , is your – the measure you're using for a p-for-p, is it specified as the same as this?

Mary Blank: Yes, we're using both the resuscitation and the management bundle for compliance check.

Reva Winkler: So, and you've had no issues with implementation and feasibility?

Mary Blank: When we put it into place two years ago in regard to the Surviving Sepsis Campaign, we had some trouble initially with the providers being able to collect the data. It can be very time consuming for those point of patient care but it's been of value in regard to improving health care quality and reduced mortality.

Reva Winkler: Now, that maintenance bundle was – I mean, if it's the same one from the Surviving Sepsis Campaign, it was found not to be effective.

Male: No, the maintenance bundles out of the new surviving sepsis document that will be out next month.

Emanuel Rivers: Yes. I think it's semantics and that is – it's basically glucose control but the key point in ventilator and so because for simplicity purposes. It wasn't that these two maintenance element were not important. It was just for simplicity, they decided to make it one uniform bundle. And I must reckon that antibiotic is actually a 2C recommendation by the Surviving Sepsis Campaign. So even though we know that antibiotics are very important if we just look at recommendations, it is not a level 1 recommendation although the resuscitation bundle is.

So I think we got to realize that if we get down to understanding and believing in exactly what these recommendations mean, it has a lower level of evidence than actually the resuscitation bundle.

Tiffany Osborn: So just to bring up a point for the committee and, you know, that is that as – the reason that I say this – I mean, what I do personally may be completely different form everything that I'm you know, putting forward one way or the other. But I'm trying to be as balanced as possible.

So what I'm trying – what I think that the committee needs to know was that as passionately as Dr. Rivers and – as passionately as Dr. Rivers is advocating for use of it, there would be others who would probably just as passionately advocate not using it. However, I don't think they would be as eloquent as Dr. Rivers, of course. But…

Emanuel Rivers: I'm just a (inaudible).

Tiffany Osborn: Yes. But I just want to make sure that people do understand that there will be, you know, fall out one way or the other. So – and based upon most of the comments that I've already told you, I mean, there is a significant – when it comes to – especially CVP, there is a significant amount of discourse going from one side to the other.

And it's, you know, there's a group that accepts it and a group that definitely does not accept it. And there's a lot of back and forth on that. So I just tell you that so that I make sure that I've provided you with the information that's necessary to, you know, make informed decisions.

Reva Winkler: Thanks Tiffany . But we really do have to move on to our last measure. We really don't have a lot of time left. So lots of food for thought between now and the meeting next week.

The last measure is measure 298 – the Central Line Bundle Compliance. And this is from IHI. Is anybody form IHI on the line? (Stan) are you with us? OK, that's unfortunate.

But let's see, who's measure is this?

Mohamad Fakih: Mohamad (inaudible).

Female: (Inaudible). Yes. Just go ahead.

Mohamad Fakih: You know, so thank you for giving me just 10 minutes. It makes my life way easier.

Reva Winkler: Thanks, Tiffany. (Inaudible).

Tiffany Osborn I'm sorry about that.

Mohamad Fakih: No, no, no. No, I'm just kidding. So basically this is a central line bundle from IHI. You know, it's a great concept but they had major issues as far as – that (inaudible) the measure. This has been used initially to cut down infection rate. Keystone has used it with the (inaudible) study. It's still being used but they had some major concerns about making it to measure.

And the major concern is it's just a document issue of a sheet. And it does not really – it may not really reflect what's happening at the bedside when a central line is placed. So that was a major issue they had with that on the checklist. The other thing – there are other things that are part of the checklist that are not just at insertion. So let's say a daily evaluation for need at the (central line site).

So this is quite a bit of work form whoever is going to look up the data and it's all manual. There's no EHR and at least with no EHR alternative. So the impact to everyone of us – well five out of six, I think. So that's high impact. And the evidence – there's quite a bit of evidence that individual components of the checklist are important.

But as far as the whole thing that the bundle played, you know, together, I'm not clear and I have not seen literature that says, really, if you don't do the whole bundle versus doing a few things out of the bundle you know, you're going to have a huge drop in – a huge increase in infection rate.

So for example, chlorhexidine has been used – chlorhexidine antiseptic has been used as part of the bundle. And we know chlorhexidine is way higher, you know, as an effective antiseptic that povidone iodine. So the scientific acceptability – the reliability was four and two had a low reliability. Usability

– you had two moderate and two – and one low. And feasibility – one low and five moderate.

One of the things – and I'm going to be honest – I was the low feasibility – usability. And, you know, if you look at the measure itself, the developer did not, you know, they're empty sections in the measure – completely empty sections, not addressed – which was of concern to me. And I think they were the feasibility and the usability, if I'm not mistaken.

In summary, the major issue would the measure they have is that it's really paper-based and it's really whatever's documented rather that what the action, you know, the action that happened when they're placing the line. So, I'll give you an example for my hospital. All the sheets we get about the checklist are always fully compliant with no correction. And it's thus making you think if you know, if this is something helpful.

I don't know if anyone has questions.

Reva Winkler: You know, are there thoughts or comments from the committee?

Tiffany Osborn: I will just have two comments and one would be about the denominator exclusions. There's no exclusion for emergent central line access and which this would not – this is not practical to do whether or not they would get (dinged) for that. And then the other just practical component is it says, "avoidance of femoral vein" but it doesn't define what "avoidance" means.

So if you use a femoral vein, are you (inaudible)? Are you not (inaudible)? The reason I asked it is because, I mean, being someone who works in the ICU as well as in the ED, there are lots of times when that's the only thing you have left.

You know, if you have thrombosis in the bilateral I.J.s and subclavians or you've got thrombosis in the you're using one of the subclavians for dialysis or something then you may only have a femoral vein left to access. So I guess the question then would be what's the definition of avoid and how would that be implemented?

Mohamad Fakih: So we have a couple of minutes, I can add a couple of things – if you look at their, you know the national – the developer of this measure, (inaudible) validity is empty. As far as – I mean, they don't mention anything – as far as I think, feasibility – pretty much the same. And the other thing that they mentioned and I think it's a great study – the (inaudible) study. But the (inaudible) study was done also with CUSP so there was another component to the insertion which is change is culture.

And it's really tough to know is the checklist by itself is really what caused the improvement. And that's mu major concern about the checklist. You know, just choosing a certain checklist – does it really end up having a favorable outcome or it's a bundle of other measures, not just that sheet of paper? And what we're asking people to do with the IHI bundle is really to just feed the documentation to us and, you know, and make it a measure where you share documentation and it's a process measure.

The last thing I want to say is we already look at the outcome measures for this so we look at the class C in all ICUs. And again, the outcome measure is the most important thing. If you have an outcome measure that's very well measured right now, so how much would a process measure help me – for an outcome measure that is so good right now, it's about one per 1000 (inaudible) in a day and even lower as far as the infection rate.

Reva Winkler: All right.

Edward Septimus: This is Ed. To confuse things a little bit more, there's a very nice systemic review of the risk of femoral lines versus subclavians internal jugulars in the September Critical Care Medicine, which sort of brings us into whether or not the femoral is as bad as people think they were.

And also the compliance rate I thought was dropped by CMS in the (IHI) action plan as well that was (originally) proposed.

Mohamad Fakih: Yes.

Female: It was dropped from that, did you say?

Edward Septimus: I think so.

Female: See if we can find out …

Edward Septimus: You might want to check on that. So this may not be necessary.

Female: The other difficulty of this measure being a bundle was while all four elements that can be recorded at the time of insertion – the daily recording and whether or not the line is still needed is very difficult going to the bundled compliance checklist.

Male: Absolutely.

Diane Jacobs: Hello. This is Diane Jacobs from (Inaudible). Can you hear me now?

Reva Winkler: Yes, hi, Diane. Great.

Diane Jacobs: Hi, I've been on for the whole call. There must be something wrong with the phone. I have 10 people looking at it so I just changed to a cell phone so I wanted to make sure that you could hear me.

Tiffany Osborn: Well done.

Edward Septimus: Hi, Diane. It's Ed.

Diane Jacobs: Hi, Ed, and Tiffany and others.

Tiffany Osborn: Hey, Diane.

Diane Jacobs: Good. Good. And this is a challenging measure. We've been discussion with NQF and it is indeed a process measure. And with that, the issues around validity and reliability and usability are clearly for consideration. And the outcome measure – the, you know, central line associated with bloodstream infection clearly is a very solid measure.

Now, that said, the experience with organizations that have utilized bundle which is not intended to be a comprehensive list of all the elements of care but a small group of interventions that when implemented together also promote

teamwork and collaboration have found to be effective in that many hospitals that have utilized the central line bundle have seen reductions in their central line associated with bloodstream infection rate. However, the premise has not been because of simply these five elements or these five components of the bundle.

Mohamad Fakih: You know, I fully agree with you and then one of the issues that I had was having the measure at the – you know, something adopted by NQF right now because there are other variables, you know, for any high reliability process in a hospital or like we said, teamwork so maybe (team steps) or (cuts) which is not addressed by the measure.

Diane Jacobs: Correct.

Reva Winkler: OK. Any other thoughts from other committee members? Any other questions for Diane as she's finally able to join us?

Tiffany Osborn: Yes, Diane, did you have any other points – is there somewhere – maybe I missed it – where it was defined what is avoidance of femoral lines? Does that mean mandatory or – because avoidance – how is that defined?

Diane Jacobs: Well, you're correct in that. it's not clearly defined and it is avoidance not restriction never to use.

Tiffany Osborn Right. Right. And so then how do – how is it determined whether or not somebody meets that – meets that component of the bundle? As far as, if somebody puts in a femoral line, how do you qualify it as an appropriate versus an inappropriate? So how is the avoidance measured?

Diane Jacobs: Well, the avoidance is measured in practice with the rationale and documentation of the need for the, you know, femoral site.

Tiffany Osborn: OK. So we're just required chart review to figure out the rationale behind the use of it. is that correct?

Diane Jacobs: Correct. These would require chart review.

Tiffany Osborn: OK. I'm just trying to qualify. Thank you.

Diane Jacobs: No, absolutely. That's a very good point.

Tiffany Osborn: But clearly, you know, the institutions that have implemented this have had good results, yes?

Diane Jacobs: Correct.

Female: So is it structured in such a way that if someone des use the femoral artery that they – that that's the only vein – that that's the only artery accessible, that they're able to say that that meets the bundle?

Diane Jacobs: Correct. That is – yes – that is the intent and the – in practice, the application of the, you know, assessment for compliance with each one of the elements.

Edward Septimus: One of the thing about the femoral line is there was an article a year or two that showed the actual risk I really more in obese patients. That's (inaudible) controversy (up).

Female: Tom, did you say that was in Critical Care Medicine last September?

Edward Septimus: No, it's Ed.

Female: Ed. Sorry, Ed.

Edward Septimus: I'll send you the article I just referenced and you can – I'll send it to the committee.

Female: That would be great, thank you.

Edward Septimus: If you haven't seen it because it's a nice – it's thought-provoking. Let's put it that way.

Female: Yes, I appreciate that. Thank you so much.

Edward Septimus: I'm going to do that right now. Tom doesn't get mad at me.

Mohamad Fakih: It's a Metanalysis, that's right? That's what you were referring to? It was not a study, it was a Metanalysis? Or …

Edward Septimus: It was a Metanalysis, that's correct.

Reva Winkler: All right, folks …

Edward Septimus: Anyway, you can review it in two-weeks (inaudible).

Reva Winkler: This is Reva. I'm keeping my eye on the clock. Are there any other comments? Anybody would like to make of this measure. Obviously you will be discussing it again in detail around each of the criteria next week.

Are there any other questions that we could quickly address particularly about preparing for next week's meeting and the discussion of the measures that we'll do over two days?

Edward Septimus: Do we want to make – if there's anybody on the phone who wants to comment on the remaining 30 seconds?

Reva Winkler: Yes, I was going to say, thanks, Ed. You're a wonderful co-chair. Is there – is anybody …

Emanuel Rivers: This is Manny Rivers, I have a quick question.

Reva Winkler: Sure.

Emanuel Rivers: Physically, I'll be there, I suppose and will I be called upon to do anything – present or should I prepare anything?

Reva Winkler: You don't need to prepare anything – very much as you've done today. The committee is welcome to ask you questions and ask you to respond to some of their issues. But no specific presentation.

Emanuel Rivers: OK. Thank you.

Reva Winkler: Anything from anybody else? Operator, was there anybody out there who wanted to ask a question or make a comment?

Operator: If you would like to ask a question, you can press star then the number one on your telephone keypad.

And at this time there are no questions.

Reva Winkler: Right. So in terms of members of the committee, do you have any last minute questions before we close today? Certainly, we'll all be in the NQF office tomorrow if you've got any questions or issues and again on Monday. For those – I hope you're avoiding Florida who maybe getting slammed with a hurricane early next week and we may have a committee member impacted by that.

But other ways, I hope you travel safe and I'm looking forward to seeing you all on Tuesday.

Female: Great. Will you be sending us something that tells us anything else that we need to, you know, any other ways of preparing – those of us who haven't had one of these meetings before?

Reva Winkler: Sure. What we're going to do is update this summary form with the note. And so you'll have one of these summaries for each of the measures. But essentially we're going to do very much as we've done today but, as I mentioned, it will be a little more structured. So we'll ask you to talk about the issues around impact, the committee will vote. We'll ask you to talk about the issues around evidence, the committee will vote. We'll ask you to talk about the issues around reliability and the committee will vote. Then it goes through a series like that.

Female: OK.

Female: When do we start on Tuesday?

Reva Winkler: Good question. Alexis, do you have it there in front of you quickly?

Alexis Morgan: We start at 8:30. We'll be sending the committees the agenda tomorrow when we send you the call summaries from today's call so you'll have all that information.

Mary Blank Alexis, this is Mary Blank. Communication has not been coming through to me. So, what time do you think you'll be sending that (inaudible) so I can follow up on it?

Alexis Morgan: It'll be tomorrow evening – late afternoon.

Female: And what time – are we supposed to be there for anything the evening before or we're just – that morning. OK.

Reva Winkler: That morning. Tuesday morning.

All right. OK. All right, any other last minute question?

Diane Jacobs: Hello, this is Diane. And I just have a question. Based on today's discussion, do you plan to take forward the central line process measure or is this not one that will move forward?

Reva Winkler: Well this was only a preliminary discussion. So it will be – all measures will be discussed at the meeting. OK? This will be discussed by the entire committee. Any other questions from anybody?

Diane Jacobs: Just one other question. So the meeting is Tuesday and Wednesday, correct?

Reva Winkler: Correct.

Diane Jacobs: OK.

Reva Winkler: All right. Anything else form anybody. All right, again, don't hesitate to contact us if you do have any questions otherwise, we really look forward to seeing you on Tuesday. And have a really good day. Thanks so much for taking the time this afternoon to work with us. We really do appreciate it. Take care everybody.

Operator: Thank you. This concludes today's conference call. You may now disconnect your line.

END