

## **NATIONAL QUALITY FORUM**

**Moderator: Andrew Lyzenga**  
**December 5, 2011**  
**11:00 am CT**

Operator: Good day and welcome to the Patient Safety Complication Workgroup C conference call.

Please note today's call is being recorded.

It is now my pleasure to turn the call to Mr. Andrew Lyzenga. Please go ahead, sir.

Andrew Lyzenga: Thank you. First, I'd like to welcome everybody for joining our call. We really appreciate that you're taking the call - the time to call in. We know you're all very busy and we gave you pretty short notice on this. So we really do appreciate that you could make it.

What we'd like to do on this call is just to do some preliminary evaluation of the measures in this that have been assigned to this workgroup. These are surgery-related measures. We're just going to do some preliminary review in a smaller group in advance of the in-person meeting. We're hoping this will help our workgroup members think through the measures a little bit more and hash out any questions they might have.

So they've got a little bit more of a comfort level with both the measures and the evaluation process itself for those who haven't done it before. We're hoping this will help us work through the measures, the reviews at the in-person meeting a little bit more efficiently.

We've assigned each of the workgroup members a measure as a primary reviewer. We don't have all of our workgroup members on the call today. If for those who are on the call, we'll maybe ask those workgroup members to walk through the measures for us. So the measure that is assigned to them. The others I can just sort of lead us through.

I think we've got the preliminary evaluations up on the webinar and we can kind of use those as a jumping off point for discussion. We can probably see where there is a general consensus on the, you know, particular evaluation criteria and where there might be a little bit more disagreement. We'll probably focus on those areas where there is some disagreement to our lack of consensus.

So before we get started, maybe we could just do a quick round of introductions. If we can have the workgroup members introduce yourself and say a little bit about yourself.

Iona Thraen: This is Iona Thraen. I'm Patient Safety Director for the Utah Department of Health and have been assigned the Wrong Site, Wrong Side, Wrong Patient and Wrong Procedure, Wrong Implant measure.

Andrew Lyzenga: Thanks Iona. Now Charlotte, are you on?

Charlotte Alexander: Yes I am. This is Charlotte Alexander, I am an independent practitioner. I chair the Safety and Quality Committee for the Memorial Hermann Healthcare System in Houston, Texas and have been involved with that for several years.

Andrew Lyzenga: Charlotte - John Clarke.

Dr. John Clarke: Hi I'm John Clarke. I'm a Professor of Surgery at Drexel University and at most of the - Clinical Director, the Pennsylvania Patient Safety reporting system which Iona now has 460 wrong site surgeries.

Iona Thraen: Yes, but you got all the money too buddy.

Dr. John Clarke: That's right.

Andrew Lyzenga: All right, Vallire Hooper.

Vallire Hooper: Hi this is Vallire Hooper. I am the Manager for Nursing Research at Mission Health System in Asheville, North Carolina. And I have the 0362 Foreign Body Left After Procedure.

Andrew Lyzenga: ((inaudible)). Susan, are you on?

Vallire Hooper: I had said something about she was somewhere else and they were pulling her in.

Andrew Lyzenga: Okay.

Vallire Hooper: Andrew so because she's not here yet.

Andrew Lyzenga: Okay, I gotcha. All right well thanks. We'll just get started then in that case. And I think the first measure we got lined up is the Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant measure. That's Measure #0267. And Iona, you were assigned as the primary reviewer for that. So why don't you just walk us through.

Iona Thraen: Well and just - I'm at a disadvantage. I'm off site and I don't have my computer in front of me. So Jessica was going to walk through the areas of disagreement.

Andrew Lyzenga: Okay that sounds great.

Jessica Weber: It looks like everyone said it had high impact except you Iona.

Iona Thraen: Of course.

Jessica Weber: Sorry and then for the performance gap, it looks like there was variation from high to low depending on the reviewer for the first part. So maybe we should do that to start our discussion.

Andrew Lyzenga: Looks like a couple said - people said there was low opportunity for improvement or not much evidence of a performance gap. Any thoughts on that from a workgroup member?

Dr. John Clarke: Well this is John Clarke and I think there is opportunity for improvement. As most people know, the problem has been recalcitrant when you look at say the Joint Commission's Sentinel Event Data. However, recently there have been some improvements. The VA has been working on this problem and has noticed about a 20% improvement.

In Michigan Hospital Association, since human factors into the OR and did a quick take of the time-out script and they've seen a 25% improvement. And we have had two collaboratives. It has not improved as a result of just having the universal protocol or telling people what to do. But when you actually get into the implementation part of it, it does seem to work.

We had one collaborative with 30 hospitals in Philadelphia where we reduced our rates by 75% in the short-term. And even after two years, it's 50% of what it was originally. And we had another very successful collaborative in another part of the state involving 19 hospitals. And they went from seven per year collectively to two per year to one per year. And now they have not had any over the past year.

So I think the answer is you can make a difference in this. You actually have to get into the implementation phase of it in order to be successful.

Iona Thraen: This is Iona, I would agree with that. I do want to explain though my response to the low impact question. In the measure itself, the measure is verbal language as the percentage of ambulatory surgical center admissions experiencing a wrong site, wrong patient event, okay.

So my first question was, this is coming from the Ambulatory Surgical Association and the percentage of ASC, the number - the code. These are rare events and using it as a rate number with the high number of procedures that ASC's do, it struck me that the rate is going to be so, so, so small that I questioned whether or not having it as a percentage was really going to be helpful.

So even when Dr. (Drexler) was quoting his numbers from Pennsylvania as being in the 400 range, that's 400 overall for all of the hospital admissions and ambulatory surgical center procedures. So the raw number is probably more in pencil because of the egregious nature of the type of event as opposed to having a rate procedure. And I'd like to hear other people's opinions about that.

Dr. John Clarke: Iona, this is John Clarke again. I agree with you 100% on the rate and I noticed that on a number of the other measures, they look at counts. They look at counts on transfusion, they look at counts on foreign bodies for instance just as an example. And I do not think that this is the kind of problem that you put a rate on because it's an event that's rare and it should never happen at all.

And I think a count is much more appropriate than a rate. So I agree with you 100% on that.

Iona Thraen: Okay.

Vallire Hooper: This is Vallire Hooper and I - the problem from my perspective with a count is that, now out of how many? I mean, perhaps a count with a rate, but you know, I really struggled with some of the measures that were just a count because it just didn't mean anything to me. And...

Dr. John Clarke: Let me ask you this. If there was one wrong site surgery everyday in Pennsylvania or excuse me in the country, would that be satisfying to you?

Vallire Hooper: John, I think it's interesting to know, but I think a count without an incident's rate is for me - is just not quite enough. If I'm...

Dr. John Clarke: Well I guess I'm arguing that the rate should be zero so that the count is zero and the rate is zero. And the rate and the count are the same when it's zero. And anything more than zero is unacceptable, so.

Vallire Hooper: And I don't disagree with that, but you know, the reason I took the performance gap as being low is because the incident is so small. And I do not agree that the incident should be zero, but the incidence is so small. But it's very difficult to show a performance gap.

That being said, I'm not sure if the focus should be the outcome or the process because also in reading the measure, I wasn't convinced that the process of universal, you know, the universal site identification time-out, etc. actually contributes to a decrease in the incidence of wrong site surgery.

Dr. John Clarke: This is John. Because we've looked at this immensely, it doesn't if it's done without best practice. It does if it's done properly and the Joint Commission tells you to do it, but they don't tell you you had to do it. And it turns out that how you do it, which is not stated by the Joint Commission, does make a difference.

Vallire Hooper: I agree, I just - my question I guess is should the focus be the outcome or should the focus be the process?

Charlotte Alexander: This is Charlotte Alexander. One observation I had as I was looking at these measures is that hopefully as we're measuring and they're giving us some indication of how we are progressing. And so I would speak toward a rate. I had a difficult time with things that were reporting only the incident's to know are we any better than we were. Which direction are we going? Are we having a positive impact?

So even with a small number, I would wish to have a rate and I would like to see over the three year period what direction we're going.

Iona Thraen: I just -- it's Iona again -- I understand the concerns and the rationale. I just think that in terms of rare events and also in terms of never events, rates are not appropriate measure. And I get what you're saying in terms of needing some sort of context, in terms of how to interpret those numbers. But I just don't see that the rates are giving us the kind of context that we're looking for as it's stated.

Now that said, two things come to mind. One is how does this one compare to the definition of the hospital reporting events for wrong site - wrong site surgeries? Do you guys know? Does the staff know if they ask for percentages on the hospital site for a wrong site surgery measure?

Susan Moffatt-Bruce: I -- it's Susan Moffatt-Bruce -- I think I'm on now. We as a healthcare system and also in Ohio, we naturally report them as counts, absolute numbers. Just because with never events, we just felt that the rate was just not helpful for us. So...

Iona Thraen: Right.

Susan Moffatt-Bruce: But that's kind of where we are at, at the, you know, the grass roots level trying to prevent this and make them never events.

Dr. John Clarke: This is John Clarke, if I could jump in on the ASF's. I think it's actually more problematic in ASF's than it is in hospitals and that's because the ambulatory facilities are very different. So some almost do entirely endoscopy, some do almost entirely eye cases.

Iona Thraen: Right.

Dr. John Clarke: And some do plastic surgery. So if you're having - if you're comparing endoscopy units to eye units and you're not stratifying for those kind of units, your numbers are going to look very differently depending on whether it's an endoscopy where the wrong site is very uncommon versus eyes where the wrong site, wrong implant is probably one of the most common of all the types of surgery that's done.

Iona Thraen: And it's also from what I've been told from my local association is where many of the wrong sites occur...

Dr. John Clarke: Yes.

Iona Thraen: ...is in the eye area. Jessica or Andrew, is this an opportunity to ask the vendor or the recommending organization if they're on board to explain to us why they chose percentage or what their - why they're supporting a percentage approach versus a count approach?

Andrew Lyzenga: I think that would be great. I believe we've got both Kim Wood and Slosburg on the line. Kim and Donna, are your lines open?

Donna Slosburg: I don't know, can you hear me?

Iona Thraen: Yes.

Andrew Lyzenga: We can hear you.

Operator: And Kim, your line's open as well. You as well Susan.

Female: Okay thank you.

Iona Thraen: So would you like - can you explain to us why this is a percentage versus a count?

Susan White: So this is Susan White. Donna, if you don't want me to jump in, just so. I think it's a matter of - with ASC's we have a big difference in sizes and a big difference in market. And I can appreciate the comment that each of the centers also has, you know, many of the centers have a focus on particular procedures.

In measuring if we want to look for statistically significant change in shift, I think the proportion would give us the ability to do that. We would be fine reporting both; I don't think that would be an issue. Reporting the count, I would say we have to separate sort of - in never events we could have bad luck if we're doing, you know, one out of a million surgeries.

I would say ((inaudible)) like 100 is acceptable, but if we're looking at shift and we want to look at statistical shift, the rate is probably the more sound way to look at that.

Dr. John Clarke: However -- this is John Clarke -- and you're the statistician. My sense is that if you do a pair analysis on something that happens at about 1 out of every 20,000 to 1 out of every 60,000 events, you're probably going to need a cohort of at least a million in each group.

Susan White: Oh you're exactly right.

Dr. John Clarke: And that way you can detect a difference. Are you not?

Susan White: You are exactly right and I struggled with this because we have another also which just are never events. And the way that some of the way that some of the questions are sort of structured, they lead you down the statistical significance path. But (Jack) (sic), I totally agree with you. It's, you know, you would need the pair analysis would not come out favorable here.

Iona Thraen: Okay and one other question I had regarding this. It talks about percentage of ASC admissions. So how are defining admissions? Because it's been my conversation with ASC, they really work on the procedure - work within the procedural world as opposed to admissions world. Admissions tends to be more of a hospital terminology.

Kim Wood: If you look at the measure definitions -- and this is Kim Wood -- you can see that we have defined admission as the patient having completed the registration process. And yes, even though this is an ASC and not a hospital, patients are actually admitted through a process...

Iona Thraen: Okay.

Kim Wood: ...on the date of the surgery. And we've set that criteria so that there is a consistent process for identifying when the patient has actually been admitted.

Iona Thraen: Okay.

Kim Wood: And just to follow onto what Susan said, the way the measure is constructed, the numerator identifies wrong site event and if you only want to know the count, you can certainly know that. But if you pair it with the denominator statement which is the ASC admission, you can also

establish a rate. So there's a fair amount of flexibility in what gets done with the measure because both data elements are collected.

Female: But the particular...

Kim Wood: Someone implements the measure, only wants to know the count, then they certainly can know that. If they want to know the rate, that's available as well.

Dr. John Clarke: Could you tell us how much extra work is involved in collecting the denominator admission rate number?

Kim Wood: Not much extra work because that is sort of a routine thing. As you can imagine, hospitals keep track of how many patients they admit and ASC's also as a routine part of their operation. Understand how many patients are admitted in their setting.

Female: Yes this is - and I have years of experience in the perianesthesia setting to include ambulatory. And to capture that denominator, that's just that you collect on a daily basis. So that is not adding any additional work to the process.

Iona Thraen: Okay and then one quick - one more observation or question. I'm going back to which is how the wrong site, wrong side, wrong patient, wrong procedure and wrong implant indicator for hospitals is defined? So if we're going to be able to for example compare apples to oranges - apples to apples and not oranges to oranges, I'd want consistency in definition related to the hospital site as well as the ambulatory surgical site.

Dr. John Clarke: Iona, this is John Clarke. The NQF has a very good definition. Not everyone is aware of it, but it's pretty straightforward. And if you're following the NQF definition, it should not be particularly debatable.

Iona Thraen: Is NQF - I'm not - use counts or percentages?

Dr. John Clarke: Well they have a definition of what constitutes a wrong site event, that the skin is punctured or a natural orifice has been entered.

Iona Thraen: Okay, but in terms of how they're reporting out the measure I guess is the question.

Dr. John Clarke: I think that's why we're here.

Donna Slosburg: This is Donna - and Andrew and Heidi, you all can correct me if I'm wrong -- but to my knowledge, I don't believe there's a hospital or inpatient endorsed measure specifically for wrong site. Is that correct?

Andrew Lyzenga: I don't believe - I believe John may be referring the serious reportable event.

Female: Right, but I think...

Dr. John Clarke: That's where the definition comes from, yes.

Donna Slosburg: The definition, but I think the question is, is there a similar measure on the hospital side? And to my knowledge, I do not believe that there is an endorsed measure.

Dr. John Clarke: Right.

Donna Slosburg: I understand hospitals, you know, select the data, but I...

Andrew Lyzenga: I think that's correct.

Heidi Bossley: Yes this is Heidi, you're correct. Just for serious reportable events, but not a measure.

Iona Thraen: Okay I need education, but how is the SRE different from these? Andrew, I need you to clarify that for me.

Andrew Lyzenga: Heidi, do you a good explanation of that? I'm not sure if there is really sort of a qualitative - I mean, they're not specified exactly as measures. They're events. They don't have a numerator, a denominator typically so they don't have rates as we're discussing right now.

Female: Right.

Dr. John Clarke: But it does raise the issue if someone - if something is supposed to be reported as an event and in many states they've adopted the SRE's as the criteria for reporting something. If these are supposed to be reported as events, doesn't it make the most coherence to report them as events? Just if it happens, you report it and then you collect a number that - reports that you get and reported out as a number.

Heidi Bossley: Right -- this is Heidi -- there's nothing within the NQF portfolio or anything that would prohibit having a measure in addition to the event. I mean, a measure would look at it a little differently because you'd be including exclusion. And depending again on what we're looking at, I don't think it's this measure specifically, but risk adjustment is needed, etc.

So I do think we've never said that if you have a serious reportable event, it's not ideal to have a measure. I think in fact it would be ideal. Specifically there are some when you look at them, you would want to have probably more of a measure when you're reporting out percentages or rates like you're talking about.

So I wouldn't let that be the reason - because we have a serious reportable event, I wouldn't discount this in front of you right now because I think there is value in having a measure on it. But serious reportable events, they're reported by states. I think it's only hospital though from my understanding. So there is a gap right now even in that reporting on ambulatory surgical centers.

Dr. John Clarke: It depends on the state.

Heidi Bossley: I'm not - I'll have to check, but I'm pretty sure.

Iona Thraen: It's state-dependent because in Utah we cover both hospitals and ambulatory surgical centers.

Heidi Bossley: Yes.

Dr. John Clarke: ((inaudible)).

Iona Thraen: Yes.

Heidi Bossley: Okay, but again I think the question before all of you and the important piece I think we're still on, but when it comes down to the scientific acceptability, I that's what I hear some of you kind of struggling with. And I do think we need to talk that through a bit more.

Andrew Lyzenga: And maybe we should just go ahead and move onto that. Right now we've got a few more measures we're going to have to review on this call so we're going to have to kind of move through fairly quickly. And evidence is one area where there was a little bit less consensus among the numbers who entered their preliminary evaluation.

Vallire Hooper: And Andrew, this is Vallire Hooper. And I just have a quick question; this is my first time going through this process. And I'm a bit confused as to with once the evidence - it says is the measure focus a health outcome? Yes. If not a health outcome, rate the body of evidence. So I got somewhat confused as to if we should rate the body of the evidence was a health outcome.

So could you please clarify that for future reference?

Female: Andrew, why don't I go ahead and answer this one. So it's a really good question, it's something that each committee kind of talk through. If you believe that a measure is a health outcome, then you're correct. Don't need you to then move further and evaluate the quantity, quality and consistency of the evidence.

Vallire Hooper: Okay.

Female: So what we typically do is ask, is do you believe this is a health outcome? If you say yes, then in and of itself, you just want to make sure that the justification for why they're putting forward this health outcome measure seems reasonable to you in the criteria. Beyond that, you're done. But I think it may be helpful especially with some of the measures we're looking at today to maybe ask that question every time.

And then if so, if you say yes, then we'll move onto the other items.

Andrew Lyzenga: Okay.

Female: Does that make sense?

Andrew Lyzenga: I think so and I think everybody said that it was a health outcome. That was unanimous. So I guess maybe we can move onto reliability and validity. It seems like there was a

fairly high degree of consensus there. Everybody thought it was pretty highly reliable and valid, although someone expressed a concern again about count being preferable to a rate.

But were there any other comments on the reliability or the validity of the measure?

Heidi Bossley: This is Heidi again, the other thing that falls within the scientific acceptability as well as precise specification which I think you started talking about a bit with using admissions in the denominator, etc. So any other thoughts you have, we're happy to capture.

Andrew Lyzenga: Thoughts or comments on that from the workgroup members? Or questions for the developer? Sounds like not.

Going onto usability and feasibility. Again, a fairly good degree of consensus there, although some said that - rated either usability or feasibility at a moderate level. Most of the others said high. Were there any comments from the group on that? Usability or feasibility of the measure?

Sounds like no comments on that either. The overall suitability for endorsement, looks like everybody gave this a yes. Do we have any comments just on the overall measure? General thoughts or questions for the developer?

Charlotte Alexander: What if -- this is Charlotte Alexander again -- would it be appropriate that we look at inpatient as well as outpatient? Is that something that would be in the purview of comments?

Andrew Lyzenga: That's something we could maybe discuss with the Steering Committee. I would imagine it's something that we could maybe put in the report as a gap area that the committee identifies, that you'd like to see a measure that applies to the inpatient setting. I think right now we're just looking at the measure in front of us which is for out patient ambulatory surgical centers.

Am I right about that Heidi?

Heidi Bossley: Yes again I think it's - and it'd be interesting again to talk to developer if they could support a measure that would be applicable beyond ambulatory care surgical centers. They may only be able to apply it with the data that they have, but I think ideally we would have measures that look at these types of things that go broad across the inpatient and the ambulatory surgical center setting.

Again, we're limited to what we have before us. But I think it's worth asking the developer if that's a possibility.

Dr. John Clarke: This is John Clarke and I think that technology or the mechanics of collecting this information are the same in both.

Heidi Bossley: Yes.

Dr. John Clarke: So you're not going to be doing anything different. And in fact hospitals in general are already reporting these to their states, probably in about 19 different states.

Heidi Bossley: Right.

Vallire Hooper: This is Vallire Hooper. Based on the discussion that we have, I wonder if it might be possible to consider stratifying this measure ((inaudible)) a procedure. And I think that that may give us a better idea of where there are actually problems because it sounds like there seems to be a higher propensity of this issue in eye cases as opposed to maybe breast surgeries or orthopedic surgeries.

So I just wonder if it would be possible to stratify by type of surgery?

Dr. John Clarke: It is possible to stratify by type of surgery. I think even if you're talking about neurosurgery where 50% of all neurosurgeons will do a wrong spinal level once in their career. You still want it to be zero. Hand surgery is about 20%; knee surgery is about 25%. This is of it happening to one person in their lifetime.

Vallire Hooper: I agree John that you want the incident's to be zero, but to get to zero you got to know where the problem area is which is what I think stratification by type of surgery may help us to do is to better focus.

Dr. John Clarke: Yes I think the people who have the problem know they have the problem, that is the hand surgeons have talked about this in a lot in the literature. Orthopedic surgeons are the ones who first brought it to national attention. The spinal surgeons have published a lot and even have guidelines on it. The eye surgeons have published it.

Those are the areas where it's really big. And those are the one - and all those people are already preoccupied with this.

Andrew Lyzenga: Maybe we can ask the developer if that was something you considered stratifying the measure by procedure and not/why not.

Iona Thraen: This is Iona; I'm going to say that the issue of stratification by procedure is also relevant to accidental puncture and lacerations and retained foreign objects. You see the same phenomenon depending on the type of procedure, different rates by I guess maybe risk or type of surgery, etc.

Dr. John Clarke: Yes Iona, you're right. And as I looked at the data, in fact it seems it's actually by body cavity. Depending on what body cavity you're in, your rates are different.

Susan White: So from the developer's point of view -- again this is Susan White -- we kind of have the same issue with this as we do with our disparity measurement. We're collecting aggregate data from each of the ASC's as opposed to patient level data. We do have plans to implement a registry in the near future and at that point, we would be able to collect on that basis.

Female: That would be wonderful.

Female: You know I think it'd be very useful; we'd love to have it.

Female: And at this end, just for the committee's information, CMS is planning to implement this measure as part of the Medicare program's ASC Quality Reporting Program beginning in October. And when that data set becomes available again, that will be on a patient level and can be tied to the type of procedure that's being performed.

So it's in the future, it's not something that we're able to do right at this moment.

Female: So this is a maintenance question - this measure's up for maintenance review. And which means that you've been using this measure for about three years now?

Female: We've been using the measure since last quarter of 2009, but can I just remind the committee that at this time there is no mandatory reporting required of ASC. CMS did just put out the final rule that is saying we will be reporting in October of 2012. This is all voluntary...

Female: Okay.

Female: ...reporting that we have been getting as Susan said in aggregate because we, you know, we felt that this was an important measure and that's what the quality collaboration has been about. So that's one reason why we can't stratify at this time, but hopefully in the future we will.

Female: And based on the voluntary reporting that you've had thus far, what has been your overall rate?

Female: Actually it's posted on our Web site. Second quarter 2011 was .031 per 1000. We have - we keep four quarters up on the Web site and you should have had access to that. But if you want, I can go quarter to quarter. I can whatever.

Female: No, no, no I'm just trying to get a sense.

Female: That was the 1200 facility, 1,400,000 admissions.

Female: Okay. Andrew, what do we need to do? Do we need to make a decision to pass this forward?

Andrew Lyzenga: No we're actually not doing any voting on this.

Female: Okay.

Andrew Lyzenga: This is really just a little bit of preliminary discussion and review.

Female: Okay.

Andrew Lyzenga: So we don't need to make any kind of decision or vote on the call right now. Just to - sort of to raise some questions, get a sense of where some of the issues are. And give the developers idea of where the discussion might go at the in-person meeting.

Female: Did anyone have any other concerns? Or is there any other variation in the preliminary voting that you want us to address? I'm trying to move this forward.

Andrew Lyzenga: Yes I think that's a good idea.

Heidi Bossley: This is Heidi; I think we're good unless there's anything else. I'm just looking at the time. You've got six more measures.

Female: Yes.

Andrew Lyzenga: Yes, yes.

Female: Maybe it would help to move onto the next one.

Andrew Lyzenga: Yes let's go ahead. And the next measure we got is accidental puncture or laceration rate. Pediatric safety indicator (one), Measure #344. John Clarke, I think we had you as the primary reviewer. I should note right now, I don't believe we have the (ARC) developers on the line today.

I think they were not going to be able to make it, but if we do have anybody from (ARC) on the line, if they could notify the operator so that we can bring you into the call. That would be great.

Dr. John Clarke: Well thank you Andrew. This measure of course is very similar to the adult measure, there's not too much difference in children except perhaps that grown-ups tend to come into the hospital with much greater chance of history of surgery and therefore adhesions and therefore the potential for accidental perforations and lacerations.

This is maintenance so it was originally implemented in 2008. And it does talk about a percentage which I think in this case is quite appropriate because there are risk stratifications. There are inevitabilities in someone who say has multiple, multiple operations on their abdomen.

Some of the things that I didn't understand had to do with the exclusion and I had to only assume that a normal newborn was being excluded simply because they had no medical problems. And that the neonat with a birth weight of less than 500 grams was being excluded. It wasn't exactly clear to me why, but I thought that one of the reasons might be that just that the numbers of those infants was so small that they couldn't really do comparisons.

But it's a question that I had. The one thing that I didn't see though with normal newborns is there's a class of accidental perforations and lacerations which I don't think is addressed here. And that is that -- and this is unique to pediatrics -- and that is when we think about an accidental perforation or laceration, we think about putting a laparoscopic trocar through the bowel.

And then in the middle of an operation or during an operation. But one of the things that happens with newborn babies is that they may accidentally suffer an accidental perforation -- or excuse me an accidental laceration -- during a C-section. And that's really not I think included in this opportunity so I'm not sure we're capturing people who get cut during C-sections.

It's a little different than the usual accidental perforation and laceration. The rationale for this type of measurement includes the global patient - the composite I guess you call it patient safety indicators. And I think that there is - the one thing that I think is really important about this, there's a rate for these things that's in some cases inevitable.

But what is not inevitable is missing the diagnosis so that there's this I think need to not so much reduce the number of events that occurs as to reduce the number of undetected events that occur where you don't realize for instance that you have a laceration or perforation. And then you

send the patient home with a hole in their bowel. Other than that, I think it's relatively straightforward.

I did have one - let's see - yes in terms of the quality - so in terms of the reliability of collecting the information, I had two concerns about that. Number one is that there are some things that are risk factors that I don't know that you necessarily capture. And I didn't see it here.

There's an attempt to identify risk factors in a variety of ways, but for instance the number of prior abdominal surgeries you have is a big, big risk factor you have for abdominal perforations and lacerations. It's not something you're going to find in the record and in the stratification. And the other thing is I think that not everybody reports every accidental perforation and laceration.

For instance, you know, if I'm operating on someone who's had six prior operations and I nick the bowel, I just sew it up and I go on. I don't, you know, this is not a big event. Likewise, I've seen reports in our patient safety database where someone's accidentally stepped on the (Bovie) while it's been lying on the patient's abdomen. And there's a little (Bovie) burn laceration and they throw a stitch in it.

And, you know, they mention it to us. But I don't think those things are always going to be reported. So but nevertheless, I think it's a very important problem. It's one of the big three surgical complications along with infections and return to OR for an anticipated bleeding. And it really needs to be identified, risk adjusted, stratified as we talked about before.

It's really - the key here is -- and they do identify the strata in this report on Page 10 -- the key here is, you know, what cavity are you in. So I think that pretty much covers it and I think a lot of it except for the accidental perforations and lacerations of newborns during delivery, cesarean section during delivery. I think that it's fairly standard, for adults all my comments would be appropriate, for adults as well as babies.

There is one other thing about the children though that I think is true. They mention under - on Page 13 under reliability testing that because some hospitals have such small pediatric volumes, that they were thinking about excluding those hospitals.

And I would be much more in favor of aggregating those hospitals because if you don't what you're going to have is a bunch of hospitals where they're doing five procedures a year. In the aggregate, their rate is, you know, 2%. And then you got another group of big hospitals like Children's Hospital at Philadelphia/Pittsburgh where they're doing thousands of procedures a year and their rate is 1%.

And if you don't measure those smaller places, you're not going to appreciate this. So whenever I see something that could be very rationally be regionalized and people talk about excluding the small places, I much rather the small places be included in the aggregate so at least you can stratify by volume as well.

And I did have one question about -- and this is just for the committee's benefit from the staff -- when we're asked to rate -- and I'm trying to find the page here -- when we're - just a second. Flipped too many pages.

Andrew Lyzenga: While you're looking John, I can...

Dr. John Clarke: Yes let's see - oh yes here on Page 19, 4C. Susceptibility to inaccuracies, errors or unintended consequences, a high, medium and low. And it's confusing to me whether that question means - high means yes it is susceptible to inaccuracies, where high means that you can in fact identify the susceptibility to inaccuracies. And therefore it's actually low susceptibility in accuracy.

So maybe someone can explain that to me because if I didn't put medium on that, I was unclear as to what a high or a low meant.

Heidi Bossley: This is Heidi, that's a really good question. I haven't even looked at it that way. We're so used to looking at it. It's really intended to say whether they've addressed that criterion.

Dr. John Clarke: Right.

Heidi Bossley: Or not.

Dr. John Clarke: So maybe instead of saying 4C susceptibility to inaccuracies, sensitivity to inaccuracies.

Heidi Bossley: We can definitely suggest that. We're looking at the ((inaudible)).

Dr. John Clarke: Okay so at least I know which way it's supposed to go. So high is supposed to be good on that one.

Heidi Bossley: Correct, right. I would say it is, it's not the inverse. Yes you're right.

Andrew Lyzenga: Well thanks John and again I'll just note quickly that since the developers are not on this call, try to make a note of the questions that you have. And we'll send this a list of those so they can try to respond at the in-person meeting and we can go over those questions again as we discuss them at the in-person meeting.

So if you have any questions for the developers, make sure to bring those up and ask us and note them and we'll bring them to developers.

Anyone else have any comments or thoughts on this measure?

Charlotte Alexander: Charlotte Alexander here and I'm obviously very new to this. I was looking for more evidence and obviously there's no evidence cited. And that's because it's an outcome measure. So on all these outcome measures, we're not going to see evidence nor are we going to see information over the three years that shows whether it was effective, whether it did anything to improve outcomes, is that correct?

Heidi Bossley: This is Heidi; you definitely would like to see the latter. Especially from a measure that's undergoing maintenance. The more detail they can provide on how it has actually impacted the quality of care, the better. Now for this one, it may be that they provided it under usability. I've lost track. But if they haven't, I think that's something we should go back to the developer and ask them specifically address if you'd like.

Dr. John Clarke: Yes to what extent does that confuse by the fact that it's part of a composite measure? So it could be that we're not - we're supposed to judge each part of the composite measure individually, right? So it'd still be valid?

Heidi Bossley: Right it should - every individual measure that's included in composite should meet the criteria. They may not - I think for this one I think Andrew corrected - brought this one forward for individual endorsement as well as consideration within the composite.

Andrew Lyzenga: Yes that's correct. All - each of the measures that we're considering today are being brought forward for individual endorsements themselves as well as being part of the composite.

Vallire Hooper: In that case -- this is Vallire -- the only concern that I have about this measure was actually in usefulness for quality improvement. And because the discussion for this measure as well as for some additional measures for this section was focused on the set of indicators and the set of measures as opposed to the individual measure.

And if we are endorsing the individual measure, then I would prefer to see that discussion focused on the measure that we're endorsing.

Andrew Lyzenga: Okay thanks.

Heidi Bossley: We can ask them to provide that.

Vallire Hooper: Thank you.

Heidi Bossley: This is Heidi, just one more time on the health outcome and the ((inaudible)); I want to make sure everyone's comfortable with what they're seeing and what's against the criteria. For the criteria, the task force that look at this and the recommendation that came out was that they don't have to provide again guidelines or the evidence explicitly like you would see for structure or process measure.

But there should be a rationale that supports the relationship of the health outcome to at least one health process, intervention or service. So again if the health - I'm just trying to provide a little more guidance as the result of the work of that committee if that helps. That is what we're looking for and what you should be provided.

Does that make sense?

Vallire Hooper: Yes, thank you.

Heidi Bossley: Okay.

Andrew Lyzenga: Thank you.

Charlotte Alexander: And Charlotte Alexander again. I noticed on several of our indicators that the rationale is that there have been focus groups. It doesn't show the outcomes of the focus groups, but it just states - is that enough of a rationale?

Andrew Lyzenga: I think they would like to see more information about what the focus group has said, what the results of that were. Something that you can certainly discuss as a Steering Committee. Correct Heidi? Do you have anything else?

Heidi Bossley: Yes I'm looking to see where they reference that. I mean, what I'm looking at explicitly is the 1C1 structure, process, outcome, relationship which is where you should see the rationale for the outcome.

Charlotte Alexander: I was looking at 3A2.

Heidi Bossley: Okay let me take a look at that too. Oh yes this is where they start talking about the usefulness and how it was demonstrated. Yes I think this is more the focus on - the 3A is more the focus on the reporting of the information and how useful that is which is different. That would help you assess the usability piece, but I would not say that is the evidence piece. I would look at 1C1 for that.

And they talk about the preventability of this event within that. But again, what we can do is make note of the question. So I for sure the denominator exclusion and also the accidental perforation or lacerations during C-section as to not being included, but the thinking is it should. Is there anything...?

Dr. John Clarke: Well it could. I'm not saying it should, but it could.

Heidi Bossley: Could, got it.

Dr. John Clarke: And this definitely happens.

Heidi Bossley: Yes exactly. No, it's a very good point. Anything related to the evidence that you'd like us to specifically ask?

Dr. John Clarke: I think one of the - it's going to be hard to capture this perhaps, but it would be nice to capture an outcome measure somehow which captured the census to whether this error was detected or not. Because I think there's really two parts to accidental perforations and lacerations. One is that it happened and number two is you didn't realize it happened.

And it's that second part - I mean, almost any area you can recover from, but if you don't recognize it then you're dead in the water. So it would be nice to be able to get some kind of complication type outcome measure out of this so we can understand not only that it happened, but that in fact led to dire events.

Vallire Hooper: You know John, I agree with that -- this is Vallire -- I agree that it's likely not the fact that it happened, but the fact that it was missed. That causes the dire consequences most frequently. So I agree this would be nice if we can capture that component.

Heidi Bossley: Okay and then you also had a question on the risk adjustment related to the small hospital? Is that correct?

Dr. John Clarke: Well there's two. One was the risk adjustment that I'm not sure you're collecting them on. I wouldn't push that because I don't think you're ever going to collect, you know, how many adhesions, you know, lengthy adhesions on the scale of 1 to 10, that's just never going to happen.

Heidi Bossley: Right.

Dr. John Clarke: But I would be against excluding hospitals that had small volumes. I can understand not singling out hospitals that had small volumes and saying your rate was 20% because you operated on five people and you had one accidental perforation. But I would think in the aggregate, it would be very useful to look at high volume versus low volume places.

So in the aggregate I think would be unwise to exclude low volume places from any monitoring at all.

Heidi Bossley: Got it. And then the last one I have is the 31C, the use of quality improvement. Make that specific to the measure, not the composite. I don't want to stop discussion on this measure, but I am trying to help catalog the questions. Is there anything else?

All right what we can do is work with the developer to make sure that these get addressed and are ready to address them at the time of the meeting.

Andrew Lyzenga: And I think we can probably move onto the next. The next one is also accidental puncture or laceration rate. This is the patient safety indicator rather than the pediatric indicator.

Charlotte Alexander: Correct and this is in adults -- this is Charlotte Alexander and I had this one -- and this is also an outcome measure. One of the issues that I had with it and this is looking at the exclusions. And part of it is that I did not understand what they were saying. If you go to 2B3 under results where they're looking at the statistical results for an analysis of their exclusions, they recommended no changes for the patient safety indicator.

Exclusion 1 should be retained, to retain Exclusion 2 and the MD14 exclusions are not candidates to be dropped in this work. So that is confusing to me. I read MD14 as the second exclusion which they said they wanted to retain as an exclusion. And then they say it's not a candidate to be dropped and so that was confusing to me.

I think many of my other comments that I put in online were lack of understanding on what we were trying to find on these indicators. So much of the information that's been discussed under pediatric as well. I would echo what Mr. Clarke said about the fact that we are probably missing a number of these, that they aren't being reported. And that indeed the ones that are being missed are the ones that are most likely to have the more severe outcomes.

Vallire Hooper: And this is Vallire, I have a question regarding harmonization as to why we have -- and perhaps it's because of these sets of indicators as opposed to individual measures -- but it would seem that we could have one measure that could be stratified by age group as opposed to two separate measures. I found that confusing in trying to do the evaluation.

Iona Thraen: This is Iona, I support that and particularly since both of these measures I think are coming from the same institution.

Dr. John Clarke: There are so many instances in which you have a PSI and a PDI, that it seemed like that was a philosophical decision made in advance up front for some particular reason. So I wonder if staff has any idea what is the origin of those dichotomies.

Heidi Bossley: Yes this is Heidi. They do have the two different indicator sets that they report, one being the adult, one being the pediatric. I suspect it's just probably in their minds it was easier to have two separate measures addressing different populations, same aspect of care or outcome. We can ask them if they would be - if it's of interest by the committee to see if they could create one measure stratified.

I don't know if it would be an issue other than they may run into some concerns as they start to develop composites and use them in the individual reporting program. But again, we'd have to clarify with them. But I think that's why. I don't think there's anything really different between the two though.

Vallire Hooper: No I agree, it was basically - it seemed to be reviewing the same.

Dr. John Clarke: I think when I read them -- this is John again -- it seemed like that the exclusion criteria were a little bit different and that may have been a factor.

Heidi Bossley: Yes that might be it, but we can ask them.

Iona Thraen: I think -- this is Iona -- I think if we're willing in other instances to ask two different agencies to work on harmonization on one measure, I think that we should ask them also either to provide us an appropriate rationale that would explain why they had not harmonized these or to take that step and to move forward in terms of the harmonization.

Heidi Bossley: We can definitely put that forward to them. You would think if it's the same developer, it should be doable.

Iona Thraen: You would think.

Heidi Bossley: Right.

Iona Thraen: But we will only think, ((inaudible)).

Heidi Bossley: We will not ((inaudible)).

Iona Thraen: That's right, we will hope. And I would argue that that applies to both the next two, transfusion reaction and foreign bodies.

Female: Absolutely.

Heidi Bossley: We can put that forward as a global collection to them.

Female: Yes.

Andrew Lyzenga: Maybe we should move to reliability and validity of this measure, any additional questions that we didn't address in the previous measure that were specific to this one.

Or if not, any comments or questions or thoughts on the usability or feasibility of this measure?

Vallire Hooper: This is Vallire again, if I remember correctly as far as usability, I just rated as insufficient because the discussion was not specific to the measure which again has been a common problem across several of these measures.

Andrew Lyzenga: Right, okay. Okay we will note that.

Female: Okay I think we can take silence as we're ready to move onto the next, correct?

Andrew Lyzenga: I think so. Next measure we have up is transfusion reactions. We have both 349 and 350 assigned to Dr. (Lawless) who was not able to make the call. So again, maybe we can just walk through this ourselves and take a look at the preliminary reviews to see where there is consensus versus on consensus or lower level consensus.

In terms of the importance of - we'll start with 349. I think, you know, there was actually a good degree of difference on both the high impact and the performance gap on this measure.

Vallire Hooper: Well and this is Vallire and Charlotte and I ranked the performance gap pretty - we were pretty consistent in our rankings. And I think both of us -- and Charlotte I'm speaking for you so jump in anytime -- but it seems both of us have a concern about the count as opposed to a rank.

And I know that John is somewhat in disagreement regarding that, but I wonder perhaps if we could not address both. You know, and capture a denominator as well as a numerator.

Dr. John Clarke: You're going to have to do it in terms of units of blood products.

Vallire Hooper: I agree, but I would think that that would be fairly easy to capture.

Susan Moffatt-Bruce: Yes I think this needs to be -- sorry Susan Moffatt-Bruce again -- this needs to be a rate I think just to make it - again looking at improvement strategies and where you actually make impact. That would be my opinion.

Dr. John Clarke: So we do get back to the same issue and I think even his comments that it was at almost at Six Sigma already and it is in fact in Pennsylvania to have ABO incompatibility. So that if you're going to show differences - I mean, it's one thing to show that a rate went from .0002 to .0001, but if you're going to show differences that are valid, are these statistically significant.

The number of events is, you know, astronomical even for sigma it's, you know, over a million. For Six Sigma would be probably a hundred million.

Female: I think it also falls into the same category as the wrong site surgery. This is a never event and besides the rareness, the context - the comparable context is zero. So I don't know that - you

know, I understand the need for rates and statistics, but I just don't know if it's appropriate in this particular type of event.

And in going along also, I think with what John is saying about the policy measures getting measured in terms of IC9 Coding and discharges, is that the right measure - the right context. Should we ask the developers to revisit how they're measuring it? Should be tied into the number of blood product units? And that's the appropriate context, therefore the rate, if you used a rate approach per blood product units, then would it make more sense?

Vallire Hooper: I would agree with that, this is Vallire.

Female: I have a clarification because again I'm new to this, but why is it that the subject and topic area is only pertinent to general surgery? Is that while we're actually measuring only within the realm of general surgery? You know, because doesn't this pertain to many other areas? Or am I just reading this incorrectly?

Heidi Bossley: No this is Heidi, that is a very good catch. We'll talk to them. It should be broader because it is medical discharges as well, so.

Female: Absolutely, absolutely.

Heidi Bossley: Thank you for finding that, that's a good point. We'll talk to them.

Female: And can we make recommendations to the provider or the agency that's making this recommendation, that they visit or revisit how they're defining this in terms of per discharges versus per blood products?

Heidi Bossley: We can - I think what we might do is first ask them - tell them that based on the workgroup discussion, it's actually preferable from your viewpoint to have it tied to the blood products rather than discharges. And asked them for information as to why they perhaps didn't do it and how feasible it would be.

The question I think I would have is that if they could extend it to that, it does mean potentially a change in the testing data that's provided, the reliability and the validity. And that may be something that they cannot do quickly.

Female: Okay I think...

Heidi Bossley: But it's worth asking.

Female: And I think because we're in this review period on these measures that that's an appropriate review feedback to be given because the science changes over the course of the last three years.

The science has changed and the need to change so rather than just rubber stamping it and saying okay we'll continue to do like we've always done, if the value of the measure is in at the blood product level and not at the discharge level, then I think they need to get that feedback and try to adjust accordingly.

Heidi Bossley: No I - that's exactly the purpose of this. So we will ask and let's see what the response is. We'll know by the time of the Steering Committee meeting.

Female: Okay.

Dr. John Clarke: It could be that they made it a count simply because they thought it would be difficult to measure the number of units of blood and they figured that a single person wouldn't likely get more than one transfusion reaction during a single hospital encounter.

Iona Thraen: But that's, you know, I mean to me that's - one of the struggles were having -- this is Iona again from Utah -- on some of these measures when they're at the 30,000 feet view, they tend to lose their usefulness. So, you know, drilling down to the blood product level which is a combination of a supply and utilization question.

And it seems to be would have more overall value in terms of how well their blood service is operating internal to the hospital as opposed to extracting it out further away from the actual operations of the organization, if that makes sense?

So for this one for the transfusion measure, when does the question of harmonization across the pediatric population and the adult population use what is the definition of the measure itself in terms of blood product utilization versus discharges.

And I don't remember if there was a third concern.

Heidi Bossley: This is Heidi, I don't have anything else unless...

Iona Thraen: Rate versus count.

Heidi Bossley: Right, yes.

Andrew Lyzenga: It sounds like those same concerns are likely to apply to the next measure as well, the pediatric.

Female: Right and I think also if you would like to have the 3B1 specified for the measure, not the set.

Andrew Lyzenga: Yes.

Heidi Bossley: Okay.

Female: I think we're starting to get the hang of this.

Heidi Bossley: You are, great. This is why we do it before the meeting.

Female: It's smart, smart.

Heidi Bossley: Yes, anything else or should we move onto the next two?

Female: We can move on.

Heidi Bossley: Okay.

Andrew Lyzenga: Okay so foreign body left after procedure. I guess if you're all comfortable with it, we can just sort of address these as a pair again.

Vallire Hooper: This is Vallire and I'm fine with that.

Andrew Lyzenga: Okay.

Female: I...

Andrew Lyzenga: Yes go ahead.

Female: Go ahead.

Andrew Lyzenga: I was just saying that...

Female: I just had a question whether or not - and I'm not a clinician, but I needed to get some feedback on some of the clinician. For foreign body left after procedure versus foreign body left during procedure and what my people are saying to me at the hospital level -- and I can't remember is this is - yes this is HRQ -- is that they don't want to report unless the foreign body leaves the OR room, okay.

So their argument is this, is that when - during the surgical process involved with putting sponges and a variety of things inside a body cavity and in the process of removing them and doing the count, sometimes you don't know for sure.

And so you might have to go back and recount and if you discover prior to releasing the patient from the OR, does that count as a foreign body left? Or should it be the line drawn in the sand, that if they leave the OR with the foreign body and it's discovered after that point, that that becomes a recordable item? And I don't know if people think about that.

Dr. John Clarke: There's actually -- this is John -- there's actually again a very good definition by National Quality Forum. And I was stumbling over that too, I was not quite sure what a foreign body during a procedure meant. But well except that there's two things and maybe they were referring to something else. But the NQF definition is very precise and I think very good.

It basically says when you put in the last skin stitch or your operation is over or you've taken your instrument out in the case of natural orifice surgery, at that point the operation is over. If there's still something unintentionally left in at that point, then it counts as a foreign body.

So if you get your x-ray while you're closing, you find that you have a foreign sponge in there and you pop the fascial sutures and you get it out before you finish the operation, then it doesn't count. If on the other hand, you close the skin even if you haven't awakened the patient and then you get the x-ray and then you go back in and open the patient back up completely, then it does count.

And I think that that's a reasonable definition.

Female: My understanding in reading this is that it had been a recommendation for modification had been made to state that it was the wound was closed, the count had been reconciled and the patient had left the room.

Dr. John Clarke: Well that would be inconsistent with the NQF definition. So I think there would probably be some need to harmonize a serious reportable event with this particular...

Female: Measure.

Dr. John Clarke: Measure.

Vallire Hooper: And I -- this is Vallire -- I agree that the definition first and foremost should be harmonized.

Female: I agree as well, I think John you and I are similar in our thought processes around this. I mean, it's very clear in most academic institutions right now that when you close the skin and then you find a retained foreign body, you have not helped that patient and it goes against every team training exercise we've ever done.

So I think we do need to harmonize the definition for the protection of the patient that when the skin is closed, that is the end of the operation.

Iona Thraen: I support all of the above.

Dr. John Clarke: Do we get a sense of what it meant to do it during the procedure? What that was all about? Because I could envision something which is not called a retained foreign object which is called an unretrieved device fragment. That's an instance where let's say you're doing an orthopedic procedure and you break - and you pull out the drill and you notice that the tip of the drill has broken off.

Vallire Hooper: John this is Vallire and in looking at both of these measures, in general it seemed that it was just too slightly different titles or one being a pediatric measure and one being an adult measure.

Dr. John Clarke: Right. Yes, yes, yes.

Vallire Hooper: But the content of the measures are basically the same. So I think that it's just a difference in title, that doesn't really imply a difference in during or after. It's just a slight difference in title.

Dr. John Clarke: Gotcha.

Susan Moffatt-Bruce: Correct, but I do think -- again Susan -- I do think that there needs to be clarification around when you do leave in objects and you choose to because of the risk of benefit ratio. I don't think that's always clear and that's where there has to be some clarification on both of these measures, that if the surgeon chooses to leave it, it's not unintended. They choose to leave it because of the risk; it's too high to remove it.

Dr. John Clarke: Yes and it's called - the FDA calls it an unretrieved device fragment as against the retained foreign object.

Susan Moffatt-Bruce: We need clarification around that and I think it's in here, but it's just very hard to read through this.

Iona Thraen: Cases that have been brought to my attention was that they had some uncertainty about it, is when sponges have been conscious enough either related to nose surgery or vaginal surgery, conscious enough at the time in the OR and sent out into recovery. And then it's the responsibility of the recovery entity to pull the sponges when appropriate that they've been left in inappropriately.

So the breakdown actually happens post-OR and so that's why I've gotten most of my phone calls in terms of trying to decide whether or not it was a reportable event or not.

Dr. John Clarke: Well there's actually another category of that which is damage control trauma surgery -- which is I'm a trauma surgeon -- and I think that anytime there's ((inaudible)) or something is left in for a reason, that should never be considered retained foreign object. But we do see a lot of natural orifice sponges, primarily in the vagina, that are left in unintentionally.

And they count at least according to the NQF admission. I think it's the issue of - I think it's really straightforward if it's documented you left something in then there's not a retained foreign object.

Iona Thraen: But it's documented that's been left in, it doesn't really - it's not the trauma surgeon, but it's ((inaudible)) to have it removed after 45 minutes or after a certain clotting time period and it's not removed. It's forgotten, you know, it's just missed in the process of care, then it becomes a retained foreign object.

So it's not the surgeon's issue, it's not the operating room issues and now becomes a recovery issue, that that follow-through in terms of care has not been done.

Female: But if we go by the NQF definition that John was talking about, I don't think that that would fall under this category. I understand what you're talking about, but particularly from a process perspective - your primary process to avoid retain foreign body particularly in the OR is that final count. So that final count will be correct if the sponge is to be removed in the PACU.

So I am not sure if we follow the NQF definition that that would fall under this measure.

Iona Thraen: Well and we - and my interpretation at the time was that yes it was reportable and they did a root cause analysis because it was a flag I guess for the breakdown between the OR and the recovery process and trying to mend some of that.

Female: Yes that almost sounds like a hand-off issue.

Iona Thraen: Yes that might have been a better way of identifying it, but at the time we did not identify it that way. It became an RFO.

Female: Because technically, you know, what do you call a Foley catheter that's left in to be pulled in the PACU?

Iona Thraen: Right no your point's well-taken, but we treat it as a retained foreign object.

Female: I mean, we just do need to be careful with that though because technically that could open up a lot of things being a PACU nurse for many, many years.

Iona Thraen: Well I think it was left even though it was consciously left whether in the OR - intentionally left in the OR, it was unintentionally kept...

Female: Correct, correct. So that that situation could occur for things other than sponges.

Iona Thraen: Yes absolutely.

Female: To include NG tubes, Foley's, ((inaudible)).

Iona Thraen: Well that's a breakdown in the process of care.

Female: Right it's a breakdown in communication more so I think.

Iona Thraen: Exactly.

Female: But I see I...

Susan Moffatt-Bruce: I'm sorry, I'm just listening to this and we've had these issues happen. I mean -- sorry its Susan again -- that's actually a practitioner as well because if someone leaves something there and intentionally, it's then his or her responsibility to reconcile the count, remove whatever they had intended to be removed and the hand-off is only one part of the process I think.

Female: Yes I think from a definition perspective, we're going to have to - brings up a good point on that, that we're going to have to be very clear on how this is defined.

Susan Moffatt-Bruce: Correct.

Female: Which my gut is to lean more with the NQF definition that John was talking about.

Susan Moffatt-Bruce: I'd be in favor of that. I have one more question for clarification again; this one speaks to this being pertaining to general surgery, again topic area. I think that they pertain to a lot more than just general surgery, both the...

Male: Events.

Susan Moffatt-Bruce: ...procedures - or both the events, (PSI).

Female: Yes and I would agree with that.

Iona Thraen: Yes I agree.

Heidi Bossley: We'll make a note of that.

Female: There is no statement that I see uses an exclusion for a drain or these other things that we talked about that were intentionally left in. What is the correct application for a drain? Is that to be included in the count of the retained foreign object?

Female: A good question - I don't know if we've ever - I'm trying to think if we've ever seen it and I don't know if that it's one of those things that may not be counted. I've seen guide wires and Vulcan needles/micro needles and chips and obviously sponges and a retractor and, you know, sort of the obvious ones. But I don't know that a drain - I don't know that I've seen any reports on drains.

Dr. John Clarke: Well for the most part -- getting back to what we said earlier -- a drain is going to be retained if it's not taken out and if it somehow slips under the surface. One of the very first cases I did as an attending was vaginal fistula after a colorectal procedure that someone else had done

and I thought the patient had a recurrent. And I went to do a biopsy and I pulled out a nice  
((inaudible)).

And told the lady, "Well I guess you don't have cancer after all." But that's more along the lines of  
what we were talking about earlier where you're not taking the vaginal sponge out or you're not  
taking the Foley catheter out or the nasogastric tube out. Only in the case of the nasogastric tube,  
relatively obviously if you don't take it out. A drain slips under the skin, not so obvious.

Andrew Lyzenga: So is this something you want to ask the developer about, whether drains left should  
be included?

Female: I think that we just need to have a very clear definition.

Andrew Lyzenga: Okay.

Female: And I would suggest the NQF definition as proposed by John.

Andrew Lyzenga: I see, okay.

Female: I would agree.

Female: And then, you know, in summary, you know, of course we have inconsistencies with count  
versus the rate.

Andrew Lyzenga: Right.

Female: The discussion that we've had, but given that numbers of surgeries, that procedures are so  
easily reported, I would see that there should not be an issue to report by the count and a rate.

Andrew Lyzenga: So was it the sense of the workgroup here that it should be a count as opposed to a rate or the other way?

Female: I think it should be a count, but that's just my opinion.

Dr. John Clarke: Yes as a surgeon, I agree. It should be a count.

Female: And I would go for rate so I can compare.

Female: I mean, I would like to - I'm open to compromise and to have both and I don't see that the denominator would be difficult to obtain. And I think that particularly from an individual facility reporting perspective, it would be very helpful as a consumer to have both.

Iona Thraen: Well and then also, this is another case of the question of stratification.

Female: Correct.

Iona Thraen: By body cavity -- I think that's what you said John -- you know, which is, you know, open cavity versus closed body cavity. The majority of the numbers that we see on our side are vaginal sponges.

Dr. John Clarke: Yes.

Iona Thraen: And sponges in general, I think vaginal is a subset of that.

Dr. John Clarke: Right.

Iona Thraen: So I mean, I don't know if an overall foreign body number really communicates. The question I guess I have is that -- and one of you, I can't remember who it is said this at the very beginning -- you know, what's the usefulness of these measures. Are we trying to judge a system in terms of their quality or are the measures sort of a beginning step in trying to understand what the problems are?

And then where do we focus our resources to improve, you know, processes to improve outcome? So a general foreign body left during procedure number in of itself is not really giving us much information. It's not until we drill down and we look to find that most of them are about sponges. And then the question of, you know, do we need to change the way we do business in terms of how we use sponges counting versus scanning versus x-rays, etc., etc.?

Female: I am in 100% concurrence with that.

Andrew Lyzenga: Okay.

Female: Do you know John the definition, the NQF definition says anything about the stratification issue?

Dr. John Clarke: Well I think the stratification issue is separate. Yes you're going to stratify as Iona said, you know, sponges you can retrieve without operating again. Sponges versus retractors versus (7-0) needles. So I think it's a separate question.

Iona Thraen: But I guess what I'm struggling with is that all of these measures as they go out as endorsed measures used by the industry, where we want to go somewhere along the line is to get a national use. Everybody's playing by the same rules to get national use of what's going on and then to look at how we can improve, you know, some component of the measure.

And without stratification in the definition, we'll never be able to get that view at the national level. It will always remain a global aggregate number that doesn't really give us ((inaudible)).

Dr. John Clarke: I agree, it raises a general - to me it raises a general philosophical issue -- this is John again -- and that is what are these measures supposed to do? Are they supposed to be a barometer of safety or are they supposed to yield insight as to how to make things safer all by themselves? I would imagine that most of them would fail to tell us the exact way in which we're going to be able to solve those problems. It may give us a few broad leads.

For instance, as we just talked about, you know, that the big problem with retained foreign objects is sponges which we already know. But I guess I pose that as a question, what exactly are these measures supposed to? Tell us where we are or tell us how to get to where we want to be?

Andrew Lyzenga: My understanding is they're really supposed to be intended for both quality improvement purposes and public reporting, you know, to tell us where we are.

Dr. John Clarke: Well I guess the question is if they're supposed to be produce quality improvement, it would seem to me that you'd have to be a lot more detailed about what you're collecting. For instance, if you're collecting on accidental perforations and lacerations and want to know the exact procedure, you're doing retained foreign objects. I want to know what object it is that was retained.

Andrew Lyzenga: Heidi, do you have any insight on that?

Heidi Bossley: Yes I think - I mean, is there intended to be reported at the facility level where you would want to get to more of that information, but as the measures are designed right now, I don't know that you can get to that because it is claims data. I mean, perhaps you could, but it may be worth

asking (ARC) if they have more information on that. And again that's where we would look for the answers in the usability and I'm looking at it now.

It's not explicitly addressed there, but I think we should ask for it.

Dr. John Clarke: So having trying to dig down on a number of these problems including accidental perforations and retained foreign objects, surgical fires and the like, I think you can be pretty successful in measuring what kind of progress you're making by getting everybody on the same playing field. Having the same definitions, having the same exclusion criteria's, having the same method of finding your data.

But in terms of actually being under - and being able to understand what the real factors are that are driving that problem in the first place, I don't think any of these measures could get you what you really need to know in order to make a real difference.

Female: So in our report - in our final report, it strikes me - a couple of things. We're doing a three year review and in three years people sitting on the phone are going to be different in terms of reviewing the next three years.

So I'm wondering if in our report, we ought to make some comment or some direction to the vendors that we're going to approve the maintenance of these measures in their current state that in the next three year period that changes have to be made or we do it now.

Something to the effect that the specificity of the measures and the definitions of the measures have to be such that they really do provide value for purposes of quality improvement, not just for purposes of public accountability. The way they're constructed right now is more about public accountability. So we could say that we're collecting data, here's our numbers and we can put that out to the public.

But if they're not really informing that these measures in their current state are not really informing the quality improvement process, I think we're really missing the vote. It is the National Quality Forum and it seems to me that that's really where we ought to be in terms of endorsing measures that are really going to help improve the outcome, you know, at the facility level.

Heidi Bossley: Now that's a very good point. If everyone agrees, we'll make sure that we incorporate that in.

Female: I agree completely.

Female: This is ((inaudible)), I also agree.

Female: I agree.

Andrew Lyzenga: Okay. Well is there any other comments on these two measures? Sort of wrap-up thoughts or?

Female: Andrew, could you scroll over a little bit farther?

Andrew Lyzenga: Yes Jessica, can you - what are you looking to - or are you looking to see?

Female: I think it was primarily related to the issues we've already discussed. It seems like their usefulness as with some of the other measures that there was - a lot of the discussion was focused on overall PDI measures as opposed to the individual measure which I think that needs to be addressed across multiple...

Andrew Lyzenga: Yes sounds like we've...

Female: But I think we've captured that, so.

Andrew Lyzenga: Yes we've identified that as an issue across a number of these measures and we'll certainly bring that to the developer. Any other thoughts on these or any of the other measures? Do you think we've captured your questions for the developer and any issues that we should sort of return to at the in-person meeting?

Female: I bet staff process is going to be easier than this.

Andrew Lyzenga: Well it's never quite so easy as you might think.

Vallire Hooper: Vallire, just as a point of clarification. For the meeting later this month, we should also go through - do we need to go through all the other measures for the other groups and upload scores as well? Or do they present their findings much as we've done with this call and then we all discuss?

Andrew Lyzenga: Yes so we will ask you to review each of the measures - all of the measures that we'll be discussing at the Steering Committee meeting both these ones, this workgroup and all the others.

Vallire Hooper: Okay.

Andrew Lyzenga: But what I think we'll ask is for this group to kind of lead the discussion on the set of surgery measures and talk about the discussion that we've had on this call, some of the issues we've identified. We'll ask the developers to come back with answers or responses to the questions that have been brought up.

But we would hope for you to sort of again lead the discussion along a little bit, you know, based on what we've discussed here just to help the full committee sort of move forward on the issues that you've identified here. And then they can identify additional ones as well, but it would be helpful for you to kind of lead that discussion based on what we've talked about today.

Vallire Hooper: Is it an imposition to ask for a summary of our discussion today that you could email out to each of us?

Andrew Lyzenga: No we should be able to put something like that together.

Female: Thank you.

Female: Thank you.

Andrew Lyzenga: You're welcome.

Female: Yes thank you.

Heidi Bossley: Andrew, should we have public comment?

Andrew Lyzenga: Yes I think right now we should do public comment. So operator, if you could ask members of the public to indicate if they have a comment.

Operator: Absolutely; ladies and gentlemen, if you have a comment or a question, please press star 1 on your telephone keypad. Again, that is star 1 to pose a comment or ask a question.

Female: We scared them all away.

Operator: And there are currently no questions or comments.

Andrew Lyzenga: Okay thank you. Well then I guess that pretty much wraps this up. I've already talked a little bit about the roles that you'll play. We'll need to ask the primary reviewer, you know that we assign to particular measures to get us started on the discussion at the Steering Committee in the same way we did on this call.

But again, you know, just the larger workgroup as well. We should feel free to chime in with any thoughts on the discussion today to sort of help the full committee understand what you've discussed already. We will - again we'll ask you to review the full set of measures before the committee in advance of that meeting and we'll send a separate online tool to enter your evaluations for those. So we'll be getting that out very shortly. Otherwise, I think we're all set.

Female: Okay great, thank you so much.

Andrew Lyzenga: All right, thank you. Well thanks again for everybody joining us.

Female: Have a great day.

Andrew Lyzenga: All right.

Female: Thanks, bye.

Andrew Lyzenga: Bye.

END