NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
April 22, 2014
2:00 p.m. ET

Operator: Ladies and gentlemen, this is the operator. Today's conference is scheduled to begin momentarily. Until that time, your lines will again be placed on music hold. Thank you for your patience.

Welcome to the conference. Please note today's call is being recorded. Please standby.

Just to remind our prior committee members joining us today, your line will be open for the duration of the call. Please use your mute button when not speaking or presenting to reduce background noise. And please do not place the call on hold. Now, let's get started.

Jesse Pines: Hi everyone. I'd like to welcome everyone here today to our second standing committee meeting for the patient safety committee. This is Jesse Pines here with NQF. I'm joined by Helen Burstin, Andrew Lyzenga, Kathryn Streeter and also Laura and Suzanne are also called into the line. So, we have a packed agenda for today.

And I think everyone should have a version of the plan for today. So, we'll run for two hours from 2 p.m. to 4 p.m. Eastern Time. We're going to do, first start with the NCQA measure which is 2371 followed by picking for the spinal part of the discussion of the antipsychotic measure that's 2337, that we weren't able to finish before we had the break for the last meeting followed by the 0684 which is the CMS measure, percent of residents with UTI.

Followed – after we're finished with that discussion, we're going to be resuming our discussion the Ad Hoc sepsis measure 0500. What we're going to do is actually something similar to what we did last December. We're going to have brief comments from two of our experts Dr. (Townsend) and Dr. (Yillie) followed a committee discussion. And also just to let you know, there are I think a few other folks who were going to be calling in for public comments on the sepsis measure. And we'll hopefully get things done before 4:00 if we can. So, you're going to do the roll call.

Male: Yes, let's do a quick roll call if we can. We'll try to move through this quickly. Just so we can see who we've got on the line. Ed Septimus?

Edward Septimus: Present.

Male: Iona Thraen?

Iona Thraen: Yes

Male: Hi Iona. I know, Jason is not here, Charlotte Alexander?

Charlotte Alexander: Here.

Male: Hi Charlotte.

Charlotte Alexander: Hi

Male: Kimberly Applegate?

Kimberly Applegate: Here.

Male: Hi Kimberly. Laura Ardizzone?

Laura Ardizzone: Here.

Male: Hi Laura. Richard Brilli, Christopher Cook.

Christopher Cook: Here.

Male: Hi Chris. Melissa Danforth, Martha Deed is not on, Lillee Gelinas?

Lillee Gelinas: Yes.

Male: Hi Lily. Steve Lawless, Lisa McGiffert.

Lisa McGiffert: Here.

Male: Hi Lisa. Gregg Meyer, Susan Moffatt-Bruce, Ann O'Brien?

Ann O'Brien: Yes, Hello everyone from California.

Male: I am. Pat Quigley?

Patricia Quigley: Right here, thank you.

Male: Yes.

Female: Hi.

Male: Victoria Rich?

Female: I see a chat from Victoria. Sorry to interrupt, I'm having a little trouble responding to yes. You should also dial in, so that you can speak. So she is on the webinar.

Male: I just – sorry we're having a fuel of phone issues here, if we get cut off just to warn you. I think we're on – did we say Victoria Rich was on?

Female: She's dialing in now.

Male: She's dialing? Nothing. Josh Rising, Michelle Schreiber?

Michelle Schreiber: Yes here.

Male: Hi Michelle. Leslie Schultz.

Leslie Schultz: Here.

Male: Hi Leslie. Lynda Smirz.

Lynda Smirz: Yes.

Male: Hi Lynda. Tracy Wang, Kendall Webb?

Kendall Webb: Here.

Male: Hello. (Al Wu)? All right. Well, let's go ahead and get started with our discussion of 2371 …

Missy Danforth: Sorry, this is Missy Danforth I joined a little bit late. I think I missed the roll call, I apologize.

Male: Thank you

Male: No problem. Thanks, Missy. And our lead discussant on 2371 is Chris Cook.

Christopher Cook: Yes, I'm here. Will the NCQA would like to give a preamble on this before I get started?

Male: Thank you, thank you, Chris.

Erin Giovannetti: Great, thank you. This is Erin Giovannetti from NQCA, can you hear me OK?

Female: Yes.

Male: We can.

Erin Giovannetti: Great. So, thank you. OK that's a busy agenda. So, I will be brief on this measure. And you on monitoring for patients on persistent medications is actually a long standing HEDIS measure. Really, the intent of the measure is to assess monitoring for people on very common cardiovascular agents. So it looks at on four different medications, ACE inhibitors, ARBs, digoxin and diuretics and looks for specific monitoring tests that are appropriate for monitoring renal function as well as other indicators.

The intent is really that with appropriate monitoring, patient safety will be preserved and we will prevent ambulatory care visits, ED visits and

hospitalizations due to adverse reaction to those medications. For this measure, we actually – recently have just updated the measure. So, that we actually contracted with researchers at Johns Hopkins Center for medication quality and outcomes to U.S. systematic evidence for us to really want to make sure that had evidence for all of the individual pieces of this measure. And I think I will leave it at that and then welcome any questions.

Male: Thank you.

Christopher Cook: OK, this …

Male: Yes, go ahead, Chris.

Christopher Cook: OK, yes, I just wanted to get started and commend NCQA in its thoroughness and in putting this application together. And I will definitely like to thank you for the extensive literature review which made everything in this easy to get through.

From that sense, we'd like to say that as we go through this hopefully, you will see that NCQA has done a good job and all the elements that are there. This is a process measure as all medication adherence measures are, and that they are not reflecting the outcome of the treatment.

But probably have that – as opposed to being a monitoring process for the proper use of the medications. It is at the population health level in the fact that they are administrative claims as well as using a lab data. And when you look at the rate, it consists of the rates across the three different classes of medications. And then supplies a total rate for the organization. But what this does is it gives you a benchmark understanding for that organization at the higher level of how they're doing in the monitoring of drug therapy. And does not get down into individual therapies or reasons of you know, either exclusions in that type of thing.

The evidence itself for the ACE and the ARBs, NCQA provided a literature review that consisted of 16 studies. And they did classify the level of strength of those studies. And it was a high mix or a high level mix of very high level, 1b type studies, random controlled trials down to level five consensus-based

studies. So very strong evidence there for digoxin, there were three consensus opinions around monitoring for potassium and serum creatinine, and then there were nine high level studies that were around actually monitoring for a dig level on an annual basis.

And then for the diuretics, for the monitoring of potassium and serum creatinine, there were 13 studies, also a mixed-in level but some very high level randomized trial information as well as down to conscientious level. So, in totality the evidence for this issue relating to patient safety, by my opinion was extremely strong and well-presented by the measure developers. And I'll stop there first to answer any question.

Andrew Lyzenga: Thanks, Chris. Any questions or thoughts from the committee on evidence?

Lisa McGiffert: This is Lisa McGiffert. So, basically this is a process measure that tells us that a provider is monitoring for these drugs for certain patients, right?

Female: For safety events, absolutely, yes.

Male: Right, yes.

Lisa McGiffert: OK, and that evidence that you cite shows that the process actually is connected with – the monitoring is actually connected to better management of these drugs, right?

Christopher Cook: That is correct. When individuals take these medications, there is strong clinical evidence that either electrolytes within – that's for the measuring potassium is affected or that the serum creatinine would be potentially affected by these medications. Or it changes status for the patient within those indicators could also create a clinical change in how the practitioner needs to change their therapy. And then in the case of digoxin, specifically, it is one of the narrow therapeutic agents. And so, it's recommended to occasionally check what that serum (dig) level is to identify and avert any adverse effects by that medication.

And so, this measure is a process measure assessing whether or not the practitioners are monitoring the therapy had at appropriate time and appropriate intervals.

Lisa McGiffert: But it doesn't measure anything about the response of the provider if the monitoring indicates that there's a problem.

Christopher Cook: Correct, and that's where the process measure as opposed to being able to be an outcomes measure.

Lisa McGiffert: Are there any outcome measures connected with this since this is been around for so long?

Male: No, (inaudible).

(Crosstalk)

Female: Sure. I mean I can speak to the outcomes associated with this are actually kind of hard to identify because it's hard to look in claims and know exactly whether or not a hospitalization resulted, I mean, from poor renal function due to long term lack of monitoring, or whether a hospitalization, you know, (received) it from, you know, problems with potassium, hypokalemia – hyperkalemia, so, that's primarily why we don't have an outcome measure that looks for those individual hospitalizations or ED visits associated with the negative effects of not monitoring just because of very hard to – using our current data systems, identify – those.

I think it would be great and we would certainly look forward to measures using electronic health records to really looking at what are the levels that people get on this and are providers appropriately adjusting medication and reaction to those levels.

Unfortunately, you know, we want a very broadly, a measure that could be broadly used and currently that don't need to rely on claims data. And so, this is what we can measure with claims data right now, but we're certainly looking to the future to look at more – using electronic data sources more measures of adverse drug events.

Lisa McGiffert: Thank you.

Andrew Lyzenga: Any other comments or questions from the committee? Hearing none. We'll move on to vote the evidence question. Just a note, we will be voting online, you should have received an e-mail related to this, yesterday. We will bring up a slide here to allow you to vote, and you'll be able to check off a box indicating which of the options you'd like to select.

Female: So, let me see, I – got an e-mail about the schedule, is that what it's on – in?

(Crosstalk)

Female: It says …

Andrew Lyzenga: You should be set up to …

Female: … join, got to SharePoint.

(Crosstalk)

Andrew Lyzenga: Are you along the webinar?

Female: Oh, yes, I see. OK, I can do it. Thanks.

Male: That's great.

Female: Just a reminder for our committee members that are also on the phone. Just make sure that you have your computer speakers turned down and then, Andrew, as you were pointing out with the voting, they can simply click in the box next to the answer of their choice and we'll have their votes counted.

Andrew Lyzenga: Thanks. So, we will go ahead and vote now or on the evidence question.

I think I've followed the response we have. So we …

(Off-mike)

Female: (Shawn) are you able to help advance the slide or can you do it from you're end?

(Shawn): Sure, let me grab it for you.

Female: For some reason, they are not able to.

(Shawn): Give, it a try now.

Andrew Lyzenga: OK, so, let's – (inaudible) votes here as we can, we have the wrong slide up there, sorry about that.

So, this is the – we're voting on 1A, the options are one for high, two for the moderate, three for low, four for insufficient evidence and exceptions, and five for insufficient evidence. I will pull up the voting slide here.

And go ahead and vote. Sorry for the confusion there.

Male: It doesn't take much.

(Crosstalk)

Male: OK.

Andrew Lyzenga: All right, that should be it. OK, it passes on 1A, so, let's go ahead and move on to 1B.

Christopher Cook: So, 1B is the performance gap, and NCQA has reported that the mean range across the populations sets that were measured range primarily from the upper 70s to the low 90s, the percentile range overall and the scores is the upper 60s to the about the mid 90s. And within this sample, he assessed an extremely large sample of 99.4 million commercial-wise, 14.3 million Medicaid-wise, and 11.5 million Medicare-wise. And so, from these, any single change in a percentage obviously affects a large number of patients.

And while we look overall but it appears we're doing fairly well over nation within this. Still having – there's still a considerable room for improvement which does affect extremely high rates of individuals, because these

medications are so often prescribed, and affects a large percent of the population.

Andrew Lyzenga: Thanks, Chris. Any questions or comments from the committee? Hearing none, let's go ahead and vote on 1B. You should be able to see the options there on the screen in front of you, and go ahead and vote. I think we're missing one, you can enter your vote.

Stephen Lawless: Hi, Steve Lawless here. Sorry I'm late.

Andrew Lyzenga: No, problem. All right, we'll go ahead. That will pass, 1B. Let's go on move to 1C, high priority. Any comments or questions from the committee on this subcriterion? If not, let's go ahead and vote. You'll be able to see the options there in the screen.

Waiting for just a couple more, great. All right, this passes the high priority criterion. Let's go ahead and move on to scientific acceptability. Do you want to say a few words, Chris or we can just take comments and questions from the committee?

Christopher Cook: Yes, I would – I will go ahead this real quick, just in the review. Are we going directly into reliability first?

Andrew Lyzenga: Yes. We shall – talk about reliability first.

Christopher Cook: OK, so, within the reliability, NCQA did do testing. They had used an Adam's approach, using a beta-binomial model to estimate reliability and the results are presented within a table on page 33 of the documentation which they provide. And basic general acceptability, minimum reliability score 0.7 is used to indicate significant signal strength to discriminate performance between accountable entities. And across the entire commercial population, Medicaid population, and Medicare population, all free as well as the total measures achieved this minimal score.

But most of them were in the 80s and 90s, the only one that did have an issue which was explained by NCQA is the digoxin levels in Medicaid population. And that was explained in the fact of Medicaid population primarily being

women and children, many of the facilities did not or reporting organizations did not have an adequate sample size to really be able to assess that. And given the ACA and (inaudible) increase in Medicaid population and expansion, one would expect that those numbers would then be able to be tested further.

Moving forward, but if you look at all three, between ACE and ARBs, digoxin, the diuretics and then as a total score overall in the multiple populations, there were very strong reliability scores and again, it was tested specifically through NCQA.

Andrew Lyzenga: OK. Thanks, Chris. Any comments or questions from the committee? If not, let's go ahead and vote. We're voting on 2A reliability, you should see the options there in front of you.

All right great, thank you. All passed on 2A, let's move to 2B, validity.

Christopher Cook: Again, NCQA has performed validity testing on their population – and approved this measure. They actually presented three different types of validity. First is criterion, data element validity which is testing whether the critical data is there and whether it was valid within what was taken. And so what they did was they actually, use the administrative claims data and went back into – compare it against the original medical records. And the results of that validity testing, the critical data element testing is reported on page 35. And from sensitivity, it is based in – it's in the mid or upper 90s. And all the categories, it did score 89 in the ARBs and ARB-combinations which is extremely high and very solid.

The specificity was also examined. Also meeting strong rates ranging anywhere from 62 percent up to 91 percent, and then the positive predictive value, four – the result there were anywhere from 89 percent to 98 percent, so, also extremely high, positive predictive value. They also then went into doing empirical validity testing and what they hypothesized was that organizations that would perform well on one of the monitoring parameters should also perform well on the other measures. And correlation matrix was put together also on page 35 which examined that, and there were good R ratios for ACE

correlating with digoxin scores, as well as diuretic scores, and then also for the dig course with diuretics. So, all of it was significantly or statistically significant at a high level. So, therefore, showing that it had good empiric validity.

And then finally, NCQA does have a rigorous and robust face validity process, where they went through four separate expert panels, and then opened that allowed for public comments from various stake holders, regarding the measure, its application and how it is used. And then one additional thing that NCQA did was they performed an inner-core trial range as a point of optional data that to be provided. And this was actually a fantastic inclusion and their – in the fact of where they demonstrated from the first core trial to the third core trial what was a statistical difference between organizations, and allow that to be used in – as evidence for what does the actual difference between organizations' mean.

And I am trying to find the page number on that particular report as well. I think it's from 39, yes, from 38 to 39 with all of the P values there, achieving high levels of significance. Demonstrating their ability to demonstrate significant difference between organizations and their performance off this measure.

And so, there are four separate different levels of validity testing that have been done on this measure, let's all leave it there.

Andrew Lyzenga: Thanks, Chris. Any comments or questions from the rest of the committee? Hearing none, let's go ahead and vote.

Great. So, it passes the validity criterion and we will go ahead onto feasibility.

Christopher Cook: And again, these are all administrative claims data sets which are standard in routine for all health plans as well as provider groups as they are submitting claims.

Andrew Lyzenga: OK. Thanks, Chris. Any comments or questions from the committee? Go ahead and vote. Just waiting for a couple more. All, right and we'll call it at

that – there we go. Thanks everyone, passed the feasibility. Let's go to usability in use. Any comments Chris or the rest of the committee?

Christopher Cook: Yes, just real quick. This measure is currently being used in a number of different areas. It is with the annual state of health care quality and the public reporting through NCQA, this measure is on the Medicaid Adult Core measure set. And then it's also within and as reported by NCQA, it is in their HEDIS measure set, so for the ACOs as well as for the health plan. And that then comes into the quality compass being able to look across different plans to be able to look for quality across different organizations.

Andrew Lyzenga: Thanks, Chris. The rest of the committee any comments or questions? Let's go ahead and vote then. You should see the – yes, here we go. All right. Thanks everyone, it passes usability. So, we can go ahead and go to a overall vote, that is on overall suitability for endorsement unless we have any comments or questions from the committee, we can vote. Anybody have anything to say?

Female: I wish they were all this easy.

(Crosstalk)

Male: I agree.

Lisa McGiffert: And this Lisa, I wish there was an outcome measure.

Female: Yes

Male: Yes. Noted.

Female: EHR as well (inaudible) there.

Andrew Lyzenga: All right. And this measure will have, thanks for efficient review.

Female: 17 to zero, thank you so much Erin for making time. I know this is a difficult day for you. I also just want (inaudible) for updating the measure when it was, you know, indicated by the last (inaudible) that did an updating. So, thank

you so much for taking that on and bringing back this so much improved measure.

Female: Great. Thank you.

Female: All right.

Andrew Lyzenga: All right. So, we will move on now to measure 2337. If you recall from the meeting, we actually got through voting on the importance and scientific acceptability criteria. So, we will just jump right into feasibility on this one.

Male: (Inaudible).

Andrew Lyzenga: Oh, yes. We have that up. It actually don't have account to the votes (inaudible) the previous vote on this.

Female: Or maybe just a general reminder of the measure for those who …

Andrew Lyzenga: Yes, that's …

Male: Yes. This (inaudible), I want to recount the previous votes up to the time we (inaudible).

Andrew Lyzenga: We will try to pull that up.

Female: First, I don't know if you'd be willing just give a quick thumbnail on the measure to remind your colleagues.

Lynda Smirz: It was …

(Crosstalk)

Lynda Smirz: This is Lynda with Kimberly and I who have …

Female: Wonderful, thank you, thank you.

Lynda Smirz: Yes. OK. And Kimberly I don't know if you want to do this or I'm happy to do it since I'm available at this point time. But, the measure was one that was to look at the percentage of children under the age five who are dispensed the

antipsychotic medications during the measurement period. The developer's rationale refer to the adverse effects that the receipt of antipsychotic medications had in children to include a number of medical problems, increased metabolic syndrome, hyperprolactinemia, thyroid dysfunction, diabetes, depression, and granulocytosis, et cetera. And we can go into more detail if anybody needs that.

Kimberly Applegate: So, I can quickly too and say (inaudible) measure, we talked pretty much at length and the developers made a lot of comments that there is no primary indications for these medications in children under five. And there was a graph in the developers' submissions showing a very rapid increase each of these medications without a clear use in very – wide variation in the Medicaid program data by state, in particular in (inaudible) foster care program.

Female: So, is everyone clear in the numerator and the denominator? Do you remember that?

Female: Yes, very …

Female: OK.

Male: And we're just trying to tally up the votes here.

Female: OK. And main issue is safety because of the issues around the – well, ones that's not clear that this – you know, their primary role and their alternative medications for the behaviors that they're being used in ADHD and conduct and disruptive and oppositional defiant disorder. And that the side effects which can be quite large percent of children are not correlated with the length of use or quantity use of the drugs. And that's mainly a metabolic syndrome (inaudible).

Stephen Lawless: This is Steve. I also have a question.

Female: Yes.

Male: Sure, go ahead.

Stephen Lawless: Two things. I may have missed it in the discussion. Was there any comments to the American Academy Pediatrics or – I know the APA commented, but from the pediatric section of the American Psychological or Psychiatric Association.

Female: Good question. I can say that I did see that there's a pretty wide consensus that this be addressed from 2008 onwards. It started with this (inaudible) general article. Then there was the American Psychiatrist Association, there's the CMS, there's American Medical Association Council on Science, there's a number of different groups that have said, "There needs to be a policy around diminished use." I don't know about the AAP.

Female: I don't see the AAP in the additional information with respect to workgroups.

Female: Although I can't tell you the person I spoke to who's the associate medical director for mental health and Indiana is a pediatric psychiatrist. And she's, you know, she was very much aware of this issue and working on diminishing use in the Medicaid program in the state. And apparently it's a national initiative in the Medicaid program.

Stephen Lawless: Thank you.

Male: And we do have a count on the previous votes. Let me just read that out pretty quickly for you. Sure. So, for evidence it was one high, 12 moderate, four low, three insufficient with exceptions and zero insufficient. For performance gap, it was 10 high, 10 moderate, for high priority it was 14 high, six moderate. For reliability it was three high, 12 moderate, three low, four insufficient with exception. And for validity, it was two high, 13 moderate, three low, and one insufficient with exceptions. So, all those passed through.

Female: Thank you.

Male: So, if everybody is ready, we can just go ahead and vote on feasibility, we'll pull that up in just a moment.

Lisa McGiffert: And – this is Lisa at this is all coming from administrative claims data, right?

Female: That's correct.

Male: Yes.

Female: And it's all payer type.

Andrew Lyzenga: Thanks. So, we do have the voting screen up now, if you want to go ahead and vote. This is a reminder that's around feasibility.

Kimberly Applegate: I did actually – this is Kimberly. I had a question about something that was in the – even some minor things that want to talks about each for registered participation. There's no fee for the participation but if you want to access the data through the database for research purposes, there's a small fee associated with that.

Andrew Lyzenga: OK. I think. And we – we got a passing vote on feasibility. So we'll go ahead and move to usability and use. Any comments or questions from the committee on this criterion?

Female: This is a new one, correct?

Andrew Lyzenga: Yes.

Female: Yes.

Andrew Lyzenga: That's the new measure.

Kimberly Applegate: Yes. And there's a planned public reporting, it isn't quite yet – I don't think they'll be any unintended consequences from what Lynda and I read.

Male: Great.

Female: Can I go back to the fee just for second. I'm sorry, because I'm reading it and it looks like even to get the numbers, it's not just for research purposes but to get your report, there's a fee associated. Is that correct?

Lynn Pezzullo: Hi. This is Lynn Pezzullo from PQA, measure developer. If can comment on that. We actually we have licensing fee things for organizations that are using

our measures for commercial use, but is in – as far as plan accessing the data, there's no fee for that.

Female: Thank you for clarifying that.

Female: Thank you.

Lynn Pezzullo: Certainly.

Andrew Lyzenga: So unless there are any comments or questions on usability and use let's go ahead and vote on that, we've got the screen up.

Just waiting for a couple more, one more I think. Here we go. All right. This passes.

So, we will go to an overall vote. This is a vote on the overall suitability for endorsement. Here it goes, options are yes or no.

All right. Thank you all, the measure passes. Thanks to the developers for joining us on the line. And thanks for to the committee for another efficient review.

We'll go ahead and move on to measure 0684, the Percent of Residents with a Urinary Tract Infections, Long-Stay. And CMS is the procurer of this measure, do we have a representative on the line? Can CMS give us a quick intro.

Laura Smith: Hi, this is Laura Smith. I'm from RTI International, the developer for CMS.

Andrew Lyzenga: Great

Laura Smith: … I'll give the – thank you for the opportunity. I'll give the introduction. This measure reports the percent of long-stay nursing home residence with an active symptomatic UTI, 30 days prior to their resident's target assessment. Long-Stay residents are defined as having been in this facility accumulatively from more than 100 days. Residents with target assessments that are for admission, readmission, or return to the nursing facility are excluded from the measure. Data are collected using the minimum data set version 3.0, which is

a condition of participation for Medicare and Medicaid-certified nursing home.

UTI are the most common facility-acquired infection in nursing home. They cause discomforting and can lead to serious complications and mortality. The growing prevalence of antimicrobial resistance increases the importance of prevention proper treatment of this infection. This quality measure provides (advantage) for facilities to monitor their approach to infection control, perineal care and catheter use. Prior nursing home studies have shown association between RN turnover and again staffing levels with facility infection rates.

With regards to measure development, while data collected for the MDS 3.0 became – began in October 2010, all data elements for this quality measure are the same as (items) that are already well-established in MDS version 2.0. A study of validity of the MDS 2.0 elements compared to perspective surveillance showed 57.9 percent sensitivity and 86.5 specificity for the UTI item. Revisions to RAI manual for MDS version 3.0 were made to facilitate more accurate identification of active UTI.

Item level inter-rater reliability testing of the MDS 3.0 item showed substantial agreement among raters, provider of level reliability analysis found substantial agreement amongst facility MDS 3.0 and 3.0 scores. Stability analysis, the provider rank changes over time using quarterly data from 2012, 2013, showed the measure is reasonably stable with approximately 50 percent of facilities experiencing rank changes or the three deciles between quarters. The measure shows variability across facilities nationally and just over 10 percent facilities have appropriate score.

Performance measure level validity analysis indicate that this measure is significantly but weakly correlated with the NQF-endorsed nursing home long-stay catheter and incontinence measures. Missing data do not present a threat to the validity of this measure. And the measures average over two quarters to minimize threats to validity due to seasonal variation.

This measure has shown a slow but steady improvement in the national mean score from a peak 7.9 percent in the first quarter of 2011, to 6.2 percent in the second quarter 2013. Although there are quality measures related to prevention of UTI and used in other study, this measure is the most valid, reliable, usable, and feasible for capturing UTI among nursing home residents for the purpose reducing UTI. This measure also reported to the public via nursing of compare, thus providing valuable information to residents and their families about quality of care and nursing homes. Thank you.

Male: Great. Thanks, Laura. So just to remind everyone, we did go through all the components of the measures. So why don't we start with evidence first …

Male: Yes.

Male: … for discussion.

Leslie Schultz: Sure. This is Leslie Schultz, and thank you for the developer for being with us today. Again, this is Percent of Long-Stay Residence with Urinary Tract Infection. The evidence – this is an outcome measure. And there are processes of care that can influence the outcome. So the catheter associated obviously, lots of strides on avoiding dwelling catheters and avoiding treating a symptomatic bacteriuria.

For the non-catheter associated standards of hydration, hygiene, mobility, (toileting), et cetera. So this is pretty straightforward in terms of the evidence of is there things we – are there things we can do process-wise to influence this outcome, the answers are yes.

Female: Great.

Male: Great.

Male: Great.

Andrew Lyzenga: So let's go ahead and vote on this unless there are any other comments or questions from the committee?

Pat Quigley: Excuse me. This is Pat Quigley, I have a comment.

Male: Sure. Go ahead.

Male: (Inaudible).

Pat Quigley: Thank you so much. And I would like to thank too the sponsors for being here. But I would like to say that I somewhat disagree with the discussion even though this is such an important patient outcome. You know, the use of the MDS data only indicate is it present or not. So, you know, that's a yes or no binomial response of whether or not there's an infection for someone with long-standing catheter. But quite frankly though, the literature that was submitted to support this indicator is really quite dated.

And we have very, very robust discussion surrounding CAUTIs at are face to face meeting. So, in my position, I would like to say that based on what is presented, I think that the evidence is really weak in relationship to this measure as an outcome measure that, you know, was just very, very dated. Thank you.

Male: OK. And just to remind that you guys, (inaudible) outcome measure. The question for the committee here is whether there is a rationale connecting at least one healthcare service or action or intervention to the outcome.

Edward Septimus: This is (Ed). I have one more question in terms of the definition and once (inaudible) analysis was done to validate the definition.

(Crosstalk)

Male: … better question to ask under the …

Female: Validity.

Male: … yes. The validity, reliability …

Male: (Inaudible).

Male: … or preciseness of the specification. And we can vote on evidence first or take some more questions on (inaudible).

Stephen Lawless: This is Steve. I also have question about the evidence actually.

Male: Yes, yes. Go ahead.

Stephen Lawless: Given the – when we have a meeting and a conversation, I think it's the gentlemen who was, who from who represented the idea of some of the other measure about catheter required urinary tract infections. And same patients with long term rehab phase, you know, they need the catheter in because of, you know, various physiologic needs. And it was a very compelling argument.

Pat Quigley: Yes. That was, excuse me, this is Pat. That was our gentlemen that came from Texas they give public comments from tier for spinal cord injury patient.

Male: Right. And so, given that conversation we're having with that with the push towards gaining catheters out. But, now this with the secondary measure to say, guys we're going to reporting long term facility for injured patients with catheters. Is this kind of like the two messages together …

Female: (OK).

Male: … seem the evidence that he was presenting is a little bit different. It was reporting the but now he was saying – he would rather endorse the evidence that gives more physiology here in terms of not necessarily pushing for catheters out for this is, this happens. And there wasn't many alternatives available. So I don't know whether developers want to comment on those public comments or not.

Female: That goes to the scientific acceptability and that comes a little bit later in this process.

Female: No. I think the real questions for the developers whether it was consideration of exclusion for spinal cord patients.

Male: Yes, exactly thank you.

Female: Just about the CAUTIY measure at the in-person meeting. It doesn't appear to be in the exclusion so such just if you could comment on that.

Laura Smith: Sure. And this is Laura Smith again. So, it has now been considered as an exclusion, and we did look at the information that is available in the MDS that would get us as close as we could to being able to identify spinal cord injury. Unfortunately the diagnosis – we're looking at our paraplegia and quadriplegia. We don't have a specific designation for spinal cord injury available at the MDS data. And when we look at the proportion of our long state population that had those conditions that's, it very small it's less than a percentage for each for of those condition.

So, they aren't – we are not risk adjusting or excluding for them. But, they are also a very small population in our long-stay population. And I think if I could just also address the general concern about how the – when we look at our long-stay population and the items that identifies whether or not there's an in-dwelling catheter present, we actually have a very small proportion of our long-stay population that would even begin to be at risk for CAUTI. We identify only 4.3 percent of the population is having in dwelling catheter that – there's some limitations of the item in terms of – we can't specify whether or not that's a Foley catheter. But that gives you sort of an upper bound on the proportion people in the populations that have catheter.

Pat Quigley: And this is Pat Quigley responding again. I'm rehab nurse and there's quite bit a work with the disabled in long term care. And I just like to say again that, you know, as our colleague is asking about those with spinal cord injury. This is not indicated for patients who need to have a indwelling catheter for people with neurogenic bladders. So, but still if we look at the evidence, the supportive evidence, even the very first statements related to nursing facility residence often develop infections. And if you look at all the literature that's submitted for this, these are prevalent. These are descriptive studies that were conducted in 1980, 1990, I mean they're very dated.

And in today's world in long term care, if anyone can get a Foley out, they're out. So, I just like to say in relationship to the strength of the evidence that this is very, very weak, the literature that's supporting this.

Female: Thank you.

Female: (Very) helpful. But, again just remember for the specific (voting) is about health outcome with rationale only because it is an outcome.

Female: OK.

Male: So let's go and vote on this …

Lisa McGiffert: This is Lisa, I have another question. So, this is not looking at people with catheters. It's looking that UTI's …

Female: Right.

Male: Right.

Lisa McGiffert: … in general, right.

Female: That's correct.

Lisa McGiffert: OK

Male: So we've got the options up on the screen here. Go ahead and vote.

All right, so the committee has voted to – so we've got an eight to 11 vote here. I think that actually falls within our gray range. So, we will move the discussion forward and consider the next subcriterion performance gap. So, if you – does the committee have any comments or questions related to performance gap?

(Iona Thraen): This is (Iona), I'd like to hear to again what that performance gap is in terms of the most recent data?

(Crosstalk)

Female: This is one element of the MDS now, currently 3.0 version. Then set the measure was originally introduced, it has reflected (inaudible) study improvement over time nationally. In most recent data and there's a table on

our site, the second quarter of 2013 which is demonstrated nationally, the mean is now at 6.2 percent. And that is down from 9 percent. The (inaudible) facility is over 13,000 that are presenting over 1.1 million residents. There's a variation across the nation with approximately 3.5 percent, (inaudible) about these facilities reporting zero cases.

The 98 percentile nationally is nearly 13 percent. And so there is variation, there is opportunity and there are organizations with (best) demonstrated performance above zero.

Male: OK. Thank you.

Female: So, is that chart – was that sent to us or included in our …

Female: It's on our website

Male: That should be on page three.

Female: Page three.

Male: Yes.

Female: And as to this period of care, the developer has done a nice job of that, of addressing race and socioeconomic data. And whether – maybe some modest differences in terms of SCS, it does not seem substantive or of concern.

Male: OK. Great. Unless there are any other comments or questions, let's go ahead and vote on performance gap for 1B. And the options should be up in front of you on the screen.

OK. So, we have – passes this subcriterion. So, we'll go ahead and move to high priority. So any comments or questions from the committee on this sub criterion.

Leslie Schultz: Well, this is Leslie. I'll kind of talk about how the statistic (inaudible) into the bigger picture. It is reflected as the national quality strategy in terms of improving all quality of the better care in making healthcare more patient-centered and more reliable and safer. It also goes to – speaks to the

affordability of care in terms of reducing the cost of the quality of healthcare for the individuals in their families. It's – this is measure that can assist in reducing harm as experienced by those, the patients or the resident. In this case it's an opportunity to promote, you know, more effective prevention and intervention (processes) for leading cost or morbidity and mortality amongst long stay residents.

And it does certainly I would think it would make the experience more pleasant for the resident to the family if we could avoid the UTI.

Andrew Lyzenga: OK. Thank you. Any other comments or questions?

Pat Quigley: This is Pat Quigley. And I would just like to say that in relationship have to the discussion with other to high priority again the literature to – that this is very dated. There's recommendation for practice in the priority area, high priority. That has a reference it's probably somewhere. But I'm not sure what it is. But the – as number 15, I'm not sure the date of that I'll look it up. But, there's a bundle interventions for help and to – able to prevent this.

So, again I decide to make the comment that I think that when these are submitted to us solidarity review should really be updated to support the evidence of today's practice.

Female: OK.

Female: There's no doubt this is a high priority. You know what? When not – none of us want our patients in long term care to have urinary tract infections. So, there's a lot of practice that's done today to really reduce this. It's not whether not there's a measure in MDS. It's really, what's being done in practice. So, thank you.

Andrew Lyzenga: All right. So, let's go ahead and vote on 1C high priority should have the options up there on the screen in front of you.

Just one more I think. We'll call it at that, the measure passes the important – criterion or that sub criterions, so we'll move on to scientific accessibility. We'll speak first to reliability …

Leslie Schultz: OK. Sure. This is Leslie again. So, in terms of the reliability that if the developer reference to several studies of sort of the face validity using the technical expert panel. And then, for the current version of the MDS 3.0 which is now a version eight. That tool has demonstrated improved stability and improved accuracy, actually over the earlier MDS 2.0 which when this measure was originally endorsed, and then re-endorsed, it was version 2.0.

So we have a more robust, more stable, more reliable tool, and this is one item in there. In terms of inter-rater reliability which is important when you're doing using this sort of a measurement. The developer's report using the gold standard reviewers and then trained-facility based reviewers. People are familiar with using the MDS 3 – demonstrated a capital of 0.80 which is rather impressive, given higher is better. And so, it's demonstrated that repeatedly and our understanding from what the developers presented as if there's ongoing reliability testing conducted on the tool including this item.

(Off-mike)

Pat Quigley: This Pat Quigley, I have a question if I may.

Male: Sure, go ahead Pat.

Pat Quigley: There's a two exclusion criteria and the one present on admission so that would be for the first rating. And the second one is that there's a urinary tract value that's missing. So, how is that handled if there's something not entered? Because usually, there's MDS data coordinators – data reporters who collect this information in the facility.

Leslie Schultz: So, there's handful of cases where we have missing information on that item have been excluded. It's 0.1 percent in the sample. So, it's not having an impact an on the measure.

Pat Quigley: Thank you.

Andrew Lyzenga: So, can we – unless there are any other comments or questions on reliability? We'll go ahead and move to a vote. The options are there on the screen in front of you.

All right. So, we have a passing score on reliability. So, we'll go ahead and move to validity next.

Leslie Schultz: OK. This is Leslie again. Again – the validity of the tool have – the developer cites three studies which include ongoing examinations of the validity by the developer itself. There are independent collaborative studies from the University of Colorado and others looking at the validity of the MDS 3.0 and its entirety. And this one particular item in particular. Actually, it was about before (inaudible) no risk adjustment. The missing data appears not to be a meaningful concern. I think the developer has done a nice job over time with this measure to specify the exclusions.

And so that – it now, incorporates a 30 day loopback. So, (inaudible) at these individuals, we want to make sure that we're not catching people who have been admitted or readmitted during that period of time because it would be – the UTI might actually reflect the processes and outcomes of care on the sending sites by versus the receiving sites.

And so, there's seasonal adjustment to account for – seasonal variation. There's two orders of data to look for stability.

And the only other thing and I know we talk about this a little bit in terms of the risk adjustment and our stratification. I've just – even though the developers mentioned that it's not a great percentage, it would be meaningfully helpful to see this population segmented into catheter-associated and non-catheter-associated UTIs.

Male: OK.

Edward Septimus: This is Ed, that’s not what the vote is about, right?

Male: Correct. It says, "As specified."

Edward Septimus: As specified, right. I mean that maybe a recommendation to the developers, but we're voting on as specified in the current document.

Female: Yes.

Iona Thraen: This is Iona, I have a question for the developers.

Male: Go ahead, Iona.

Iona Thraen: So the version 3.0 improved if the tool has been improved over the course of time. And, in parallel the infection rates have gone down, do we know what impact the improvement of the instrument has had on the rate of infections as declared by the MDS instrument?

Female: So, I can give you some information on that, so, during the development of the MDS 3.0. The 2.0 version of the assessment was completed at the same time as the 3.0 version of the assessment for a subset of residents involves in a – that were in the facilities that were involved in the testing of the new 3.0 assessment and – so the facility level rates where calculated or using the 2.0 version of the items and then the same measure was calculated using the 3.0 version which actually the major changes have to do with the manual instruction.

And we see that the rate that we've calculated using the 2.0 version was 10.2. And for the MDS 3.0, that was calculated on using this the same patient residents, excuse me, the rate was 7.3. So, that initial modification to the manual which essentially added criteria to the requirement for coding whether or not there was an active UTI in the prior 30 days, it required – there'll be symptoms, that there would be a diagnosis that was reported by an authorized licensed staff to a physician nurse practitioner that are – depending on the state laws. That there would also be significant laboratory finding and the current medication treatment of UTI in the last 30 days. And those modifications were made to improve the accuracy of the UTI detection.

So, I think …

Male: Great.

Female: … we do see the rate of – the evidence suggested the rate of both positive went down with the 3.0.

Female: Very helpful. Thank you.

Andrew Lyzenga: Great. Thanks. Any other questions on validity before we vote?

Female: I'm sorry, just one quick question. When did that happened? What year?

Female: So, this was with the implementation of the – are you talking about the actual – so the implementation of the MDS 3.0 was in October of 2010.

Female: So, I'm looking at your data, this arts at 2011. Thank you.

Pat Quigley: This is Pat Quigley. If I like – I'd like to just add to that, if you – another question too to support Iona's question. In relationship to practice, there's processes that are done for program evaluation patient management, but the MDS data is actually collected at specific points in time when a resident is admitted to a residential care. Maybe you could give some of that highlights because it's not complete every week if you will, when a resident is in a long-term care of setting to be able to change practice.

Female: That's correct. And so, there are three different types of sort of overall groupings of assessments. There are the assessments that are completed for residents who are in there skill nursing facility benefit. And the intervals for those perspective payment assessments are five days, 14 days, 30 days, and 90 days. This measure excludes the five days, because we don't want to be getting person on admission of cases. And then, the measure includes also the OMRA assessments which are done at – on a quarterly basis that can be comprehensive so there would be annual or if there was a significant change in condition.

Female: Thanks.

Male: Great.

Female: Let's vote.

Andrew Lyzenga: So, let's go ahead and vote. We're voting on subcriterion in 2B, validity and we have the screen up there on the webinar. Go ahead and start your vote. OK. So – should have this is in a gray zone again.

Male: 61 percent.

Andrew Lyzenga: (Inaudible) 61 percent.

Male: You're right.

Andrew Lyzenga: So let's have this and we'll go – and go ahead and move to the feasibility. Any comments or questions from the committee on this criterion?

Leslie Schultz: This is Leslie. In terms of the feasibility this data are already being recorded. They can be captured electronically. There's not a (cease) or registry participation, the burden of manual chart review is it is updated.

Andrew Lyzenga: Great. Any other questions on feasibility before we vote. All right. We'll move to the vote then. Go ahead.

All right. So, we've got a passing vote here too. So we will move ahead to usability and use.

Leslie Schultz: OK. Again this is Leslie and this measure is used for public reporting. These data are demonstrated on nursing home compare, it can also be used for quality and performance improvement. And there is benchmarking capabilities having this measure.

Andrew Lyzenga: All right. Is there any comments use and usability before we vote? OK. All right. Hearing none, let's go ahead and vote.

All right. So this passes as well. So we will go and move to a overall vote. All right. Pulling up the screen here and we're voting on overall suitability for endorsement. Does the measure (meet) NQF criteria for endorsement, yes or no? And you may begin voting.

All right. It passes. So that measure will be recommended and we can now move ahead to …

Charlotte Alexander: Andrew, this is Charlotte Alexander just make a comment on the one we just passed.

Male: Sure. Sure.

Charlotte Alexander: We had a request that there be stratification by whether there's an indwelling catheter or not. And could we also ask them to try and stratify by quadriplegia, paraplegia?

(Crosstalk)

Male: It's a great idea.

Female: Yes. We'll ask them (inaudible) of those analysis (inaudible).

Female: Thank you.

Male: Great. So, at this time we want to move in to the Ad-Hoc review discussion. Do we have Dr. Townsend and Dr. (Yillie) on the line?

Male: Yes. I'm here just …

Male: OK. Great. So let me first start with – so, (Ed) is going to give us a brief overview and then we're going to have move in to the actual discussion. Go ahead.

Edward Septimus: Thank you everyone for joining. And I want to thank everyone for their input last Thursday and some of the information that has been shared with me and some members of the committee. Just by a way of review and try to put the foundation for our discussions. As you remember last year, NQF-endorsed measure 0500 for Severe Sepsis and Septic Shock Management Bundle which became lactate blood cultures, broad spectrum …

Female: Right.

(Ed): … antibiotics, fluid administration, vasopressors for hypotensive, unresponsive patients for fluid. And if hypotensive or initial lactate greater than four to measure CVP and SpO2 and then to remeasure lactated, the initial lactate was elevated. Going our discussions last year, there was this – there's a lot of debate over the use on invasive monitoring which is element F which is what's all for discussion today. In the end, NQF endorsed the measure including F based on the current published evidence.

NQF stated at that time as new evidence emerge from ongoing trials, that we were committed – that is NQF was committed to convene an Ad Hoc evaluation of the measure. On March the 18th, the process trial was published online and peer one, tier one journal on the New England Journal of Medicine. This is a multicenter or randomized trial on patients identified early in the emergency department with Septic shock. Based on that article, the American College of Emergency Physicians is now requested in Ad-Hoc review of element F that is invasive monitoring based on the results of the process trial. So that meant that – invasive monitoring was required if it's made – and met those data elements.

As you remember last Thursday afternoon, the patient safety standing committee that conducted our initial hearing to see if the consistency of the evidence is changed. We heard from four internationally respected experts (Don) (inaudible) and Alan Jones speaking to remove the requirement for invasive monitoring.

And, Sean Townsend and Manny Rivers who (woes) the committee to wait until the results of two pending trials, the one on Australia and the one in the UK. There was broad agreement that as the result of Manny Rivers' sentinal publication on early gold directed therapy in 2001. And subsequent publications of the Surviving Sepsis Campaign in 2004, 2008 then in 2012 which was actually published in 2013, as well as many other publications that the mortality from severe sepsis and septic shock have declined substantially. There was also a broad agreement on some core principles that it can – that included early recognition, adequate fluid resuscitation, timely administration of broad spectrum antibiotics and measurement of lactate. There was a no disagreement that this should not continue to be endorsed.

Lastly, it was agreed at the (ProCESS) trial was a very thoughtful study to examine if all aspects of early gold directed therapy were necessary for selective patients in the emergency department with septic shock. We had a good discussion of the methods and process and whether the results were generalizable, since this was conducted in emergency departments in academic medical centers.

In addition, (ProCESS) did not address severe sepsis and patients outside the emergency department. In an editorial that accompanied the (ProCESS) trial which was contained on our materials, create (inaudible) from (U-Mass) are concluded that he felt that the (ProCESS) trial identified early recognition, early administration of adequate fluids, and timely administration of antibiotics as really being the backbone of treatment.

And that, it was felt that we should reconsider the requirement for invasive monitoring in all patients.

We have some excellent discussion from the developers and the representative of the Surviving Sepsis Campaign. That was considering that – they were going to look at revising recommendation but they felt that the recommendation should be based ongoing research and grading new evidence based on the strengths of the grading recommendations. It was believed that we should not rush to judgment that took 15 or, excuse me, 13 years since the sentinel Rivers study, and many other supporting studies.

Other developer and the representatives of Surviving Sepsis Campaign would not necessary opposed the change, but they felt that we should wait for the results of the two additional studies based on some limitations to the (ProCESS) trial. To be clear, the (ProCESS) trial is a major new publication in furthering the science around the treatment of septic shock. The patient safety standing committee, I believe is an incredible group of men and women who come from all walks of life. Our (charge) today, we'll need to weigh the strengths and weaknesses of this new trial to determine if the consistency of the underlying evidence has changed enough. And if we should recommend

that element F be removed. And it emphasize as a requirement, it does not mean that physician judgment cannot take place.

For those subset of patients who have persistent hypotension and lactate greater than or equal to four. I am confident we will reach the decision based on the weight of the evidence always putting the safety and outcomes over our patients first and foremost. So, with that as an intro, I think – is Sean going to speak to first?

Sean Townsend: I'm here (Ed), I think that was a lead to talk about.

Edward Septimus: OK. Well Dr. Townsend who has been more – real backbone to the Surviving Sepsis Campaign is going to speak first. And I think (Don Yillie) who is – one of the prime authors of the (ProCESS) trial will speak second. And we've asked each of them just keep their remarks to within five minutes, Sean?

Sean Townsend: Thanks, (Ed). And I'll begin by assuring you all that I will take less than five minutes on my remarks. I don't want to take that too much of your time out as we consider this today. I'd like to start by thanking the process investigators for working with me over the last several days.

Male: Hey Sean, are you on a speaker phone there? Are you – maybe take it off speaker, I think it's little (inaudible) little feedback.

Sean Townsend: I'm not on a speaker phone, is this better?

(Crosstalk)

Sean Townsend: Here we go. I (inaudible) hotel in (Mali) and I'm doing my very best to get a good phone here, so. I thought – you don't have to all feel bad for me about that or anything but.

Female: No. None.

Sean Townsend: Hopefully you can hear me well, I'll do in my best.

(Crosstalk)

Male: Great.

Sean Townsend: And what I did want to say is that I really want to thank (Don Yillie) for working with me over the last several days and weeks actually, to keep communication open as we look at what's the legitimate criticism of the study and what isn't. He's been truly outstanding and I appreciate all his help and the process investigators have been really wonderful in that regard. I'd like to thank (ACEP) for being as dedicated opposition, every good initiatives deserves one and (ACEP) is certainly been steadfast in that regard.

And of course I have to thank Ed Septimus who continued those doing expert and remain standing after all this time. My final thanks of course to the NQF panel, who had to consider this measure on its expected date. In many ways your job is to (inaudible). This is complicated material, options are (high), and you are expected to be experts in the field and (inaudible).

I think that's probably to jumping point today that it's my (strong), this committee will not let opportunities (inaudible) by abruptly changing the course. Of course, the scientist have laid out a poem, a scientific poem that the scientific review committee, you must stand above the (inaudible) and ask if the science is complete. You should ask the investigators, did you follow all the plans you've laid out? I think this committee is faced with great fortune as well and this has been the developer has extended in agreement, you move (item). If all the data comes out then it looks like – element F is (inaudible) as a consequence.

So these things considered, I think the evidence-based for 0500 took over 13 years ago to build. If you recall the Rivers trial published in 2001, since that time, there's subsequent publications which confirmed the result of the trial in over 60 journals.

I'd basically say that medicine or the advance of science turn out 24/7 news channel, it's not like CNN. I think it's hard to remember that in our (inaudible) it has to be now, scan the document and send this (inaudible) have. That's still something is done in the (14) that way, it's not our choice whom we're going to find 5370 just because we heard the (pair) we're not going to locate it

tomorrow. If I – I would revise that four weeks ago, it took four weeks for a muscular tendon – this injury to heal. And I have no choice but to wait that through the time until I'm better.

As we get guidelines, well, they promote every four years on sepsis unless the therapy is shown to be harmful, there's no need to move at light speed. This trial says early gold-directed therapy, give all the (sepsis) and other aggressive (distraction), resuscitation strategy. Because now, today, there's only (inaudible) therapy is harmful. The trial was published just four weeks ago, there's still questions being asked and answered about the trial. The committee is now through no particular (inaudible) of its own, being asked to make changes after less than two hours of public consideration on the basis of one of three resuscitation trials in the work.

And that maybe seeing it based in retrospect, the committee could break and turn the page. As I mentioned, it took 13 years to evaluate (inaudible) measure. Now we see one new trial but no (inaudible) with the experience of the vast majority of US hospitals, 4,500 community hospitals. This committee has a duty I believe to assess those hospitals to move cautiously. And it must be remembered that this is the potentially charged moment comes under the threat of (inaudible) imperative. There is no consequence to an appropriate delay to evaluate this new trial and the two others coming.

No consequence with two and a half years. Please listen closely to everyone's comments and find out just what the harm is in waiting. Please ask yourself what the bad thing will happen if I wait for (inaudible). The right thing to do is to follow the investigators plan. Their plan and Dr. (Yillie) can confirm, as published in the (inaudible) medicine has always been to analyze all three trials together. I provided you a copy of their plan in the supplemental materials from the intensive care medicine. I'd like to (quote) from page 1768 for a moment. Healthcare centers are predominantly (inaudible) academic centers with established departments with a vision of emergency medicine and critical care medicine. The (inaudible) centers include mix with academic and regional centers.

Academic centers to know all these research and whole study protocols (inaudible) both enrollment in a broader set of hospitals made to increase study generalizability. So, why do they think (inaudible) all three together? It makes the conclusion more generalizable for this community. It's (ironic) but true that we need Europe and Australia, the office generalize or academic center study to our community centers. This is not about geography, we investigated the three distinction between US centers and smaller regional centers intentionally. It wasn't on the basis of where the centers were. They worried about generalizability. If they could imprint it should concern the you as well.

Ask yourself just one of the questions, does this needs to eliminate element F immediately come to protect patient address or provider interest. I would just ask you to know, as I've heard comments about central line complications in our last call, that process should know higher (inaudible) central line complications in the early gold-directed therapy arms versus the other two arms. So we have no new evidence in that topic. And this question was already decided by the committee previously. In summary, I urge this committee to overcome this completion to react to incomplete information (inaudible).

I highly request the committee to vote to preserve 0500 and to schedule another Ad-Hoc review when the meta-analysis of all three trials is complete. I'll conclude where I began with (inaudible) folks involved in this work, all the parties at this stable and especially the committee members for the time (inaudible) consideration. And in the end, we have only one (inaudible) at heart, the optimization of (inaudible) for this real specification. Thank you for your time.

Male: Thank you very much, Sean. (Don) – you're on the phone?

(Don Yillie): Yes, I am.

Male: OK, if you'll …

(Don Yillie): And thank you again for the invitation. I appreciate that and I want to thank Sean in the same way for being willing to discuss many complex issues of the

test few days, having served on an NQF committee I actually fully understand the task at hand and my job is to try to make that as easy as possible. You planned on evaluation of this at the end of the process trial, not at the end of three trials. The reason there are three trials is in the US and in Australia and in the UK is not to define generalizability in the US but define generalizability across the globe. That was the part of the discussion that was (omitted) as it was read from the – med analysis, it was also to look for smaller findings that were in none mortal outcomes.

We'd never indented and does not say that in the med analysis that define generalizability in the US with non US sites. (ProCESS) is the largest RCT investigating this topic in the US. And the question you have to ask yourself is, do you think that an RCT in a different setting will be more generalizable to the US not more generalizable to the world which was – are a secondary (game). And obviously we want to (inaudible) the US and hopefully the world later on. There are two distinctly different events. Secondly, the standard to it – except the measure is not to prove that it doesn't cause harm. It's actually to prove that it causes benefit in the vast majority. And I think the process data are clear on that, we conducted an RCT where two of the arm did not require a central venous catheter.

The few patients who got a catheter did not have it use to drive care. The data are very clear on that and yet, there was no superiority. Mandating one approach when in fact two other approaches are equally good exposes patients to intervention that they may not benefit from and that they could have harm from. Obviously, we did not detect that on the trial but there is no clear benefit from it. And a quality measure that says that there is one way to do this simply does not protect the interest of the patients. We did not see any (drifts) or contamination, we did not see any time effect. We did not any size or volume effect. No matter how many times we look at that, we did not see any difference in the sickest of the sick. We looked very, very hard.

This is not the only trial. The Jones Trial in 2010 also using lactate clearance came to the same basic inclusion, that central venous catheterization while helpful in some, was not mandatory. So you have two trials, each that are larger than the original one, each that have rigorous designs in contrast to

observation trial not even clear that the central venous catheterization was done as describe in the (inaudible) trial.

It's hard to make those 60 plus odd trials as evidence of criterion F, there evidence that paying attention matter and we all agree about measures A trough E.

I urge you to stick with the things that we know matter, bundles exceed because we are willing adapt over time based on evidence, we do that in cardiac arrest work and myocardial infarction work and we're doing it now in sepsis. Nobody is asking to turn back the time, I do not think the trials done overseas with especially the same basic design are going to generate data that are more generalizable to the US. Hopefully, all three together will be more generalizable to the world.

Male: Thank you, (Don). So I guess at this point we'd like to turn over to the comments from the committee and I think when we're finished with our discussion, we will have public comment. And then, I think we will vote on the measure.

Lisa McGiffert: This is Lisa McGiffert. I had (ProCESS) question about – this is ad hoc review but because it was one that was schedule when 0500 was originally presented. We need to sort of re-endorse it as maintenance, is that correct?

Male: No, that's not in fact – it was re-endorsed last year with the stipulation that if new evidence have become available (inaudible) which is for any measures for NQF. That someone could ask for an ad hoc review in between the three years cycle.

Lisa McGiffert: OK. And because that's been asked for, then we do a full review.

Male: No, no, no we're only doing review of element F.

Lisa McGiffert: OK.

Male: That is in sorting central lines and measuring SpO2 if patients are persistently hypotensive despite of adequate fluids where the initial lactate is greater than pr equal to four.

(Crosstalk)

Female: Could I ask a question to – could I possibly suggest – could we here some public comments because I feel like this 14 of us has really debated this issue and I'm sure, I don't – I can't speak everybody but for me my mind has not changed. I heard the same thing from the same two people as reread this things again, maybe some of the public comment to generate some other discussion points, other than to what we've all ready all said before.

Male: Good idea.

Iona Thraen: This is Iona, you know, before you go there I just – quick play. So when the determination was made to conduct an ad hoc review about existing measure because of emerging evidence. What are the criteria to standard for the emerging evidence? Is that one (made) trial, a trial that's that a randomize control trial, a randomize control trial that's been validated? What is the standard for the emerging evidence?

Male: So, you know, that it's – more of a qualitative decision for the committee whether the consistency quantity and quality of the evidence has changed sufficiently to justify making the change of the measure.

Female: And particular consistency …

(Crosstalk)

Stephen Lawless: Can I ask one question of the developers or the …

Male: Can state your name for everybody, please.

Stephen Lawless: Sure, Steve Lawless. I have a question. Up to – in terms of the outcome, what is supposed to this – all these processes, so the articles and different technique, what is the goal standard outcome of survival we're trying to achieve?

What's out there in the literature as – this is a 10 percent 15 percent 20 percent versus statistically no different. I mean, is there a study with that, this is right now the idea we're going for.

(Don Yillie): This is (Don). I'm not the developer, would you want me to …

Male: (Inaudible) you guys had the passion about it. So what I'm asking potentially is this something is a 21 percent survival versus the 20 percent survival versus – is there something else there that said, we're aiming for 10 percent guys and this is how you do it. I just don't what outcome percentage we as the committee would be able to say, "Wow, this is what we're aiming for versus …

(Don Yillie): OK, that a fair question. So prior to as initiating the trial, the only trial that it had a positive benefit and was an RCT was the original Rivers trial which was a 16 percent absolute difference. We decided that a smaller difference would still be important and our trial was – is power to detect 67 percent of an absolute difference. You asking different question, could even smaller be meaningful it is but it takes legions more patients.

And we're not talking a few thousand it takes, you know, multiple of thousands even bigger likely than the three trial put together. If you're looking for smaller differences obviously, there are none significant difference among mortality rate above 60 days, 90 days and 1 years amongst the arms. They are not identical numbers. They just don't mathematically different that how the data are presented.

The real goal is to make sure we drive it as well as possible, I think everybody on the phone recognizes that well, 18 percent to 21 percent is better that the 30 percent to 46 percent. Its still remains one of the most mortal diseases that that at emergency physician or an intensivist will interact with. And so, we'll always be driving for lower and the way to achieve that is by focusing on the things that matter the most.

Sean Townsend: Yes. And this is Sean. I would to say that that the metric what (Don) said and I think, you know, this also one of the lowest mortality rates we've recorded

(inaudible). And so, in many ways I think if they target the (ProCESS) trial, if they target more hospitals to import as we know now that community hospitals are nothing like that standard. Their mortality rates are 33 percent and others has 30 percent central lines, you know, this is much different than what (ProCESS) was able to do. So in many ways, (ProCESS) sets up the bar very high for us in the community hospitals, it would be great to be like that.

Male: Well, actually the process central line looks very much like the community and the non-gold directed arms, you know, it is 50 percent. It should look more like to community than the original Rivers trial which is a 100 percent use of the (inaudible).

Male: So I just for the purposes of moving this forward. There was request to have a public comment period. I know that we have about 20 minutes left and I know that there other folks on the line who are waiting to speak. So can we go ahead and …

Male: Yes. We have – system operator, can you open up the lines for public comments or enable public comment.

Operator: Yes. All lines are open for public comment

Male: Is there comment – for the comment, please make sure we – state your name and where you from.

Alan Jones: Hi. This Alan Jones can you hear me?

Male: Yes, we can hear you, Alan

Alan Jones: All right, speaking on behalf of the Society for Academic Emergency Medicine that opposes the measure when it was originally endorsed, and specifically, the opposition was for (inaudible) of the measure. I wanted to make a couple of points that I think, get lost a little bit in translation when to begin to talk about the granularity of data, the first thing is to recognize that the Surviving Sepsis Campaign has done yeoman's work in driving down the mortality rate associated with sepsis. We recognize that that is an

international effort that is really looking at all of the data that's been published across the world.

What we are about now is what happen in the United States, and the (Arise) trial which is being conducted in Australian and New Zealand and the Promise trial which is being conducted in the UK, are really not going to shed any light on the US experience. The way to the medical care system is organized there in terms of emergency departments and ICUs, the way care is delivered is not generalizable in any fashion to the United States.

And so to say that the process trial and the results of that trial are not generalizable to community EDs, takes it even a step further to try to say that the experience of a UK ED or and Australian ED is going to be anymore generalizable to community EDs in the US. Actually they'll be much, much less generalizable in those systems.

So the Surviving Sepsis Campaign is international, what we're talking about here in this measure is really what can drive quality of the US and what is the best US experience we have right now are the results of the process trial. And the second important point is that to date there has been not one single trial that isolated the central line and showed benefit of the central line.

Actually, the Rivers trial and the (60) non-experimental study that are quoted by the developer in the Surviving Sepsis Campaign have always shown that early intervention seem to improve care. But part of the vast majority of that early intervention is early recognition, early source control of antibiotics, early resuscitation and, oh the by the way, with that, a central line.

There is not a single study that showed benefit of the central line and actually when you look at the Surviving Sepsis Campaign data, when they isolate this (CVP) or the (SEDO2) measurements and normalizing those measurements, they are not statistically significant which shows that – as if not those measurement – if the early recognition and resuscitation component, that are the most important.

Male: Alan, thanks. We do want to, you know, we have about 15 minutes left here. Well, I don't think there are few other folks..

Male: Yes. I'm done.

Male: … for public comment. So, if we could ask the next public commenter to please try to limit to about three minutes or less, any comments that you have.

(Crosstalk)

(Bryan Wind): This (Bryan Wind) here from (Inaudible), may I have the forum …

Female: I think …

(Bryan Wind): … from the public?

(Off-mike)

Male: Was there (Mitch Levi) who is on?

(Mitch Levi): Yes, this is (Mitch Levi). I just wanted to have – before (Bryan) speaks if I may, I represent the Society of Critical Care Medicine and along with Sean on the Surviving Sepsis Campaign. And I have to say to the committee that although I think, you might be hoping to get more information out of this public commenter that help you to make decision, I'm sure if that is the forthcoming. I think – we've heard both side and think blankly in these public comments, we'll wind up hearing a little bit more politics and polemics that are may not actually help you.

I think I all ready heard exactly data from Surviving Sepsis Campaign stated in a way that's not entirely accurate based on the data which is that 75 percent on the patients are in fact from the United States. So I just wanted to say on behalf on the society, that we value this process. I think that the Surviving Sepsis Campaign has always have the interest of knowledge translation which is bringing the right research to the bedside and the interest of patient care and facilitating good research to the bedside.

And we still feel that way, and if decision of the community is that, yes, (CBP) is not supported by that data, then the campaign would consider changing our recommendations when the other two trials are out so that we the ability to the best care for patients. So, I think you've heard all the information, I think you have the ability to make the decision. And I know on behalf of the society that we're sure you'll do what's right for the – for patients with this metric.

Male: Thank you, (Mitch). I think (Dwayne) was next.

(Dwayne): Yes. Thank you very, very – Thank you (Dr. Levi). I just want to express, you know, I know I have two to three minutes, I do have a lot to say. But I background, I practice both (inaudible) medicine and medical intensive care, so I see these patients pretty much regularly from the ED, from triage, all the way to the several days or weeks of ICU care.

So let's talk the processes as far as generalizability. Most of the hospital enrolled have already published, advertised publicly that they have sepsis protocols in place. So by that fact, the standard care on all of these hospitals have all ready been pretty much contaminated by what we call sepsis bundle. So it's very to really make conclusion that the use of care is truly – those usually care that's out there in the community ED. And 31 hospital and most of this are academia high level very, very – you know, have ED ICU team cohort which is not across of the thousands of ED around the country. The mortality of 20 percent, so I think it's the sensitivity of sepsis recognition. A lot of these patients, you know, with a 20 percent mortality where we already – where, you know, three hours (fluid) resuscitation all ready has been received before randomization.

Some of them were all ready intubated, some of them got vasopressors, some of them got two to three or plus liters f fluid before randomization. So that's truly the early code like a therapy idea was to capture the patient early and also to resuscitate them when they are very (inaudible) delivery dependent which is not the case with the sepsis patients in the (ProCESS) trial. So to make conclusion that, you know, process means early corrected therapy was

not effective, or just as effective as usual care. I think we have a wrong patient's population.

So, and in summary, the concern I would have is that if we take away some of the absolute or some of the criteria of early intervention of proper hemodynamic monitoring, including central line, we will continue to see the patients occasionally, get transferred to me from the peripheral, you know, or community ED on two (inaudible) via peripheral line with (inaudible) seven and eight, and what were setting ourselves for is that those was patient will get transferred to the ED go to the ICU, my intensivist colleague will not be as keen on getting to the best side quickly because the peripheral IV is OK, because, we don't need central lines anymore.

And this is what I'm worried about is that when we do have the very, very sick patients, the mortality of 40 percent to 60 percent, we're not going to do anything except fluid and antibiotic …

Male: (Inaudible) I'm sorry to interrupt, but we really have to …

Male: Sure, yes. So I think that's the concern I have …

Male: OK.

Male: … when we conclude (ProCESS) as a generalizable in the United States.

Male: OK. Thank you.

Male: Anymore public comments operator?

(Phil Dillinger): This is (Phil Dillinger)

Female: Yes …

Male: (Phil Dillinger), hello (Phil).

(Phil Dillinger): Hi. I just have a really quick comment. You know I'm ready to go by whatever the committee rules and God bless you. But, you know, when I read the centers that were involve in this trial and I think this was – it was a very

good trial. It's not the hospitals that I've been – all over of the United States within collaboratives for the last 8 to 10 years, getting them to start up severe sepsis performance, improvement programs. And that's what bothers me more is, you know, where we're going to live them with the decision we make whatever it is, that's all I got to say.

Male: Thank you, (Phil). Any other public comments, we could certainly have comments, from the community.

(Anghel Kaus): Hi, can I have the attention of the forum. My name is (Anghel Kaus) from University of Kentucky. Just to add to the workgroup, Dr. (Win) said regarding the process trial. It was conducted in – I mean 85 of those centers are about that number had all ready sepsis bundles, plus the trial investigators only for the patients for the six hours. So we don't really know what kind of care was received after that. And there is evidence that even when delivered late, early or directive therapy can be effective. And those hospitals had – most of those hospitals had those interventions. So that's all my comment.

Male: Thank you.

Male: Thank you.

Male: Any final comments before we hand this back over to our co-chairs for the vote.

(Manny Rivers): Hello. This is (Manny Rivers).

Male: OK. Go ahead, (Manny).

(Manny Rivers): Just one comment. I approached the National Quality Forum almost six years after the gold directed study was published in 2001. So, there was 40 to 60 publications already done (inaudible) and posted on National Quality Forum. And more importantly, is that it took the National Quality Forum five or six years to approve it even after initial denial. So with that persistence, my reason for approaching them was because the sepsis mortality at that point in time was 40 percent to 50 percent. So even with the fact that it was denied, I thought there was a need – it was not a rushed to judgment, and I'm glad the

committee accepted it because we've seen and accepted measure that hadn't exactly drop mortality from a 40 percent to 50 percent range down to currently 20 percent as shown by (ProCESS).

So I think this is a celebration actually of the NQF process and also, this measure and we sit, not get caught off in the idea that, you know, we need the rush to judgment when these patients were managed and accumulated over time. And people have there appreciate the (longevity) that it took to get to this point and that a two-month decision after publication is made is not based on history of the NQF process.

Thank you

Male: Thank you.

Male: Thank you, (Manny).

(Don Yillie): Again, this is (Don). The CDC was only added in at the end and much of the delivery of the improvements on sepsis mortality as in measures A through F, and we all agree on that and we also celebrated. We're talking about the central venous catheter driven parts of it, and even in the sickest of the sick and we don't have data to prove that it helps.

Male: Yes. And this is (inaudible). The only last (inaudible) my comment was to think about where there's some improvement in quality, (inaudible). And I see part of that (inaudible), yet.

(Todd): Hi. This, (Todd) (inaudible) can you hear he?

Male: We can hear you.

(Todd): OK. Hi, thank you for the time. Spoke on the last thought and I'm just speaking to a point that Sean brought up, you know, why should we wait or can't we wait how does this has to do with the community. You know, well other will looks to NQF. And, you know, specifically, living in New York, you know, the New York State Department of Health tried to put into effect regulations that are, you know, and law on sepsis monitors. And they were

originally trying to model after the NQF measure figuring we'll assume this will go through to CMS. So it will be easier for everyone.

So, I think just to answer the question, whether the NQF going to CMS decision may take a year, other organizations and state legislators that are looking at this for guidance. You know, and then New York's specifically, we took everything from A through E but did eliminate the central line measure. And part of it isn't because people don't want to do central lines. You know, and I'd say that's, you know, (Bryan) and (Manny), you guys – your works has been great and all that. And I don't think eliminating our F says, "OK, don't do the central line." I think, you know, the patients you described in that central line may well be fine and there are certain cases where it good.

But what we're talking about here is applying it to every patient that meet the criteria. You know, and there definitely some EDs at least in New York where, you know, they are not even required to have a physician on. They can be done by, you know, advanced practice practitioners and stuff in the community. You know, and putting that I think can be hard on the practitioner side but then also on the patients side asking, "Yes, how much benefit are you getting from F outside A through E?" I think is a little bit put into question, you know.

And I think (inaudible) association did with 60 hospital including community hospitals, you know, showed that using an early intervention, using various other methods to assess fluid responsiveness an perfusion and all that, you know, have shown to make a very big difference.

So I would say to that point, you know, when talking about for F specifically, you know, there are – it doesn't make a difference right now. And I think that's one thing to community or both committee should take into consideration.

All right, thank you. And that's no disrespect everyone. You guys did great work and, you know, we practice (inaudible), you know, our academic center. So thanks for the talk.

Male: Thank you very much.

Male: Right, any other …

Female: So, any losing remarks before we vote then?

Male: From me?

Female: Yes.

Male: I think we've heard a great discussion. I think the question – I think it was really nicely framed by the last speaker. I think everybody agrees that A through E should certainly hardwired. The question is just after the (BL) requirement, all people who meets that criteria get us – get a line and have monitoring or should be up to the physicians clinical judgment. I think then a question is that the process provides that quality and consistency of evidence that would supports changing F in the measures. So, If there' no other comments I guess we …

Patricia Quigley: (Inaudible), this is Pat Quigley.

Male: Yes, Pat. We hadn't heard from you for at least 10 minutes.

Patricia Quigley: Thank you. I'm proud – I did raise my hand and I appreciate the public comments but I just wanted to make sure we had a quorum for this vote, and the reason being, I know we have 25 members on our committee and I think I heard Lisa say 12 voting members. I just want to make sure we have a quorum. There was a point where we have 19, and then 17 and I just want to have – make sure that we did. Thank you.

Female: Yes. We're consenting that but it looks like we do. We also had somebody who's find out who all ready left (inaudible) vote.

Male: And one who will be entering a vote verbally on the phone as well.

Female: Yes. I didn't hear any number 12, the last votes that have still …

Male: Yes.

Female: … 19. I think we're OK but thanks for asking.

Patricia Quigley: Sure.

Male: OK. Well, I guess the moment of truth.

Helen Burstin: Yes. So, this is Helen. Just as that you one additional question listed up there that does have a question on with a just yes or no. And again, you know, we – this ad hoc review is part of the endorsement process whenever anyone raise a question about a potential change in evidence. And also the fact we agree to do this as part of the endorsement of the measure last year.

So, we're essentially asking like (inaudible) on one question in light of the new evidence, do you believe that there continues to be the quality, quantity and consistency of the evidence for the (inaudible) compliance. Yes or no?

Male: So, yes would be retained measure item F and two would be to remove item F.

Female: Good.

Male: Thank you.

Male: So – is the additional question stated is really not so clear, if a committee vote on additional question is needed?

Male: Sorry. So this is – Helen verbally said, that the question that the committee is does, you know, with this new evidence has the consistency quality or quantity of evidence change sufficiently to change the measure. So essentially, what we're saying is one would be to – is retain item F, so keep it in and two, is to remove item F.

Helen Burstin: Right. Based on the change of evidence.

Male: Based on the change of evidence, right.

Male: Is everybody on the committee clear on the question before then?

Female: Yes. Thank you.

Male: Yes.

Male: One is retain, two is remove.

Male: All right, we're going to go ahead and vote. You may start now.

(Off-mike)

Female: Oh, gosh.

Male: And Kim Applegate …

Male: Kimberly Applegate, I think is on the phone. Could you give us your verbal vote.

Male: So, one is a …

Male: One is to retain item F, and two is remove item F.

Male: Are you there, Kimberly?

Female: Operator, do we still have Kimberly?

Operator: Kimberly's line has disconnected.

Male: OK. Thanks.

Male: She did sent – I thought she send a – did she send me a vote but I don't know if I should vote for her.

Male: It sounds pretty good to me, whatever it is.

Male: Kimberly wanted to – will a put a vote of no from what she sent me.

Male: OK.

Male: So, based on the voting on the webinar and the votes we receive by proxy, we have seven votes to retain item F and 11 vote to remove item F.

Male: Eleven?

Male: Yes.

Male: So the percentage is not showing to here, but that percentage is over 60 percent.

Male: I believe so …

Male: Yes. I think it is.

Male: We have calculation here, sorry.

Male: Sixty one percent is …

(Crosstalk)

Male: OK. I guess any other comment from Andrew, since we're actually (inaudible) to being on time.

Andrew Lyzenga: So we will follow up with the committee with next steps. We'll give you some information on what happens next. We'll also be following up with developers just to touch base with them about updating the measure.

And yes, we will be releasing the committee's recommendations for public comment. We'll be drafting up the committee's discussion and recommendations, and that will be posted on the NQF webpage for public comments. I believe we're scheduled do that by May 22nd. And we'll follow up with you on the again then.

I think that's it, and thank you all for taking the time for this call. We really appreciate you come in and giving thoughtful comments and providing your votes. And thanks to all the developers and the public commenters as well. We really appreciate your input. We will go ahead and sign off. And again, we appreciate everybody's input. See you all later.

Female: Thank you, bye-bye.

Female: Thank you.

Female: Thank you so much.

Male: Bye all.

Female: Bye-bye.

Female: Thank you.

Operator: Ladies and gentlemen, you may now disconnect your line.

END