NATIONAL QUALITY FORUM

Moderator: Andrew Lyzenga
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12:00 pm CT

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

Andrew Lyzenga: Welcome everybody to the conference call of the Patient Safety Complications Steering Committee today.

Just as a quick reminder the purpose of today's call we had a few follow-up issues that we wanted to take care of after our in person meeting. And we've just got just a few measures that we're going to review a little bit further some additions that have been made by the developers. So with that I'll hand it over to our co-chairs.

Pam Cipriano: Okay thank you, Andrew. This is Pam Cipriano. (Abilika) is on the phone as well.

We'll just -- unless Andrew or Heidi, do you have any introductory comments before we start on Measure 450?

Heidi Bossley: No. I think we're going to just try to get through the three measures if at all possible in hour. I think we can but most of the voting will occur off-line on ((inaudible)).

Andrew Lyzenga: Yes we'll do the voting afterwards.

Pam Cipriano: Okay I forgot about those steps. Okay so the first measure a pulmonary embolism or DDT rate.

And as noted there is additional evidence based on an AHRQ publication on patient safety indicators which addressed our - some of our previous questions.

Let me first ask if there are specific questions from the committee. And then if not is there someone from the measure developer on the phone?

Andrew Lyzenga: We should - and we should have somebody from AHRQ on the line here.

Pam Cipriano: Okay. So the question is are there additional questions from the committee?

Female: No.

Pam Cipriano: Okay is there anyone on the line from AHRQ?

Jeffrey Geppert: Well this is Jeff Geppert from the Patel - from the (AHRQI) Support Team but I know Patrick Romano is scheduled to join us and he can address because he's the co-author on the paper's any questions...

Pam Cipriano: Okay well maybe what we can do is hold on Measure 450 and come back to that and go ahead and move to 419. Does that seem okay?

Female: Pam the only thing that may be an issue is that Patrick is only - he’s supposed to get on and be available until 1:20.

Pam Cipriano: Until 1:20, is that what you said?

Female: Until 1:20 in the afternoon.

Pam Cipriano: Great.

Female: So operator can you make sure that Patrick Romano is not on the line?

I guess we'll have to - yes Pam why don't we go ahead and if there's specific questions for him we can take them and follow-up and...

Pam Cipriano: Okay.

Female: ...do the rest of the discussions...

Pam Cipriano: Okay all right. Let me just clarify because I've got a variety of documents in front of me. The agenda that I'm looking at doesn't have 501 but previous versions did or - and the TDF has it. Can you verify are we doing 501 again?

Andrew Lyzenga: Yes we are doing 501 again.

Pam Cipriano: Okay thank you. I might have an old copy that I printed on the agenda. Okay so are we ready to move 2501, confirmation of ventricular tube placement?

Andrew Lyzenga: Sure. And we've got - the Dr. Phelan on the line here. And he can speak a bit going through that about the changes he made to the testing results?

Pam Cipriano: Okay yes and I think as everyone will remember we did recognize that there were a variety of ways to confirm placement.

We had some questions about whether or not we needed to be more specific in terms of how the evidence supported each of these. So if we would - we can go ahead and go ahead and ask (Colin) our colleague from Cleveland Clinic.

(Colin): Hi. And I'm very willing to yield my time if Patrick comes on and he needs to leave pretty quickly. So we could skip this if you guys are willing to do it. Because I know Patrick is busy and I don't want to lose his input on that prior measure. So I'm very willing to do that if you want to do that.

Andrew Lyzenga: Thanks Dr. Phelan.

Pam Cipriano: Thank you. Go ahead.

(Colin): So the first question was asked was to modify the specifications of the measure. And this was included and I can't remember the number off the top of my head of the section of the order. But I can find it here quickly. It was like 2.A15.

And what was done to that measure was to be defined it by the ASEP Prep which is the American College of Emergency Physicians Practice Resource Guide about confirmation of endotracheal tube placement.

And it defines the three methods of appropriate testing for confirmation of endotracheal tube placement and where in the record it could be found which could be LIPs notes whether it be physician or nurse or a respiratory therapist.

Pam Cipriano: Okay are there any questions? The actual language too does relate to either repeat laryngoscopy and Title CO2 and esophageal detection. Did you want to comment specifically on the inclusion of those three?

(Colin): Is that a question to me or to the group?

Pam Cipriano: Yes.

(Colin): To me?

Pam Cipriano: Yes, I'm sorry. What is your name? I didn't hear it too well?

(Colin): Dr. Phelan, Mike Phelan. Mike...

Pam Cipriano: Mike, thank you very much.

(Colin): ...is fine. Yes the inclusion, the three methods that are, you know, pretty much well studied and the prep goes through the criteria of why they picked those three for inclusion for confirmation of endotracheal tube placement.

There are other means that can be used to assess, not confirm endotracheal tube placement.

Some of those like physical exam findings are not sensitive enough to be included as one of the methods of testing and confirming endotracheal tube placement.

So if you said well if I listen to bilateral breath sounds you can very often be misled to think the endotracheal tube is in place by saying oh I hear bilateral breath sounds because it’s sensitive enough means of testing that. So that was not included.

Also chest x-ray, I think people have mentioned well I use a checks x-ray or I can see the chest x-ray. That's a bi-planar method.

You can never really access the exact location whether it's the trachea or the esophagus because both of those organs lie on top of each other.

So it would be very difficult to say well I use the x-ray as a means of confirming endotracheal tube placement.

You can check position on the endotracheal tube placement but you really couldn't assess whether it's actually in the trachea or the esophagus?

Pam Cipriano: Okay. And then we were to review the reliability and validity. And I think you just went over the reliability that we're talking about 100% chart review.

I'm sorry; documentation with chart review was 100% documentation by one of those three LIP categories.

(Colin): Right.

Pam Cipriano: Any questions on that or any questions on validity?

Male: Hey Mike...

Vallire Hooper: This is Vallire Hooper, I have a few questions concerns about this overall measure and I don't know if this would be the appropriate time.

Andrew Lyzenga: Sure.

Pam Cipriano: Okay Vallire go ahead.

Vallire Hooper: My first concern is...

Female: ((inaudible)) conditions.

Vallire Hooper: ...I do agree that this can certainly be a high-impact. I'm not convinced that the data supports that there is opportunity for improvement.

I guess what I would be curious to know is of all of the incubations that occur in the ED or that arise to the ED already incubated what is the incidence of an appropriate placement?

And so therefore my additional concern is that this is a process measure as opposed to an outcome measure.

And I'm afraid falling back to our discussion at our in person meeting that this is somewhat of a checkbox measure that may require that somebody actually takes the time to go back and assure that they check to the appropriate box.

But I'm not sure that the data supports that there actually is a problem with appropriate placement.

(Colin): I guess the first issue is in the emergency department it's probably much lower than it was than the data supports inappropriate placement. However it does continue to happen.

And the ED literature supports anywhere -- and this is why it gets kind of nebulous -- anywhere from 5% to 25% of EDs are misplaced when they're coming in from an EMS system.

So it really depends on what EMS system you're coming in from. If you're in Oregon it's 0%. They have a highly trained paramedic, you know, group and they have very specific - and if you're in Timbuktu up in my state Ohio, where you volunteer paramedics the number could be much higher.

And no one's even looked at Timbuktu, Ohio they've usually looked at academic medical centers around there.

So the patient's being brought in by an EMS service the number ranges anywhere from 5% to 25% of misplaced tube, endotracheal tube placement.

When an ED physician is intubating the exact number again is nebulous because hopefully you recognized that you've misplaced the tube and you put it in the right place or you perform (hychothyrodomy) which is surgical airway.

So hopefully there'd be almost none but it's very difficult to tell when patients end up in the morgue if you don't do an autopsy that the tube is actually in the wrong place.

So no one's doing that study looking at every intubation and saying well how often did we actually - what was the actual incident?

Practicing emergency room physicians will recognize hopefully if they're in the wrong place if they're confirming endotracheal tube placement, remove the tube and replace it in a correct place.

So I think it, from a patient safety perspective I think it still is - the significance is still pretty high to me.

Whether that is documented in the medical records or not is a whole (nother), is a whole issue that I'm trying to get at with this measure is hopefully by the documentation even if it's by a checkbox I mean I would be embarrassed if someone was going back and just going back and check boxing and saying they did it without actually performing the actual method of confirmation.

Vallire Hooper: I understand that. But I guess my question would be it's - because apparently this measure was approved in 208 is have we seen any improvement in the detection of misplaced endotracheal tubes as a result of this measure?

Because this must be - most institutions hand abstracted as opposed to electronically abstracted...

(Colin): Right.

Vallire Hooper: ...I am greatly concern about their labor that this - because I also remember reading somewhere that you're recommending two independent abstractors.

So I'm very concerned about the labor intensiveness in relation to the fact that this is really only looking at a process as opposed to an outcome.

(Colin): And this data is so difficult to get at that I looked around numerous different places to try to figure out how I could do this, whether to use a large airway registry that was developed out of Harvard for emergency medicine. But it only included like ten or 15 hospitals.

The closest I could get to any kind of look at this was something called Get With the Guidelines Resuscitation. It's a large ACC cardiac arrest registry, an in-hospital cardiac arrest.

Some of those are included in the ED but some - most of them are excluded from the ED. Most of so-called airways are excluded from the ED unless it was in a cardiac arrest situation.

But they still included some ED patients if they arrested while they were in the emergency department.

And in that database they included a confirmation of endotracheal tube metric actually within the - and that's a registry where the hospital pays money to join, they train data abstractors at the hospital how to extract data from cardiac arrest patients that occur in their hospital.

And they collect some 70 some outcome measures or measures and then submit them back electronically to the registry.

And one of the reasons I wanted to actually look at that registry was because A, it gave a broader audience.

Even though this measure is specific to ED there's no registry like that in emergency medicine although I've pushing for one for about three years trying to get a larger registry specifically looking at airways in the emergency department. But that needs resources, time, and money and none of that has come through.

But this one is already in place. And it's for a hospital-wide cardiac arrest patients. So patient arrests, they get some drugs, they sometimes need an airway or most of the time they need an airway and then they started abstracting data from this.

And they included lucky for me because I just happened to - our hospital happens to belong and I happened to see the list of metrics and one of them was endotracheal on confirmation.

And in looking I actually asked the ACC registry if I can look at all their data. And we're in the process of publishing a - an article right now on exactly what we retrieved from that data.

And though it does not identify the exact question that you're asking did we identify more misplaced tubes?

However it shed some very interesting light on this subject. About the same rate when we started at our hospital which was about 18% we could not find documentation anywhere in the chart -- nurses, RT, physicians, note -- that there was a confirmation place even though our confirmation performed even though we know the patient got a endotracheal tube.

There was another 18% of patients that had inappropriate methods documented. Someone would document I heard bilateral breath sounds. And that was the sole means of identification that they confirmed placement.

So already there is a gap in the documentation practices as well as the appropriate documentation practices.

And another 50% have the appropriate End-Tidal CO2 or redirect look or some other method to actually look at that.

So from that data at least what I can glean and some of those patients were part of the emergency department. I didn't get - do a deep dive into the data to look exactly at the ED data because I was more concerned with the overall data.

But it points out to me that there is a gap in knowledge and performance of confirmation of endotracheal tube placements.

And this is kind of one of those metrics that you really need to be 100%. Someone has to document somewhere that yes we check confirmation.

And whether it does end up being a checkmark I'm happy with that. I'd be really surprised if during an arrest someone would check that they checked endotracheal tube confirmation with an End-Tidal CO2 device, you know, an (EasyCap) or whatever and it didn't actually get done but it's currently just not be appropriately documented.

Steve Lawless: Yes hi. This is Steve Lawless. I have a question for you...

(Colin): Sure.

Steve Lawless: ...and this may change the measure or not. I don't know.

(Colin): Sure.

Pam Cipriano: Steve can you hold for just one second? Can we check...

Steve Lawless: Sure.

Pam Cipriano: ...with the operator to see if Patrick Romano has joined? Operator? Operator?

Operator: Patrick Romano has joined.

Pam Cipriano: Okay Steve if you don't mind holding your question and Mike as well if we...

Male: No.

Pam Cipriano: ...Patrick can you tell us what - do you have five minutes on your time calendar or more?

Patrick Romano: I have about ten minutes.

Pam Cipriano: If it's okay with the group I appreciate your indulgence. We will hold on this continuing discussion on 501. And let's come back to 450 post-operative P/E or deep vein thrombosis rate and the additional information provided by AHRQ in the patient safety indicator.

Patrick, if you - could you kind of orient us to the additional information?

Patrick Romano: Sure. So as the committee recalls there was some discussion at the previous meeting regarding the suboptimal criteria and validity of this measure based on studies in which the code data were compared with the manual review of medical records.

So our strategy in response to that was twofold. One was to link the indicator logic to present on mission recording the diagnosis code.

And second to ((inaudible)) to recommend changes to IC9CM codes that would provide for more specific codes and also of course trigger clearer education about the appropriate use of those new codes.

So the studies that we distributed last week represent a second look at both criteria and construct validity for this indicator after the implementation of these new codes and POA reporting.

Pam Cipriano: Thank you. That was very helpful.

Patrick Romano: I'm not - okay I'm not going to summarize the findings of the studies but just suffice it to say that we acknowledge that there are, you know, some limitation.

Obviously they were based on volunteer hospitals or academic medical centers that were able and willing to ramp-up quickly to undertake this kind of validation work.

I think ARHQ has an ongoing commitment to this enterprise and to conducting broader scale validation studies. But we did want to share this information with committee.

Pam Cipriano: Okay again that was very helpful. Questions from the committee?

Ed Septimus: Yes this is Ed. I mean so this is heavily based on physician documentation correct?

Patrick Romano: Well yes. The coded - IC9 coded data is always based on physician documentation, correct.

Ed Septimus: Was there any focus at these academic centers for getting physicians to document better?

Patrick Romano: Well there was certainly focus on getting them to document the timing of the conditions better.

Generally the occurrence of the condition is relatively obvious from the fact that a diagnostic test was done and then some treatment was initiated.

Where there is, you know, more of a role for physician education and documentation is in distinguishing the particular cases that may have been pressed on a mission versus the cases

that developed during a hospital stay and Dr. White and others have experienced but then sometimes it's not as clear as it might seem.

Ed Septimus: You know, well that's been the challenges of administrative data. So I was just curious as to how that tracked with perhaps validation.

Patrick Romano: Well I should say it's not a challenge of administrative data per se. It's a challenge of the clinical scenario and the documentation of the clinical scenario.

Often when we have physicians that are uncertain about what's going on are deliberately vague in the medical record. And then the coders use vague codes because we're vague.

So this is an ongoing process but it reflects really underlying physician uncertainty.

Pam Cipriano: Are there other comments or questions for Patrick?

Lisa Moores: This is Lisa Moores. And I guess the thing I'm still struggling with with this measure and, you know, it is noted in a comparison to the competing measures, but the role for having two measures, you know, 450 and then 376 are potentially preventable DTE. If you could explain why you think we need both?

Patrick Romano: Well I believe that these are not technically classified as competing measures. Is that correct? I'll direct that to the NQF staff.

Female: Yes I think this is part of what the committee needs to discuss. But they do - Iona you were specifically asking about the other measure that the joint commission incidents, (correct)?

Female: Yes. So if you look at NQF it's (funding) is VTE6 or 0376 is this potentially preventable venous thrombosis?

So there's some subtle differences between the measures. I don't know that I'd call them ((inaudible)) if that's the word, you don't want but related and...

Female: Yes.

Female: ...I'm not sure why VTE6 captures this theme?

Patrick Romano: Well I should say the difference is really not so subtle because the AHRQ measure is a measure that's based on defining an at risk population and then assessing the incidents if you will, of these events among patients who are deemed at risk during a hospital stay.

The joint commission measure is focused on patients who have the event. And what portion of those patients seem to have a preventable event based on the specific type of prophylaxis that they received or lack thereof. So it's really quite a different focus.

Our focus really as is suggested in one of the papers that we distributed is I'm looking for opportunities for improvement that may go above and beyond the joint commission measure specifications.

So it's quite possible that if a patient received a low molecular weight heparin prophylaxis they would comply with a joint commission measure. Therefore it wouldn't be deemed to be a potentially preventable VTE and yet we know the patient wasn't ambulated for three or four days after surgery or maybe the low molecular weight heparin wasn't continued long enough.

And so there's still opportunities for improvement. And that's really what outcome measures are about.

So the ARHQ measure is a pure outcome measure. The joint commission measure is sort of a composite of an outcome measure and a process measure. So it's quite different conceptually. I think they're related but the differences are not minor.

Heidi Bossley: Right. This is Heidi. Just to give a little background on - from the NQF perspective. The - you look at the measure intent and it's just as Patrick described and my reading of the key measure is that are different intent but I would say that as he said they're related.

Where it gets challenging is the joint commission one is paper-based. The ARHQ one is administrative claims and so they could - we could ask them to harmonize as much as possible but I think there will be challenges based on just the data source itself.

But I - my interpretation and the discussion of the committee I thought - really thought that they were two different intents of the measure.

Iona Thraen: This is Iona. This is Iona. This is a bit off topic but I just want to put it in the parking lot for future reference.

I think this is an illustration of where the committee needs to go in terms of as I reviewed the whole long list that was sent out recently in terms of beginning to bring these measures together where they're related and defiance whether they're a process measure or an outcome measure and what the differences are as a grouping or a clustering approach so that we can have better understanding how these relate to each other, don't relate to each other as we move forward. But it's a parking lot issue, sorry.

William Conway: Yes Pam, it's Bill Conway. I think at our last committee meeting the concern with this measure was the rate of false positives that had been reported and apparently these new studies show that with changes it ICD9 criteria and present on admission those false positives have been markedly decreased. Is that fair Patrick?

Patrick Romano: That's our assessment. Of course we'd feel more comfortable with that conclusion if we had a larger group of truly nationally representative hospitals. But certainly these pilot data look extremely promising.

Pam Cipriano: Thank you, Bill. Thanks doctor for that as well. Are there additional questions on 450 then?

Ed Septimus: Hi. This is Ed again. So are we asked to consider this or are we going to put - wait for other studies to be done in a larger setting?

Heidi Bossley: So this is Heidi. I can give you some - unless Pam or Bill you want to say something?

Do you want me to kind of outline what I think the next steps are for the committee?

Ed Septimus: Yes.

Heidi Bossley: So I mean I think you have to look at what's before you now. I think you need to factor in what Patrick and ARHQ has provided as supplemental information.

Where we left off in the evaluation of the measure was you couldn't complete the scientific acceptability assessment because you wanted to see the final set of data.

So what we'll do is we'll go out to you with another survey tool that asks you to finish up your voting on scientific accessibility.

And we'll do usability and feasibility just because we want to get this done once. If it doesn't pass scientific acceptability we don't feel it's reliable and valid and precisely specified then it would be voted down and not past scientific acceptability.

And then you'll be asked to do a yes no vote just so we complete it in case, you know, again it passed scientific acceptability and we go all the way through.

But the question I think here is is there anything additional that Patrick or ARHQ could provide now that would answer it or do you think you've got enough information to provide the evaluation?

Ed Septimus: I think the crux of the judgment call is the - with the small amount of study data available that he believes that more data is probably going to be concurrent with that or should we wait?

Marc Moote: So this is Marc Moote. I just want to chime in. I think that this is a - if we're comparing 450 to 376 this is an infinitely better designed measure and will provide at least some standardization for inter-hospital comparison if we standardize these codes.

Whereas 376 by contrast in terms of its definition of a potentially preventable event you could essentially deliver one dose of prophylaxis and meet the measure. And I don't think anybody would call that a preventable event.

So if we're deciding between the two I think that this is clearly a much better design measure. I would certainly feel comfortable based on the evidence that had been provided in supporting it for implementation now. I don't think any further study at least today would change my vote.

Pam Cipriano: Okay. I think in the interest of time and respect for Patrick's schedule as well I think there's been good discussion about additional information, the reduction of false positives, being able to review on our votes usability and feasibility.

So if it's okay with the committee I think we will go ahead and move on unless there's any, you know, real burning questions.

Patrick Romano: If there are additional questions were happy to address them through (interest) and through email.

Pam Cipriano: Right okay thank you very much Patrick. I appreciate that. Okay let's...

Patrick Romano: Thank you.

Pam Cipriano: ...get back to 501. We just concluded some discussion where (Mike) was addressing the question of the difference between actual results of potential harm related to misplacement versus the value of the measure of was the process verified.

And I think there - and Heidi and others you may want to comment. I think this is one of those measures that the checking the box if you will for the process ends up being a proxy for was the right activity done that actually has the impact in terms of having a quality outcome?

In other words if - because if you skip the process then presumably you didn't check the placement which then creates that 5% to 25% margin of error.

Heidi Bossley: That's correct. And I think where we left off was the question on the specification changes and then whether he provided sufficient information on reliability and validity. But I know I think Steve had a question.

Pam Cipriano: Yes Steve I'm sorry, we put you on hold.

Steve Lawless: Sure, no problem at all. The question I have for you is with the ET tube placements. Since time is critical after an ET tube and you've...

Male: Right.

Steve Lawless: ...given the reference of the EMTs coming in...

Male: Right.

Steve Lawless: ...the person has been intubated, by the time you get to the ER you've confirmed placement yes or no it's too late.

Why not have it so at the time of placement whether in the field or not ET tube confirmation is performed?

Like in the ER doing it after maybe a half-hour after the intubation has been done...

Michael Phelan: Is useless, yes.

Steve Lawless: Yes.

Michael Phelan: I agree. But I also understand that we have to take baby steps.

Steve Lawless: Okay.

Michael Phelan: I would love to have a metric that said within 20 seconds of endotracheal tube placement you have to have this done.

I think the gap is so wide with documentation practices...

Steve Lawless: Okay.

Michael Phelan: ...as it stands right now that this first step at saying yes, let's start documenting EDs because I have a feeling just from - because the joint commission contacted me because I've published a little bit on this, they wanted something a little bit broader that covered hospitals.

I have a feeling that they have a metric that they're waiting to submit for in-hospital cardiac arrest cases that is actually requested time even though I at that time I said you guys, you know, think there's a large enough gap that if we get this piece fixed that the next piece can be well everyone who would be doing it would know that it can't be 30 minutes after the - you know, after the placement. It has to be done immediately.

And it would trickle down to EMS services. Because then once this metric starts being utilized as a patient safety metric then all of a sudden hospitals would turn around and tell their EMS hey, you know, stop putting tubes in patients. You're missing 25% of them. By the time you get here bag these patients.

And actually (Gauchette), one of the articles that's included it's JAMA article, she actually wrote an article about pediatric intubation that was so often misplaced that the recommendation at the time was for any pediatric arrest outside the hospital bag these patients when they come in, stop putting the tube in.

Steve Lawless: Right.

Michael Phelan: And this was I can't remember the year but (Gauchette). And I think it's cited in one of the references that I have listed on there.

Steve Lawless: Right...

Michael Phelan: But for that exact reason is that they were missing so many of them and coming in, you know, after seven minutes you really don't want to have seven minutes of ((inaudible)). You want to just bag them and get them to the hospital.

Steve Lawless: Great thank you.

Michael Phelan: You're welcome.

Pam Cipriano: Okay were there also any questions on reliability or validity?

Andrew Lyzenga: Well could Mike could you - when this is conditionally endorsed in 2008 for the purpose of conditional endorsement is to wait for additional studies.

I can't tell from the write-up here what's been done in the past three years to test this measure for reliability and validity.

Michael Phelan: There were three studies done. One was a surveillance study developing just the airway registry that I did just trying to capture how to identify which patients we want to include in the measure which would be anyone that arrived to the hospital intubated and anyone that you intubated.

And so we developed a mechanism, very difficult to identify these patients without a surveillance mechanism up front because some of these patients die and go to the morgue, some of these patients go to the NICU, some of these patients actually extubate themselves in the ED after being, you know, brought in by EMS or even after we've intubated them. They wake up and pull the tube out.

So very difficult to capture it unless you do a surveillance so I actually wrote a paper and I can't remember if I cited it as a surveillance paper.

The next paper in American Journal of Medical Quality looked at if we do this surveillance mechanism can we go back and review the charts to see for - specifically for physicians documentation?

I didn't look at nursing and respiratory therapy documentation at that time. I just really wanted to focus a quality project on improving physician documentation.

And we were able to show that there was a gap. And through education and improvement we actually improved our physician documentation.

The third study was at American or an SEM abstract based on the ACC Get with the Guidelines Registry looking at a larger population is there actually a gap in the documentation practices for confirmation of endotracheal tube placement?

And all three of them showed that that there was - we're able to do it and identify the patients that need to be identified.

The second study was able to show that there's a gap in the emergency department. And the third study was more a wider gap in a hospital-wide system.

(Sally): Michael this is (Sally). I believe that those - discussion of those articles I was scanning through this and it looks like they're on Page 17 for on the actual measure.

Michael Phelan: Okay.

(Sally): I am - the study that you were the lead author on it appears that that was a single hospital study. And I'm scanning...

Michael Phelan: Right.

(Sally): ...this and what was the sample size of that study? And I'll be honest, and I've not had an opportunity to pull that article and review it.

Michael Phelan: Yes. If I remember correctly I think we looked at six - 500 or 600 patients and I don't have that right in front of me either.

(Sally): Okay. And is the second study is - because it appeared that that is an unpublished...

Michael Phelan: It's being - we're working on the publication right now. That I believe had 76,000 patients in it.

The total number in the registry was I think 176 .The ones that got intubated were about 76,000.

And the abstract is actually published. There was an abstract that we published in Society of Academic Emergency Medicine because it was presented at that forum.

And there is an abstract published on that. And I believe I'm the lead author. I can't remember who the other is -- (Joe Ornatto), Mike Phelan, and (Hugh See). And I believe that reference is included as well on the Get With the Guidelines Registry data on endotracheal tube innovation confirmation documentation.

And I'll see if I can find it in my...

Pam Cipriano: So are there any other questions? Again we've just reviewed the testing for validity.

Are there any additional questions or any additional information (Mike), that you think would help reinforce the fact that you think that there have been - there's - there've been some additional studies with...

Michael Phelan: Right.

Pam Cipriano: ...a sample the does suggest that this measure does have validity?

Michael Phelan: Not really. I guess the one thing that I always get concerned about is on patient safety metrics.

When you have to be 100% on them like checking two patient identifiers before giving a blood transfusion, you know, I tried to think of all the lists of patient safety things that I would love to have done to me and all my patients when they do this.

If someone were to put into restraints I hope there'd be an LIP order within, you know, 100% of the time. And I don't know what timeframe you would put on that.

But if you're putting someone in restraints I would hope there's an LIP order stating that you needed restraints.

And the same thing with something like allergy or penicillin, 100% of the time none of those patient should be getting penicillin.

All those really hard to construct, you know, like scientific validity, and I always go back to the article from what was it? I think it was the Lancet about, you know, looking at this kind of stuff with things like, you know, the - can we prove the scientific validity of parachutes for the gravitational challenge?

I would hate to be in the subset of patients that you weren't 100% of the time giving them parachutes and...

(Sally): But...

Michael Phelan: ...along the same lines of this 100% of the time there should be some documentation. And it'd be great if we can get it instantaneous as they walk in the door in the ED or, you know within minutes of placing the tube.

In true practice I think it happens most of the time but the documentation is lacking. And in a highly complex system as (Gulandi) has pointed out without checklist, without something reminding people to do that like a patient safety metric I could see it being missed and never showing up on anyone's radar unless someone did an autopsy, found the tube in the esophagus.

So I could see this happening. And for the one or two patients that it may make a difference on I think it would make the world of difference.

Whether or not someone who arrests in the field and is down for 30 minutes and gets a tube and then it's in the wrong place and I don't know about that but I would love to have 100% of the time someone saying hey I documented that this endotracheal tube is in the right place.

Pam Cipriano: Okay. I think in the interest of time we're going to have to move on. And so I think if committee members have more questions I'd ask you to send them to staff and, you know, we'll - we could - we'll try to get additional information.

Michael Phelan: Do you need me any longer on the phone call?

Pam Cipriano: Mike, thank you very much.

Michael Phelan: You're welcome. Have a great afternoon everybody.

Pam Cipriano: Thank you.

Michael Phelan: Bye-bye.

Pam Cipriano: Okay moving on to 419, documentation of current medications we have this - the actual review and then we'll look at the related and competing measures in just a minute.

There's been a clarification made that in 2A1.1 speaking of being able to document to the best of their ability.

Andrew Lyzenga: And I - this is Andrew I believe we have Sharon Hibay on the phone if she wants to just make a very quick comment on the additions or changes that we made to the measure?

Pam Cipriano: Okay. Sharon's from CMS?

Sharon Hibay: Actually I'm from Quality Insights of Pennsylvania. I believe on the phone we also have Don Wilson from Quality Insights, Dr. Dan Green from CMS and (Ken Schwartz) from CMS.

Pam Cipriano: Please go ahead.

Sharon Hibay: But Dr. Wilson would you like to give a synopsis or would you like me to move forward?

Dr. Don Wilson: It doesn't matter Sharon. Go ahead.

Sharon Hibay: Okay. So there was a committee request, changes to the specification that we made for additional clarity that the measure is a visit-based measure. And that language was provided a change in the description also throughout the rest of the measure specification and the numerator and denominator information.

You asked for an adaptation to the best of the providers knowledge and ability that the medication list was current and included the four points of medication documentation which for the medication name, dose frequency and (roots).

There was also some discussion that we had in relation to the authorized representative caregiver and/or healthcare resources being utilized in that best effort attempt to document the medication.

The medications were to be documented at each visit. And it was also to be a current list of medication.

So upon submitting the G code as we talked about the HCPCS code, the numerator code for reporting successful completion of a clinical action all of those pieces are implied that it was a -

the list was current, it included again name, dose frequency and (roots) it's a visit-based measure and that by submitting the code it was the provider's best attempt, best knowledge and ability to have information submitted.

There was also language on the NQF form that was clarified related to the importance of the measure.

We added - just clarified the importance performance benchmarking gap analysis, of course the impact information.

Pam Cipriano: Thank you. Are there questions from the committee?

Male: So is the main change here that we've added the qualification to the best of his or her ability?

Sharon Hibay: There's a number of changes to the measure specification. Again Dr. Wilson if you or Dr. Green if you'd like to chime in I'm happy to have you help.

First of all the - going ahead, was someone speaking I'm sorry?

Male: Yes I started to say Sharon I think that one of the main as Sharon pointed out was I think there was some confusion and some - I mean good criticism was that it was a bit vague last time whether we were talking about it being an encounter based or a visit-based measure.

So we tried to clarify it and make the language much more clear just to show that based on number of visits is in the denominator.

So and I think we kind of agreed on that language actually during the meeting last time to the best of her knowledge because there was a question about how do you know that it's accurate what the provider writes.

And I think we had some discussion as I recall and everybody kind of agreeing that, you know, that the provider can only, you know, use his best - to the best of his efforts, you know, right what he - using information at his fingertips at the time of the visit.

So the best information he can glean is the best you can expect of the provider at that time. There really is never going to be a definite way to say that it's 100% accurate.

So I think we kind of agreed as I recall that this language is something that's affective best his or her knowledge and ability would be the way to go.

Iona Thraen: This is Iona. So can - maybe this is a staff question. Can you just describe how this one is different than 0019 documentation of medication list and the outpatient records other than the specification of how?

Heidi Bossley: This is Heidi. So I'm looking at it right now. 0019 has actually been retired.

Iona Thraen: Okay.

Heidi Bossley: So the developer's no longer maintaining it. I'm not sure I have the reason why but you're right, otherwise it would have been almost the same thing if not identical.

Iona Thraen: Okay.

Heidi Bossley: Yes.

Janet Nagamine: This is Janet. I just have one comment about what I think we might be getting at in terms of specifying that it's to the best of the provider's knowledge.

As someone who does this all the time in the ER I can tell you that there's a lot of emphasis on the list but not on accuracy and I think that the gap there has to do with the fact that the patients themselves cannot tell you for sure what they take.

And so I don't know if in the future or on this measure we can focus a little bit more on reconciling the bottle, the list.

Because when you look at the bottle and you tell the patient is this what you're taking it's often not what they told you is accurate on the list.

And so, you know, I don't know if that's language or process that we might want to include.

Don Wilson: I mean this is Don Wilson again. I mean I think it was certainly our assumption that by including to the best of her - his or her ability that, you know, you would sort of rely on the judgment of the provider to recognize that fact.

And if he's got a patient that he knows may not be reliable that he, you know, ought to go that extra effort and look at the bottles if they're available.

I mean they may not be available, you know. So that kind of goes into that kind of why it's hard to say that you must look at the bottles because they may not be available.

But by saying to the best of his or her ability that they've got an accurate list is kind of where - kind of we kicked this around. And I think when we kicked it around at the meeting last time is kind of where we ended up thinking it was probably the most appropriate language.

Janet Nagamine: Yes. And I think that that's fair to acknowledge. But I will tell you that our ER nurses go through our list. And I will go through it. And 90% of the time that list is not accurate.

Don Wilson: Right.

Janet Nagamine: It was done by an RN reconciling with the patient. But then when they - when I compare it to the bottles I end up making a lot of changes.

So there's, you know, what you would...

Don Wilson: Right.

Janet Nagamine: ...we would think happening and there's what is. There's plenty of data that says that when a pharmacist goes back and looks at the med reqs list that somebody did that accuracy is probably 10% to 15%.

Don Wilson: I think I'm sure you're right. You know, I'm - and I think as somebody else talked about before about the baby steps piece, I mean even just getting and making sure that the provider's for sure are making that - taking that effort to make sure that they really have tried again to help you to the best of their ability to come up with the right list.

You know, it is definitely there's still a gap in even that happening.

Janet Nagamine: I hear you. You've got to at least try. You got to at least ask.

Don Wilson: Right exactly.

Janet Nagamine: But I - as we refine our measures those are things to think about.

Don Wilson: Sure.

Janet Nagamine: Okay.

Female: Okay and again I think a lot of the concern is...

Male: ((inaudible)) that every encounter in every location every time? I - there just doesn't seem to be very much focus to this measure.

Male: It's based on every encounter based on if you look at the encounters that are specified in the denominator. So they're based - basically the outpatient ambulatory visit codes.

Male: All right so what does a family practitioner do who just treated a patient for something, they come back a week later without any known change in their medication? He's supposed to run through the med list again or how does he check off the G code?

Dan Green: This is Dan Green from CMS if I may jump in here. The idea is and I'm sure you would agree that any time a patient comes into your office for a new problem even if it's a week later that the medication list would be reviewed with the patient to see if there any changes.

The patient could have been seen in the emergency room and then prescribed something. Patient could have been seen by the orthopedic surgeon just for their six month follow-up for their osteoarthritis or what have you.

I agree that I think it was Janet that was talking about the potential for inaccuracies in the list, you know, given patient recollection and what have you.

But I think we would all agree that every time a patient is seen in your office it would be reasonable to make an effort to document if there any changes in the medications and what the medications are for the patient.

I think as electronic health records and e-prescribing are more broadly adopted I think we'll be able to get more accurate lists through the pharmacy benefit manager, et cetera.

But in the interim again I guess I'm a little puzzled because I'm - while a basic measure I'm - I can't see how this could be a bad thing and could only be a good thing.

I mean Mrs. Jones may remember that she's on a given medication next week that she doesn't remember that she's on this week.

And if that's your only access to find out from Mrs. Jones by, you know, if she comes in the following week I mean we would want to have as complete a list as possible.

So I just want to throw my 2 cents in to the discussion. We tried to make the measure comply with the wishes of the Steering Committee when we last met. I guess it was a month ago or so. And that's why we've come back with these changes.

Male: Well, you know, nobody disagrees with the importance of med req. But I mean a measure that is this broad in scope that isn't very focused, you can actually cause problems by inaccurately classifying somebody's practice. That's a...

Ed Septimus: Yes this is Ed. I would imagine there's an awful lot of gaming that could go on with this measure as well.

Male: Yes there's no audit attached to something like this.

Male: Well look I mean, you know, we run TQRS here. And I would suggest, you know, that there's gaming that goes on in a lot of these programs.

I mean we had people saying, reporting an AT off of a CP2 code for every single patient they saw solely for the purpose of being counted for reporting and getting an incentive.

Obviously that's not what anyone's...

Male: Right.

Male: ...you know, intent is on the call here today of course. But I think that it's a reasonable measure that we want to encourage eligible professionals to get in the habit of tracking the medications each time a patient comes in.

It's an important part of the history and physical even if it's not for annual visit.

Male: Right.

Male: And I think this is a good start.

Male: I think that...

Male: I agree it's a very important goal. My question is, is this going to impact here this particular measure?

Steve Lawless: Yes, this is Steve Lawless. We have an electronic record system and others - electronic record vendors are doing this pretty religiously now.

I would say it does impact care positively.

Male: Well in the electronic world. And also implemented this in the electronic world too and it worked beautifully with e-prescribing and...

Steve Lawless: Right.

Male: ...we had a beautiful way in which we did med req. But in a non-electronic world...

Male: But if we're starting to raise the standard versus the maintenance I'm - I think this is going to expect that the rate would be low but I think this would be a really positive driver.

Don Wilson: This is Donald. And if I can jump in and just say to look at the numerator and note that we added to the measure actually.

And we're saying that by reporting G8427 the professional is attesting that he has documented the current medications to the best of his ability and knowledge.

So, you know, I guess you have to sort of depend on the professionalism of the, you know, EP, the Eligible Professional, you know, to be honest that if he, you know, after you put that code down he's actually saying I'm attesting that I did this.

Pam Cipriano: Okay so I think we've pretty fully explored the potential pitfalls of the measure. Again it's accuracy versus 100% that is probably not achievable.

So I think with that discussion let's move for just a minute. We have two other items that I know we're not going to be able to complete today.

One is to look at this measure and the similar measures that are available and then - and have a discussion about what might be our next steps to look at those and then similarly recommendations for future measure endorsement.

If we look first at the table that was provided for similar measures or competing measures as you will see there are four different measures.

And I guess Heidi, we would look to you is it possible that we could perhaps initiate an off line or off telephone discussion and be able to collect some recommendations from the committee either first with questions but then recommendations about potential harmonization?

Heidi Bossley: Yes. So I think what I would - and we'll summarize this in an email kind of outlining I think the key questions before in the committee.

And in this instance I would really say that we'll see how the discussion and the voting of 419 go forward.

And then if it gets passed then we'll have - we'll also provide some guidance and have the committee provide some input on whether you think that these are - I think they're more related measures potentially, whether you think that there are measures -- and I think this is a question to the committee -- are there measures that are endorsed now that are closer to the outcome and those are the ones that should be targeted.

We'll layout a few questions like that and have you do an email dialogue on that. Because the real question to the committee today is given seeing what measures are out there and the measure before you against the criteria what is your recommendation on that measure? So we'll kind of summarize that in an email as we send out the survey monkey.

Pam Cipriano: Okay thank you.

Don Wilson: This is Don Wilson if I could just jump in real quick. Because we looked at a couple of these measures when we were setting out...

Pam Cipriano: Don?

Don Wilson: ...to develop our measure.

Pam Cipriano: And we're out of time. Can I suggest that we perhaps have you provide some input and give us a paragraph...

Don Wilson: Sure okay, no problem

Pam Cipriano: ...addressing that? Why don't we do that?

Don Wilson: Sure thanks.

Pam Cipriano: That would be great, thank you. And then similarly for recommendations for future measure development we have a - an opportunity to provide some input. And that again I think we'll need to do through email.

Andrew Lyzenga: Yes. And that's fine. We've already got a few exchanges coming back and forth here about that.

Pam Cipriano: Great okay. So Andrew or Heidi do you have any additional instructions for the group?

Heidi Bossley: No other than I think if everybody can just indulge us for a second we'll do a public comment and have the operator open up the phone lines.

Pam Cipriano: Oh yes thank you.

Operator: And all phone lines are open.

Andrew Lyzenga: Is there anybody on the line who would like to provide public comment?

Pam Cipriano: All right.

Andrew Lyzenga: Sounds like none.

Pam Cipriano: Okay. So again, Andrew, if - you'll be sending out a poll for the voting and these measures then?

Andrew Lyzenga: Yes. And along with some - a summary of some of the issues we've talked about here and a bit of background. And we'll yes, we'll get that to you and have the vote out to you so we'll conduct the vote online after the call and we'll be in touch with next steps and follow-up information.

Pam Cipriano: Great, okay thank you very much. I appreciate everybody's indulgence. It's a large group with a lot of topics to cover.

Sorry if everyone didn't get their 2 cents. But again if you've got additional questions or need additional clarification prior to the voting please don't hesitate to send that in.

Andrew Lyzenga: ((inaudible)).

Pam Cipriano: And thank you for measure developers and their comments as well.

Male: Thank you Pam.

Male: Thank you everybody. Have a good day.

Pam Cipriano: All right thanks everybody.

Female: Bye-bye.

Female: Bye.

END