NATIONAL QUALITY FORUM

Moderator: Lindsey Tighe
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12:48 am CT

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

Lindsey Tighe: Okay, well with that, Dr. Gore, if you want to begin with Measure 0389 and if you have the lines for the AMA-PCPI folks open we can go ahead.

John Gore: Okay. So Measure 0389 is a measure that is currently part of the PQRS. And it's looking at over-use of bone scan for patients with low risk prostate cancer. So, low risk prostate cancer is defined by the patient's PSA, their Gleason score and their clinical exam. And the measure looks at the proportion of patients who did not have a bone scan at any time since their diagnosis of prostate cancer.

And in terms of importance of the measure, prostate cancer, you know, clearly is an important condition, highly prevalent. Incidence is something like 200,000 patients per year. A measure related to over-use of imaging, I think, is also important, given the cost of excessive imaging studies and the value that we think bone scans have in these low risk patients.

The evidence presented justifying the measure is all low level evidence. It's mostly administrative data and single institution data about the utility of bone scan in low risk patients, where the likelihood of having a positive bone scan in these patients is far less than 1%.

But the measure appears to have at least strong face validity when looking at an expert panel and their consideration of the measure. It seems to be very reliably assessed according to data that the PCPI submitted from its use in PQRS, and it seems to be a highly usable measure. And so I put yes for approval of the measure.

I don't know how much detail you want me to go into about the measure itself or concerns about the measure...

Lindsey Tighe: Please, if you have any concerns go ahead and raise them and we'll have a discussion about them.

John Gore: Yes, I mean, I think the main concerns are that the evidence underlying it is weak, but frankly I don't know that that's important for this measure. I don't know that it would be important to generate new evidence for bone scan, because every study that I've seen looking at use of bone scan in low risk patients demonstrates non-utility.

So it doesn't seem like it's a clinical question. It seems like something that has been consistently demonstrated not to be useful in low risk prostate cancer. In terms of how it's measured and how usable the measure is, the only thing that I was surprised by was how poor compliance with the measure was.

Because my initial impression might be that it's a measure that already has very high adherence, so continuing as a measure may not be that high yield, but data from the PCPI suggests that it's actually, that compliance is concerningly low. And then, you know, I don't know how important the issue of disparities are for this, but there's not a lot of data on disparities in either over under-use or over-use of bone scans in general in prostate cancer.

There is a lot of evidence on disparities in stage-up presentation and mortality in prostate cancer, but this measure doesn't really have anything to do with that.

Female: Okay. Well, at this point, would the rest of the workgroup members like to present their concerns or questions?

Jerod Loeb: This is Jerod. I guess both as a prostate cancer patient as well as a measurement expert here at the Joint Commission, and I have spoken to this issue on a call before, but I'm a guy that had a PSA of 1.29 and in just over a year had a PSA of 535 with a positive bone scan and a Gleason 8.

In fact my bone scan was done before my biopsy, and I literally went from the urologist's office down to get my bone scan, and it was horrifically positive. So I guess I cringe at the notion of under-use of a bone scan, although, sorry, you know, for the personal view here, but I sort of cringe at it and I would urge that this is a measure that is important.

I'm not sure about this whole notion, under-use versus over-use versus misuse, but sometimes people are the exception rather than the rule.

John Gore: I would agree but, you know, I think that that is a glaring exception. And when you had your bone scan done you had a PSA over 500. And so no one would question the utility of a bone scan in that circumstance.

Jerod Loeb: Absolutely. I totally agree.

Elizabeth Hammond: This is Elizabeth Hammond. I'm worried about the low prevalence of the problem. It sounds like this measure, if the prevalence of this measurement is, or the prevalence in low risk patients is 1%, then is this a meaningful measure for us to be endorsing?

Male: Then the over-use is much more than 1%.

John Gore: Yes, the over-use is at least 25% in different series, and as high as 35% to 40%.

Elizabeth Hammond: Okay.

John Gore: The issue of positivity of a bone scan in low risk prostate cancer is that the rate of positivity of a bone scan is far less than 1%.

Elizabeth Hammond: Okay.

John Gore: But the prevalence of over-use of a bone scan is quite high.

Elizabeth Hammond: All right, good.

Female: Okay, any other questions or discussion?

(Crosstalk)

Female: ...on this one.

Lindsey Tighe: Have any questions for the developer?

Jerod Loeb: Hi, it's Jerod, one more quick time. The - I don't argue with the comments just made about prevalence of over-use but we didn't note it in the write up. It probably belongs there but it isn't there.

John Gore: Yes, I think there definitely needs to be more evidence. The main article that's cited for over-use, prevalence of over-use is an article from VA Data, and that cites an over-use rate of 25% and a percent positivity of bone scans in low risk prostate cancer at 0%.

Steve Edge: This is Steve Edge. Has anybody done this in SEER Medicare? It would be relatively easy to do.

John Gore: Yes. The problem with SEER Medicare is that PSA wasn't included in SEER just until 2004, and so it's only with the most recent iteration of SEER Medicare that it could be looked at with the specific designations of low risk use in the measure. So someone could look at it now.

Steve Edge: Yes, well that would probably be very useful. And anybody who's got the data, this would not be a hard one to look at.

John Gore: At all.

Elizabeth Hammond: Oh, no, I think...

Steve Edge: And Jerod's comments are very appropriate, but it is, you know, if we backed away from this, you know, there's a lot of literature in breast cancer and colon cancer and others that, you know, routine screening has no impact on outcome, but it's a real thorny issue to the individual person who has something found on a scan. And, well I talk about this every day at ((inaudible))...

John Gore: I mean, it really comes down to, you know, we all believe in population health, but at the end of the day, patient-centered care requires treating an individual and...

Steve Edge: So Jerod, I'm going to challenge you a little bit, and I'm sorry to take the personal issue with you...

Jerod Loeb: Oh no, go ahead.

Steve Edge: Was yours, yours wasn't really - you didn't have, you would not have fallen under this measure.

John Gore: No.

Jerod Loeb: No, I...

Steve Edge: Somebody measured your PSA, you had a PSA of 500, and you appropriately were sent to the bone scan.

Jerod Loeb: Right, I was sent for a bone scan the same day and had my biopsy next day.

Male: Right.

Steve Edge: Right. But you would not have fallen as an over-use under this measure. You would have fallen as an appropriate use because you were not a low risk prostate patient when you had that PSA of 500.

Jerod Loeb: Totally agree with you.

Male: Yes, the other way to frame this is, there's a large fraction of those unneeded bone scans that had red herrings found on them that turned out to be degenerative disease that got the patient anxious, maybe underwent an unnecessary biopsy, et cetera.

Steve Edge: This is obviously the big issue with these scanning studies is that, is the false positive rate. And I study breast cancer, breast MRI is just an enormous problem for us right now. But when you look at the individual patient who has the lesion found because they have an unnecessary breast MRI or an unnecessary prostate bone scan now, it's hard to look them in the eye and tell them their scan was unnecessary.

Male: Right.

Male: Here, here.

Male: We all live with it.

Jerod Loeb: Some more than others.

Male: Yes.

Female: All right.

Steve Edge: Was there any estimate of the cost saving - of the cost of applying this measure versus the cost savings? I mean, we talk about high cost studies, but in reality a bone scan is not terribly expensive given the overall cost of treating prostate cancer.

Lindsey Tighe: Is there anyone for AMA-PCPI on the line who can speak to that?

Diedra Joseph: Hi, this is Diedra from the AMA. We did not include any cost savings data, but that's something that I can certainly take a look at within the literature and see if I can get that to you.

Lindsey Tighe: In their earlier comments about the Medicare data, would that be something you'd be able to provide, too?

Diedra Joseph: I can check with that measure analytic staff and see if we have access to that particular data. And I can offer that if we have access to it.

Steve Edge: I'm not sure you'd need to hold this up, but I think, moving forward, that this is something that could easily be tested in SEER Medicare, and advise future iterations of this measure. While I say it would be easy, I understand for the person actually does the work, it's not quite as easy as I said.

John Gore: Yes, but it's not, it would not be a study that would require a lot of labor intensive programming, for sure.

Lindsey Tighe: Then generally looking across the rest of this, (it really looks), everything was rated moderate to high. So if there are any points of discussion that you all want to raise, feel free, but from our end there's nothing that we need to call out, specifically.

Female: Okay.

Male: Yes.

Female: Okay. So Dr. Gore, I believe you had the second measure, 0390 Prostate Cancer, Adjuvant Hormonal Therapy for High Risk Patients, also an AMA-PCPI measure.

John Gore: All right, one second. So, this is likewise a measure that has been adopted and measured within PQRS. The measure relates to the percentage of patients with a diagnosis, now on the other side of the spectrum of high risk prostate cancer, based on their PSA, their Gleason score

and their clinical exam, who are receiving external beam radiotherapy to the prostate, who concurrent with their external beam therapy were given hormone treatment.

In terms of the importance of the measure, similar to the previous measure, prostate cancer is a highly prevalent cancer. In terms of initial treatment of curative intent, anywhere between 30% and 40% of patients in most series get external beam radiation therapy as their initial treatment.

So this measure at least deals with a reasonable percentage of patients. Now, of those patients, the proportion that have high risk prostate cancer at presentation is fairly low, relatively, but low in the context of prostate cancer still is a substantial number of patients. In terms of the evidence underlying hormone therapy associated with external beam radiation for high risk prostate cancer, this is mostly evidence derived from randomized controlled trials.

So this is not expert opinion or based on single institution studies, this is higher level evidence. They didn't go into detail on a lot of the studies that are the underpinnings of this measure, but there have been several clinical trials looking at adjuvant hormone therapy for intermediate and high risk prostate cancer, and they've very consistently shown a benefit.

In terms of reliability and feasibility, the measure has fairly consistent reliability in terms of ascertainment. In terms of feasibility and usability, it seems to be fairly consistent. I was actually quite surprised that the initial PQRS data demonstrated fairly substantial non-adherence to the measure, although that data is from 2008, so more contemporary data may show higher compliance with the measure.

In terms of concerns, I mean, it seems like this is a fairly reliably ascertained measure, in terms of how the data is generated. In terms of its validity, that validity is derived both from RCT evidence as well as from high approval ratings from a panel that approved the measure, and so I said that this measure should again be approved.

Female: All right. Are there - thank you Dr. Gore, and thanks for taking on two measures, by the way. Are there any additional comments that you had, or concerns for the developer?

John Gore: You gave me two fairly easy ones.

Female: Okay. No, all right, for the rest of the workgroup, comments or discussion or concerns about the measure?

Steve Edge: I thought this was one of the better ones.

John Gore: Yes, I agree.

Steve Edge: I mean it's, there's great data supporting it, and...

Female: Okay.

John Gore: I mean, the only thing that I can think of is just that the high risk population of people with localized prostate cancer at presentation is not a huge proportion. But still, in the context of a very large denominator, the numbers are probably substantial.

Female: Okay. All right.

Lindsey Tighe: Yes, if there are no other comments we can move on.

John Gore: That was easy.

Female: Okay, great. Good measure. Next on our agenda is 0382, the Oncology Measure, Radiation Dose Limits to Normal Tissues. Dr. Marks was our lead discussant for this measure.

Larry Marks: Okay, that's me. Thank you - we'll pull out...So this is, external beam radiation is given often to patients with these cancers, yes, there's pancreas and lung, and it's considered basically standard of care to set dose constraints for the normal tissues before you initiate therapy.

So this is a very bread-and-butter sort of metric. The, high impact - the opportunity for improvement is where this falls down. I would have guessed this would have had, you know, a 90-plus percent adherence rate, maybe 95%. It's - you almost can't do your job, you can't sign a prescription without looking at the lung doses or the kidney doses.

And the idea that you wouldn't do this before you treated somebody, it is malpractice. And indeed they do report a compliance rate of 89.42%. And they write, the mean performance is 89%, showing an opportunity for improvement. I don't know if a 10% gap, and I'd - willing to bet that that 10% was just, you know, poor documentation of what was actually done.

So that's where this falls down. The opportunity for improvement, I think is low. It is a reasonably valid measure. There's reasonable data relating the doses to the lung and the kidneys and the liver to the outcome of the patient, so it's an important thing to monitor and to look at. One could, relatively - get this relatively quickly out of most treatment planning systems, so it's pretty reliable.

It's available electronically, so again it's relatively reliable and valid. My main concern again - there's no data on disparities of care, just looking through for this. It's, is it useful for public reporting? I wouldn't think so. This is sort of hard to explain to the public, I think, because it's a pretty technical sort of point.

It is generated as a byproduct of usual care. It's available electronically. So, overall I guess it's suitable if a 10% detriment in current performance is deemed to be worthy enough of having this measure. So I think it's a reasonable thing to measure. I don't know what the gold standard is. Is 89% compliance presently considered high enough to say we shouldn't be measuring this metric? And that answer I don't have for the group.

So overall I think it's, yes, so I'd pose that question to the NQF staff, what the right threshold is for upside potential, if you would.

Female: Well, actually we would throw it open to the rest of the experts here on the workgroup to discuss that potential aspect of it.

Larry Marks: Okay.

Female: And did you have a overall recommendation for this one?

Larry Marks: Yes, overall I think it's a reasonable thing to measure. Again, I suspect that it's being done very close to 100% of the time now. And the fact that the data says it's 90% of the time, I think 10% of the time it just wasn't coded properly or the patient was treated emergently. So when you do something emergently, you don't have the dose constraint set.

So that would be my main concern. Maybe the people who proposed this are on the line and could comment about the 89% number.

Female: Is there someone, AMA-PCPI there that could discuss this?

Sam Tierney: Yes hi, this is Sam Tierney with the AMA-PCPI. You know, unfortunately the only data, we weren't able to find any data from the literature to support the opportunity for improvement, and the only data we have is from the use of this measure in the PQRS program.

And the mean performance rate is 89.42% as you said, but unfortunately they did not provide data regarding variability. And we have seen, at least with other measures in the PQRS program where variability is reported, you know, significant opportunity for improvement based on the variability of the range across practices.

But that information wasn't available for this measure. We could certainly try to do some more research to see if we could get any additional information to document a gap in care opportunity for improvement, but unfortunately all we had available to us at this point is the PQRS Data.

Larry Marks: Okay.

Pat Ross: Hey, this is Pat Ross from Ohio State. So, I understand your concern about, is a 10% or 11% improvement enough. But I question whether or not you're being naive in assuming that it's being done in those 11% of the patients. I mean, if there is, I mean, it seems to me that, from what you've said, if it isn't done it's malpractice, that's how you started the discussion, so...

Larry Marks: Yes, I agree, yes.

Pat Ross: So 11% of the patients being treated, then, are being treated at a level that you would describe as malpractice. Am I interpreting your...

Larry Marks: Well, unless they were treated emergently or with palliative intent very quickly, something like that. So, we don't - for the typical curative case it should be 100% or it's...

Pat Ross: Right, so really what you're describing is a never event, right? You should never not have done this calculation, am I right?

Larry Marks: That's correct.

Pat Ross: So I think it's a valued measure, then.

Larry Marks: I guess the only time you would never do it, you might do it, if you knew intuitively that your field was acceptable. Let's say you had a small lung cancer in the apex of the lung, and you put a small radiation field on. You know from your years of experience that the dose constraint for the lung is going to be met, and...

Pat Ross: Yes, but I think that's - but that's why we're trying to develop metrics, right, to get away from intuition. I mean, I don't agree with that.

Larry Marks: Yes. Yes, again, I think it's a reasonable thing - never, zero is a very small number. You know...It's true. You know, when you...

Male: Very well put.

Larry Marks: Yes.

Steve Edge: What's the ((inaudible)) outcome if one doesn't do this?

Larry Marks: Your risk of - so, in the lung, your risk of pneumonitis is very well related to the mean lung dose, for example, or the lung dose volumes. So you always have to look at the lung dose volumes before you sign your prescription to make sure that you're not going to kill the patient, or put them at too high a risk of radiation pneumonitis.

So the, it's, the downside is a risk of a complication. It's not a certainty of a complication, but it's a risk. So, you know, we all have these, sort of, guidelines that we go by of how much lung can we take to 2000 or 3000 or 4000 rad before we put the patient at an undue risk of pneumonitis.

The only other, if you have a peripheral lung lesion, the only organ is really the lung. So this is, did you say they want a minimum of two sites? If you're doing conformal radiation on a peripheral lung lesion, and again I know it's intuition, but you know you're not near the esophagus, right, the tumor is 10 centimeters from the esophagus, and you're 10 centimeters from the spinal cord, so I don't even really need to measure the dose to those areas.

We do it, because, you know, it's part of our compulsive nature, but if I didn't draw the spinal cord or the esophagus in a peripheral lung lesion, I don't know if I'd be guilty of malpractice in that setting. But for the typical Stage 3 lung patient it would be malpractice.

So maybe clarification, maybe Stage 3 lung patients for two organs, certainly one organ in every patient, you know, the lung should be specified in every patient, what the dose is to the lung before you treat the patient.

Pat Ross: That seems to make sense.

Larry Marks: Yes. And for the abdomen, you treat the pancreas, you always have to worry about the liver and the kidneys. So there you get two organs for the pancreas. You know, do the people who promoted this, who suggested this, what do they think about one organ as opposed to two organs, to get us away from this challenge of the lung?

Sam Tierney: This is Sam Tierney with the AMA-PCPI again. You know, that's something we could take back to our clinical experts and see, you know, I'm not exactly sure why two was selected, but we

can certainly take that question back and see, you know, the example you provided, for instance, and see what the thinking was behind the two tissues just to provide some more information and clarification.

Larry Marks: Right. But if the, but again, it's a reasonable metric. It is quantitative. It's relatively easy to gather, I think.

Female: Okay. Any other discussion on this one? And it sounds like we have a question that the developer's going to take back to their experts. Okay, then that's the end of discussion for now on 0382. The next one is 0388, Prostate Cancer, Three Dimensional Radiotherapy. And I have Dr. Ricciardi as the lead discussant for that one, also an AMA measure.

Rocco Ricciardi: Thank you. This is, it looks like it's up for an endorsement maintenance review.

Female: Right.

Rocco Ricciardi: It was originally endorsed in July of 2008.

Female: Correct.

Rocco Ricciardi: In brief, it is a process measure evaluating use of three dimensional radiotherapy for a clinically localized prostate cancer receiving external beam radiotherapy as primary therapy. I, looking through this, there are no denominator exclusions that I noted. The data aggregation is for all ages and all patients with a clinically localized prostate cancer receiving radiation as primary therapy.

And when I, you know, as someone who looks at this stuff, my question would be, then, how the denominator is aggregated that, if it's in like, electronic medical record or administrative data, are they able to exclude recurrent prostate cancers and confirm that it is primary therapy?

They don't mention how far back they would look through electronic record or the administrative data to, you know, exclude those patients who've had recurrences, or how they identify that this is actually a localized tumor. Based on the ICB9 codes they provided, they certainly can't determine.

The measure does directly address a specific national health goal, so I graded this as high. It, there's certainly opportunity for improvement. Reading their text, only 49.2% or 49.9% meet the actual measure in the past in 2008, I think was the year that they gave us. So there certainly is room for improvement.

Although it's not a health outcome, I didn't mention, the process measure, the data do come from fairly good sources, retrospective data population bases and studies and meta analyses as well as consensus guidelines. You know, again with respect to reliability and validity, my concern is just the chart abstraction or the electronic medical record abstraction, and how we are able to exclude the recurrent tumors, the non-locally advanced tumors.

And, you know, I'm not a prostate cancer specialist by any means, but certainly brachytherapy is a fairly useful tool for these patients. And I'm not sure if those are excluded because it is focusing on external beam radiation alone. Maybe someone from the AMA can comment on that.

There's no contradictory evidence that I can identify. The studies are fairly accordant, and it certainly is a usable measure. And it is feasible. The authors have shown that. But again, my concerns would be potential inaccuracies and coding locally advanced - and coding metastatic disease or patients who've had or have adjuvant therapy for radiation.

Those are my needs, my concerns. Otherwise, I think this is a very good...

Lindsey Tighe: Sam or Diedra, do you have anything to add in response to that?

Sam Tierney: Yes, thank you. We can appreciate the question, and currently for use in administrative claims data we have a CPT2 code that would be required to identify patients for eligibility for this measure. And it's code, it should be included in the submission information, it's Code 4200S, which indicates external beam radiotherapy as primary therapy to the prostate with or without nodal irradiation.

So someone reporting on this measure in PQRS for example would have to also include that code to indicate that the patient was eligible for this measure.

Male: So would proton beam radiation be an exclusion for consideration for the measure?

Larry Marks: That's a great question.

Elizabeth Hammond: That is a good question.

Larry Marks: It wouldn't - as it's written, it just says external beam radiotherapy, so it would be included.

Elizabeth Hammond: Is there a specific extra CPT code for proton beam?

Sam Tierney: There is not. There is one, CPT2 code just for your information that would indicate the patient was not eligible for that, this measure, and that's Code 4201F. And that would be required in a program like the PQRS program that's just, sends your claims reporting only.

And just to offer for your information, the code descriptor for that measure says, external beam radiotherapy with or without nodal radiation as adjuvant and salvage therapy for prostate cancer patients. So it doesn't specify anything about proton beam radiation, as you're questioning.

Male: So basically if you did proton beam, you would have to just put an exclusion code on.

Larry Marks: They are all getting three dimensional conformal therapy with protons.

Male: Yes, or should it just be folded into the measure, so percentage of patients who receive 3D, IMRT or proton beam?

Larry Marks: Yes, I don't really know if you need the clarification, because proton is just a sub-type of 3D conformal.

Male: Yes, so then rather than say 3D or IMRT, should it say, who have three dimensional planning or something?

Larry Marks: Yes, because IMRT is three dimensional planning, also. I never quite understood the nomenclature there.

Male: Yes.

Larry Marks: There's also one where there'd be, expected rate should be 100%.

Male: Yes.

Female: Sam, is this something that you would be able to take back to your committee?

Sam Tierney: Yes certainly, we could get some clarification regarding proton beam radiation. In particular, you know, maybe some more information about the use of the CPT2 codes for the, to exclude patients who shouldn't be included in the denominator.

Female: Okay. All right, are there - any other discussion about this one? Anything else we might want to get clarified? Okay, thank you. Thank you Dr. Ricciardi. And we'll move on to Jerod Loeb, 0625, History of Prostate Cancer, Cancer Surveillance by Active Health...

Jerod Loeb: Thank you very much. Let me start by wondering if anyone from Active Health Management is on the phone.

Lindsey Tighe: Hey Danielle, can you check that please, and if they are, can you open their lines?

Operator: Absolutely. And if you are with that company please press star 0 at this time.

Jerod Loeb: It's on fire somewhere.

(Crosstalk)

Jerod Loeb: Well, should I go on?

Operator: And the - what was the company name one more time?

Jerod Loeb: Active Health Management. That's the measure steward.

Operator: And it appears we do not have anybody on the line from that company.

Jerod Loeb: Well let me start, then, by talking a little about Active Health Management, because I was not aware of who they were, so I did a little bit of my own investigation. And it turns out they're a wholly branded stand-alone business that's been owned by Aetna since 2005.

And they focus on population health, and much of their Web site is devoted to disease management, particularly with respect to cost savings, clinical decision support and something they obviously have as a proprietary piece called a care engine system. So a lot of this is a black box that is a little difficult for one to open, which was troublesome to begin with. So let's talk about the measure itself.

From a relevance perspective, the numerator and denominator make perfectly intuitive sense. And as I've said before, as a guy that's been dealing with prostate cancer myself for the last seven months, I find it absolutely astounding that there would actually be a numerator that says, men who had at least one PSA level in the past 12 months who have been under, with the denominator being men with localized prostate cancer who have been under treatment with curative intent.

And later on in their write-up, I will tell you quite personally it makes me sick that their data show that in 2011, 20% of men identified by this measure indeed did not have recommended follow-up PSAs. If that is indeed the case, that is a strong piece of evidence in support of a huge gap, and a reason for the measure. That's the good news.

The bad news is, I do not believe, and I will apologize for having checked the yes box at the end here, suggesting that the measure is, in fact, suitable to move forward, because I in fact believe quite the opposite, and reviewed it all over the weekend again, and this morning yet again to verify that my initial inclination which was sort of spotty based on some good things and some bad things about the measure.

I was driven in part by that gap that I identified a few moments ago, suggesting to me that we really do need a measure. But the more I've looked at this measure the more I believe strongly, in contrast to what's listed at the end of my Survey Monkey that this is not the right measure.

And I'll give you a couple of reasons, not the least of which is, as best I can tell from the write-up, they've got a huge database - indeed they talk about 20 million patient records in the database, but interestingly enough, the average age of the population is 37, 51% of which is in fact female. And they tested the measure in their database.

They talked about 279,966 patients from a major health plan, assuming that's an Aetna plan. The average age of that population was 35, and 52% were female. They did that data abstraction just last year, but that's, in fact, the only test data that I was able to note in here, and that test data raises my eyebrows as to whether the population cohort is, in fact sufficient to really feel comfortable that this measure has been tested adequately.

The rationale for denominator exclusions here, and that's really right on Page 1, there are eight different exclusions, some of which, once again, would raise my eyebrows. So, for example, a patient admitted to a skilled nursing facility in the past three months, de novo, why would one wish to exclude that patient if the patient is at a SNF? I don't really see that.

And I - there's a few others that are in denominator exclusions that make me wonder. The reason I'm somewhat walking a fence here is because I really think we need a measure that addresses this issue if in fact the data regarding the notion that 20% of patients that are being treated for prostate cancer do not have follow-up, a follow-up PSA in 12 months.

If that's true, we need a measure. But my argument is, this is not the measure. I do not believe that it has the science behind it in the context of reliability testing and I would not recommend the measure go forward.

Female: Thanks, Jerod. Are there other comments and concerns from the rest of the workgroup.

John Gore: Absolutely. This is John Gore. I have a lot of problems with this measure. You know, getting back to this issue of how important it is, you know, the one thing I would ask about that data that shows that 20% figure is, what time frame are these patients out from their treatment?

There's no kind of time delimiter on this - you know, guys who are ten years out and have what appears to be a very effectively treated cancer don't need an annual PSA anymore. So there's no specification of any kind of time delimiter, and there's no specification in this study of potential under-use of PSA surveillance for time.

In terms of the evidence base, you know, all surveillance strategies for prostate cancer are based on expert opinion. There's no evidence that different surveillance strategies are better or worse at predicting, you know, recurrence or salvaging treatment.

And so - and the other thing that I just have a huge problem with is, this is not like the radiation measures that we looked at before, or the bone scan measure where it's really quite identifiable who the treating provider is. What provider do you assign responsibility for this PSA surveillance? Is it the neurologist, the radiation oncologist, the medical oncologist, the PCP - I don't even know how you assign responsibility for this measure.

Jerod Loeb: I couldn't agree more. Your comments are far more erudite than mine. Mine were sort of gut, but you're absolutely right.

John Gore: So I gave this a big no, as well.

Elizabeth Hammond: I'm convinced by what others are saying that it should be a no.

Male: Yes, I think those, the argument's very compelling that this should not be something that we move forward.

Male: I would add if in fact this is within the realm of what NQF is going to do as part of its process, I would put a strong resounding asterisk on the need for a good measure in this realm.

John Gore: Yes, I agree.

Male: Although this measure doesn't cut it.

John Gore: Yes, I agree.

Lindsey Tighe: Yes. At the in-person meeting (was), you guys identify - got the ((inaudible)) after reviewing all of the measures, and certainly we'll make note of that right now, that this will be one of those areas.

Jerod Loeb: I just want to put that divot in because I'm not going to be able to be at the in-person meeting, so I just wanted that voice to be heard.

Female: Okay. Any other comments about this one?

Lindsey Tighe: We'll reach out to the measure developer for this so that we can identify the concerns that you have before the in-person meeting to see if they have any information to provide at that point.

Female: Okay. All right, thank you Jerod, that was great. And the next one we have is 1790, Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer, put forward by STS. And we have Dr. Ross for that one.

Lindsey Tighe: And is there anyone from STS on the line? Oh, we could get to open their lines, Danielle?

Operator: And if you're with STS, please press star 0 at this time.

Pat Ross: Well, the good news is at least when you asked for them to press star 0 there was no fire engine in the background, so maybe that's a good sign. This is Pat Ross at Ohio State, and I appreciate the chance to go through this particular measure.

The steward is very reputable, the Society of Thoracic Surgeons has a longstanding history with outcomes registries and this is another example. The risk-adjusted morbidity and mortality for lung resection is quite encyclopedic.

If you look at it it's, it encompasses both the open as well as minimally invasive approaches. The only thing I think we need to add in there is that it includes open and thoracoscopy, but an increasing number of these are now done with computer-assisted, or robotic-assisted, so we really need to be sure that we're going to capture all of those as well so that they can be stratified.

The, we're looking for all in-hospital complications, so - and predominantly pulmonary complications of pneumonia, ventilator support, pulmonary embolus, but as well as some technical complications such as brochopleural fistula, bleeding, as well as the cormorbidities of myocardial infarction, and of course the mortality is listed as well.

So I think that this is very likely to have high impact. Pulmonary resections are done in a variety of clinical settings by a variety of clinical teams that, from small community programs with general surgeons to large academic centers with pure thoracic surgeons. So there's a whole spectrum of teams that do these procedures.

And I think the ability for everyone to benchmark against a standard will clearly improve patient care and our ability to assess how these procedures are done. So I do think that there is a lot of opportunity there. The database itself is quite robust. This proposal is based on a 36-month report, and there are over 22,000 - in fact it was almost 23,000 cases that were able to be accessed within that.

So there's great reliability, 95% based on the audit in 2011, which was up from the year before where it was just under 90%. So I think that it's a large database. It has proven itself for reliability by internal and external audits, as well as by the number of studies that have been presented within the past two years at the Society meetings where the database has been accessed and evaluated. So I do think there is a lot of reliability to this.

The, there is - if you look back on the, as you go through it, because all of these events, all of the operations have a procedure code, all of the complications are easily coded. So the retrieval of accurate information, as long as the patient is in that hospital, is very good.

The mortality, obviously, can be captured regardless of discharge, but one deficiency within the system and you can't make it 100%, is that if there are late - even if within the 30 days, if there are post-discharge complications those may not be captured. So there is one small potential hole within the completeness of the data.

There is - we move on through the, I think the test results, the analytical method are all very good. And, moving down here - I think this is a good measure. There are a couple of questions on the usability. Not every hospital reports to the SCS, so that obviously, you know, the hospital has to be a participating member. There is some cost to it, although it's small.

And I was amused and I know Steve is on the phone, I don't know who other surgeons are in the room, but in one of the segments there was a comment that said, surgeons easily grasp this

result, implying that there are concepts that we don't easily grasp. So I was a little bit amused that that made it into the final text, just a small editorial comment.

So I do think that this is a good measure. I think it will be easy to implement, easy to assure accuracy. But most importantly, I think this type of measure will give us a good look at a spectrum of procedures done in a spectrum of hospitals, and it needs to be done because there is a wide range of mortality and morbidity for the same procedure as we look at the number of institutions in which it's done. So I would say yes for this measure.

Operator: And we do have Vadie Reese with STS on the line.

Pat Ross: Great.

Vadie Reese: Hello.

Female: Good morning.

Pat Ross: How are you today? Thanks for joining us. I was extolling the virtues of the STS database. I hope you were able to catch that part of it.

Vadie Reese: We sure were. Thank you very much. And there was no malice aforethought for the comment of surgeons easily grasp this concept.

Pat Ross: All right, all right. I hope not. But I wanted to edit it out though, for the final version.

Vadie Reese: I would agree. Me too.

Pat Ross: Does anyone have any questions for me, or comments?

Vadie Reese: No I don't think so.

Pat Ross: So does the lack of, I guess for the - does the lack of the, I mean, my guess is, is that the participating centers are those who have active thoracic surgery programs, and yet the data that we may really want to access are those places that don't do a lot of thoracic surgery. So there's a little bit of an issue there. Would any, STS want to comment on that?

Donna McDonald: Well, this is Donna McDonald from the STS National Database. We do, we did open the database up to general surgeons, and we do currently have 15 general surgeons participating in the National Database, so it's...

Pat Ross: Compared to how many thoracic surgeons?

Vadie Reese: Several hundred.

Donna McDonald: Right.

Vadie Reese: About two hundred, I think.

Pat Ross: And it's voluntary, right?

Donna McDonald: Correct.

Vadie Reese: Correct.

Donna McDonald: I think one of the challenges of the General Thoracic database as opposed to our Congenital and Adult Cardiac databases is that we don't know the denominator for general

thoracic surgery, because as you've just mentioned, both general surgeons do thoracic procedures as well as general thoracic surgeons. So it's not quite as clear cut in terms of what the actual population out there is.

Pat Ross: So we have that, actually, though, but we can gain that, because we know from other databases what the total number of pulmonary resections are. So I think that it would be, if we move this measure forward, I think we always have to couch it in terms of what percentage of the total we're really capturing.

Donna McDonald: Okay.

Pat Ross: Because you might be benchmarking the 400 centers that have busy programs and, you know, it's the others that may need to be included as well.

Donna McDonald: That's fine. And in terms of, you had a question, I think, about procedures open and thoracoscopy, and would...

Pat Ross: Right, and including robotics in there.

Donna McDonald: Yes.

Vadie Reese: Yes, we have a field - we can collect that information.

Pat Ross: I think that might be useful for stratification down the road.

Operator: Before I begin, please make sure your sound is turned up so you can hear me. Do you hear me?

Female: Was there anything else that you'd like us to comment on?

Pat Ross: No, I think it's a good measure. Anyone else on the committee have a question?

Elizabeth Hammond: I think it's a good measure, too. I totally support it.

John Gore: Yes, I think it's an admirable pursuit. I think it requires some complicated abstraction, and so it's definitely a little bit of an arduous measure, but I think it's a definitely an admirable pursuit. I wish more general surgeons would participate. Because isn't there some evidence that if you look at the whole denominator of thoracic surgeries, that more are done by non-thoracic trained surgeons?

Pat Ross: Correct.

John Gore: Yes.

Pat Ross: And even within this field of cardiothoracic surgery, there is a differentiation between those who do thoracic surgery and those who do cardiac and thoracic. So there are actually three tiers. So I do think that that's one potential limitation to this. And then the only other comment, and since we're, you know, we're dealing with this as lung cancer, the question is, should there - there's no real oncologic outcome that gets measured.

And if we're going to go this route, I mean, is it possible not just to have the short-term morbidity and mortality, but to include some long-term measure that says, what is the oncologic difference within these groups as well. And I don't know, maybe that's, it's time for a separate measure.

Elizabeth Hammond: Yes. But it's so, the measure's arduous the way it is. I think that would really make it difficult to...

Pat Ross: Okay, so we'll leave it with the 30-day morbidity and mortality, then.

Donna McDonald: And if you have some suggestions as to how we could attract more general surgeons, we'd be happy to hear them.

Pat Ross: Well, I do think that it, as this measure moves forward and it should be presented, you know, as a measure, and get a little space at the American College of Surgeons Meeting as it comes forward here in October. I mean that, you know, nothing prompts participation as much as advertising and what the impact could be.

So that would be a possible - I don't know whether the STS database has ever gone to that meeting or not, but it might be a useful thing.

Donna McDonald: Yes, we do. But I appreciate your comments, and it's something that we can certainly make very visible.

Pat Ross: Very good.

Female: Great, thank you. Is there any more discussion on 1790? Okay, hearing none, we'll move on to Dr. Hammond, and 1853, and I'll go ahead and open the floor to Dr. Hammond.

Lindsey Tighe: Actually, Danielle, if there's anyone from CAP on the line, if you could open their lines.

Operator: I'm sorry, what was the company name?

Lindsey Tighe: It's the College of American Pathologists, CAP.

Female: Right.

Operator: Okay, just a moment. I believe we have Michael Cohen from CAP.

Elizabeth Hammond: All right.

Michael Cohen: That rumor is true.

Elizabeth Hammond: This measure is Radical Prostatectomy Pathology Reporting. The College of American Pathologists is the measure's steward. And the measure is to try to define how many radical prostatectomy pathology reports contain the relevant pathology staging information as well as the Gleason score and a statement about margin status.

The importance of the measure, we've had a lot of discussion on this call about the health significance of prostate cancer and its morbidity and mortality, so there is a high impact related to the large number of men who are affected with this disease. The - let's see, there is the, there have been two studies that have tried to address the, regarding performance gap.

One of them is a CAP Q-Probe study, which showed that about 11.6% of prostate cancer reports had missing elements. And another study from the American College of Surgeons database found that there, a slightly, well, pretty similar amount of discrepancy. The, so the measure has, there is no data about disparity.

The, it is a process measure, not a health outcome measure. There is evidence that - there's a lot of evidence that prostate cancer staging information is critical to patient care. And the basic, and there is, this has been addressed by both the College of American Pathologists as well as a consortium of groups in Australia and the, where a bunch of data was collected about the importance of this kind of data to the, to patients.

It's called the Cancer Protocol Review Panel, CPRP. There is, so there is a lot of evidence that there, that this measure can, the information can be consistently gathered and collected. Let's see here, so - trying to think. We don't have, so there is a gap in performance. The measure is important. The reliability and validity have not been carefully evaluated as yet, but the College of American Pathologists says that this is under way.

It would be predicted that the measure would be highly reliable, because this data has to be collected on all patients, since cancer reporting is a requirement across the United States, and the data is collected in tumor registries as well as in, from pathology, extracted from pathology reports.

So one would expect that there would be a good reliability and validity, but the data hasn't been, the data's in progress. And we need to hear what CAP says about those two studies that are going on. That's really the only important point here. It should be possible, the feasibility of the measure is, I would think very good because of the point that I just made, it's being collected by tumor registries.

It's - in many institutions this is an electronic measure. Certainly the cancer registries in large parts of the country are already collecting information electronically. So I would think that the measure could, would be very feasible. I believe that it's a highly, it would be useful also for public reports.

There's a lot of interest in prostate cancer, and because of the new data out about active surveillance in men with prostate cancer, there is much more interest in the relationship of radical prostatectomy grading and results in the general population. So having public reporting might help to make sure that we have the Gleason scores and margin status and that, and that staging information adequately collected on patients.

So I think public reporting might be something that could happen. So I think that the measure is suitable for endorsement if we find out that the reliability and validity, doing audits of records actually comes forward. This is a PQRS measure that has been proposed for 2012. And as I understand it, it's a time-limited measure, indicating that the, those proposing the measure have 12 months to put the measure in place.

Female: Was there, someone else had a response?

Operator: We have Fay Shamanski and Julie Cantor-Weinberg, also with CAP, your lines are open.

Fay Shamanski: Thank you, this is Fay. Can you hear me?

Elizabeth Hammond: Yes.

Fay Shamanski: Okay. I didn't, I'm sorry; I don't know what the question is.

Elizabeth Hammond: The question is to describe what, the status of the testing. It said that the reliability and validity testing are under way.

Fay Shamanski: It's in the planning stages. It's, we've had some delays, so there's nothing much to report at this point.

Michael Cohen: This is Michael Cohen. There has been a preliminary study but with help of the AMA in conducting sort of a feasibility study about abstracting information such as this from electronic medical records. And I think the upshot, and I think Fay will correct me if I'm wrong, is that - and as Liz pointed out, this is readily feasible.

Elizabeth Hammond: Right. The main reason why I believe it's feasible is because of tumor registry reporting. I mean, this has to be reported in tumor registries across the United States, and that's a Federal requirement. So I would think that we would be able to, if we, I would wonder if the reliability and validity testing couldn't be, we couldn't query tumor registries for that information, to find out.

Julie Cantor-Weinberg: Also - this is Julie Cantor-Weinberg with the CAP. The, as some of you may know, the Meaningful Use Rule came out last week, and public health reporting of cancer is one of the Meaningful Use Stage 2 measures. So, presumably as that's done, this would pick up at least some of this kind of data and be another method.

John Gore: So my only concern and the reason I just put no is just that it seemed that the measure was proposed in advance of any data supporting the reliability and usability and feasibility, and it just seemed like that data would help inform a lot.

And then I also, I just didn't understand some numbers that the CAP Q-Probes data indicates that almost 12% of pathology reports had missing elements, but that actually, then you keep reading and 52% of the reports had missing elements, or 42%...

Fay Shamanski: So I can - this is Fay Shamanski, I can explain that. So the 12% is reports with, all reports with any elements missing. And the 52% is referring to the percentage of missing elements that...

John Gore: I see, so of the missing, 52% were missing that, I see, okay, that makes sense. So is this considered, I mean, would this be considered similar to the, you know, oncology planning discussion before, where this should be sort of a never thing, so...

Male: Yes, yes.

John Gore: Okay, so we look at 12% as being as being a meaningful number.

Elizabeth Hammond: It's a meaningful because it is a never thing. It is not acceptable for any report to have this information not available.

Lindsey Tighe: And just to clarify, this measure is up for time-limited endorsement because it wasn't provided with the reliability and validity testing information. Essentially we're asking you to evaluate what's in front of you, and then if the measure meets the endorsement criteria with the exception of the reliability and validity testing, it will receive time-limited endorsement and the developer will have one year to provide full testing data. And the measure will be reviewed again at that point.

Elizabeth Hammond: Oh, that's great. That was what my question, I - so we, if we vote yes for this measure, then there is, then the developers will have one year to provide us with the important data, right?

Male: Yes.

Female: Yes.

Elizabeth Hammond: Okay, that's great. Well I think it's really a critical measure, similar to the ones that were discussed, where it's a never event, basically, and we need to change the numbers from 11.6%.

Male: I agree.

Female: All right.

Lindsey Tighe: Any other comments on this measure? Okay, well we do need to take a break for NQF member and public comment, if there is anyone on the public lines. So if, Danielle, if you wouldn't mind opening all lines, and we'll take any member and public comment at this point.

Danielle: Absolutely, just one moment. And all lines are open at this point.

Female: If you have any comments, feel free to say so now.

Diedra Joseph: Hi, did you ask for public comment?

Female: Yes, we did.

Diedra Joseph: Sorry, I couldn't hear. This is Diedra at the AMA-PCPI. I just wanted to note, wanted the local members to note that Dr. Howard Sandler was on the line for the discussion of the prostate cancer measures, and he was unable to get through. I guess his line wasn't open and he was having some issues, so he had to leave the call.

But is it okay if we just send you his feedback via email along with the other data that you requested, since he wasn't able to participate or comment?

Lindsey Tighe: Well if you ((inaudible)) us at NQF, we'll be able to disseminate it to everybody.

Diedra Joseph: Okay, thank you.

Female: Any other comments from the public? Okay. You can also still email us with any comments and any other comments from the workgroup members? If not, we'll go ahead and adjourn, and thank

you all for your work on reviewing these and submitting these. Our next steps, Lindsey will tell us our next steps.

Lindsey Tighe: And next steps, we have three other workgroups meeting throughout the week. You should have received agendas and dial-in information, and you're welcome to listen in on those calls if you would like. We'll be providing little bullet point summaries of, kind of, the hot key concerns about the measures to everybody at the in-person meeting, though.

Other than that, we're meeting in person in Washington, D.C. March 13 and 14, you should have received a draft agenda. We don't expect it to change, really just working to finalize it internally. Other than that, unless there are any questions I don't know that I have any information for you.

Male: Sounds excellent.

Lindsey Tighe: Great.

Female: Lindsey, thank you.

Male: Thank you very much.

Male: Thank you everyone.

Larry Marks: Lindsey, can you hang on a sec, I want to ask you a question.

Lindsey Tighe: Okay.

Larry Marks: Lindsey, are you there?

Lindsey Tighe: Yes.

Larry Marks: Hi, Larry Marks here.

Lindsey Tighe: Hi. Sorry you had so many problems with the survey.

Larry Marks: Yes, I'm a little techno-challenged, I guess. So I figured it out in the end. It was deleting the cookies. I learned what a cookie was in this process. And I learned how to delete my cookies in the process, which was sort of interesting. So thank you for helping me with that. My question has to do with - what's that?

Lindsey Tighe: A lesson you never wanted, I'm sure, but...

Larry Marks: No, no, it's fine. Now I learned something new. So my question has to do with flights back on that day, is that Tuesday or Wednesday, I forget?

Lindsey Tighe: Yes, the 14th?

Larry Marks: Or when the meeting is, yes. So, ideally I want to take the earlier flight back. I guess I'll miss the last half hour or hour of the meeting, it looks like, if I did that. Is there a possibility of changing the order of some of the things? Because I guess my session is the last one.

Lindsey Tighe: Oh, I will look at that. Yes, I think on that day we should be able to change the order.

Larry Marks: ((inaudible)), yes.

Lindsey Tighe: And what time will you need to leave?

Larry Marks: Oh, I don't have it in front of me, but the flight, I think, was like at 4 o'clock, or 4:30, does that make - I think it was 4 o'clock.

Lindsey Tighe: Okay.

Larry Marks: So if I need to leave there, like, by 2:30 or something like that.

Lindsey Tighe: Okay. Yes, we can definitely accommodate that. I don't think that should be an issue.

Larry Marks: Thank you. I'll get the time of the flights and I'll send it to you in an email just so we'll be sure about it, okay?

Lindsey Tighe: Perfect. Thank you very much.

Larry Marks: Hey, no, thank you. I appreciate your flexibility.

Lindsey Tighe: Great. We'll see you in a couple of weeks.

Larry Marks: Hey, great, thank you so much, appreciate it. Okay, bye bye.

Lindsey Tighe: Right. Thank you Danielle.

Operator: Thanks Lindsey, have a great day.

Lindsey Tighe: You too.

END