THE NATIONAL QUALITY FORUM

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PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE

NATIONAL VOLUNTARY STANDARDS FOR PEDIATRIC CARDIAC SURGERY

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OUTCOME MEASURES REVIEW WORKGROUP

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WEDNESDAY
OCTOBER 21, 2009

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The Outcome Measures Review Workgroup of the Pediatric Cardiac Surgery Steering Committee met in Congressional A in the Hyatt Regency Washington Hotel, 400 New Jersey Ave, N.W., Washington, D.C., at 11:00 a.m., Howard Jeffries, Co-Chair, presiding.

MEMBERS PRESENT:

HOWARD JEFFRIES, MD, MPH, MBA, Co-Chair
PATRICIA A. GALVIN, RN, BSN, CNOR
ALLEN J. HINKLE, MD
SYLVIA LOPEZ, MD

CONSTANTINE MAVROUDIS, MD
JOHN E. MAYER, MD

NQF STAFF PRESENT:

LISA HINES

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OUTCOME MEASURES REVIEW BREAKOUT WORKGROUP

11:06 a.m.

CO-CHAIR JEFFRIES: So, I guess at first just we'll talk about how we want to do the documentation. One person can do it. We can have the secondary do it for each of the measures as we go through it.

DR. MAVROUDIS: Are we going to take all the measures one at a time?

CO-CHAIR JEFFRIES: We are going to go one by one.

DR. MAVROUDIS: Are we starting with Number 1?

CO-CHAIR JEFFRIES: No, we're starting with 13. We have 10 measures, 13 to 21.

DR. JENKINS: No, actually we're starting with 12. That's the whole procedure checklist.

CO-CHAIR JEFFRIES: 12, you're right. I'm sorry.

DR. MAVROUDIS: Well, if you have one person doing the minutes for consistency sake, it probably makes a lot of sense. I don't know if anyone would volunteer to do it.

CO-CHAIR JEFFRIES: Does anybody volunteer?

I mean I agree, I think, for consistency, but it might be just easier to have secondary do it just so that one person isn't labored -- if that's okay.

DR. JENKINS: Yes.

DR. MAVROUDIS: If I may stick my nose in here a little bit, and that is I've never seen these before up until a couple of days ago, these indicators, and I really think that the process is excellent. These are really good indicators.

Jeff, congratulations. You and your team have done a marvelous job. It just seems like every question I had, I just read the next sentence and it answered it.

So, I just wanted to mention that.

DR. J. JACOBS: Thank you.

CO-CHAIR JEFFRIES: So, the first measure, I think, is Number 12. The procedural time out.

Patricia, you're the primary on that?

MS. GALVIN: I am the primary.

CO-CHAIR JEFFRIES: -- and, Gus, you're the secondary.

DR. MAVROUDIS: Yes, I wrote something down.

CO-CHAIR JEFFRIES: Do you mind keeping the -- tracking the --

MS. GALVIN: The notes.

CO-CHAIR JEFFRIES: The notes.

DR. MAVROUDIS: You know something? I'm happy to do it and I'm happy to type it. I have no idea where to put it.

CO-CHAIR JEFFRIES: Yes. We're going to --

DR. MAYER: I mean I don't mind doing this.

DR. MAVROUDIS: Are you sure? I'm happy to do it, John. I just don't --

DR. MAYER: Well, what I'm worried about is just passing the thing around --

MS. GALVIN: Okay. So, this measure is the use of an expanded pre-procedural and post-procedural time out. The use of the expanded pre-procedural and post-procedural time out would include the following elements: the conventional pre-procedure time out which includes identification of the patient, operative site, procedure and history of any allergies.

A pre-procedural briefing where the surgeon shares with all the members of the operating room team the essential elements of the plan, including diagnosis, plan procedure, outline of essentials of anesthesia and bypass strategies, anticipated or planned implants or device applications, and anticipated challenges.

The post-procedural debriefing is

where the surgeon succinctly reviews with all members of the operating room team the essential elements of the operative plan identifying both successful and opportunities for improvement.

This debriefing should take place prior to the patient leaving the operating room, or its equivalent, and may be followed by a more in-depth dialog involving team members at a later time.

The actual briefing in the operating room is intentionally, importantly brief in recognition that period of transition may be a time of instability and vulnerability for the patient.

A briefing or handoff protocol at the time of transfer or arrival to the intensive care unit at the end of the operation involving the anesthesiologist, surgeon, physician, staff on the intensive care unit, including critical care and cardiology and nursing.

So, whether or not the facility implements an expanded pre-procedural and post-procedural time out for all patients undergoing pediatric and congenital heart surgery, the time out includes the following elements: The conventional pre-procedural time out -- actually, that's pretty much what it says in the first statement.

So, to open for discussion just on that piece, the WHO time out has become sort of the standard or a template that has been used in different settings and I don't know if that is what was used in the development of this concept here.

DR. J. JACOBS: What we wanted to do is actually expand on that so that the standard time out that JCAHO requires that is from WHO and that is used really in every hospital in the country, that's number one on the list of four.

MS. GALVIN: Okay.

DR. J. JACOBS: And then numbers

two, three and four are elements that our group thought are also important process elements to really provide good quality care.

And there's a substantial amount of peer-reviewed literature that supports that. Marc De Laval from Great Ormond Street has written a lot about the importance of having pre-procedural briefings and post-procedural debriefings with the operating room team.

And then Alan Goldman from Great Ormond Street has written a fair amount about handoff protocols, which is a very vulnerable time for the patient when the patient gets in the ICU and the responsibility for the care of that patient shifts from the surgeon and anesthesiologist to the intensive care unit team.

So, the source of this number one is the -- Element Number 1 of this comes from JCAHO and the standard time out. Element Number 2 and Number 3 come from research done

by Marc De Laval and others supporting the pre-procedural and post-procedural team debriefings.

And Element Number 4 comes from peer-review literature about the importance of having a structured process for the handoff in the ICU.

DR. MAVROUDIS: If I may. If I may.

MS. GALVIN: Yes.

DR. MAVROUDIS: When I saw this yesterday, I implemented a couple of these things in our time out that we did in the operating room, which I thought was a great idea.

And as I was doing it, I realized that it is -- as it indicated to say yes or no, that it was done or not done as an indicator, requires a rather complex -- a number of things that have to be done just to say yes.

And then if you miss one, does

that mean yes plus or no negative? You know what I mean?

MS. GALVIN: Yes.

DR. MAVROUDIS: And so I think that it is cumbersome in its inclusionary criteria here on how much -- for instance, when the child is unstable and you don't do the post-procedural briefing, who makes that decision? How does that get reported?

So, I think that a time out, an expanded time out to include anticipated challenges, the bypass strategy, I think that's excellent. That's easily -- that can be measured.

I'm not sure about how to deal with the post-procedural debriefing, although I started doing it and I think it's a good idea. I'd like to see it more didactic so that the person who is looking at this, who is observing this to mark whether he did or he didn't do it, will have clear-cut elements and not that many so that they can really put that

together.

DR. J. JACOBS: I think that's an excellent point. An analogous situation could be the adult cardiac surgery indicator of whether or not one uses an internal mammary artery.

So, when a program tracks whether or not they use this internal mammary artery, there's some patients where it would be a disaster to use an internal mammary artery and there's a list of known reasons why.

If the patient is a diabetic with a previous sternal problem or if the patient has problems with a subclavian artery, meaning that the internal mammary is not going to be good. So, there's reasons you would not use the internal mammary artery.

So, the indicator is tracked in a way that in situations where it's inapplicable that can be accounted for.

And very similarly here if a patient is very unstable and requires the full

attention of the team just to get them out of the operating room alive, you don't want to be standing there talking about well, how did their case go.

So, I think the same way we can track mammary usage and have appropriate exclusions, this could be tracked with appropriate exclusions also.

MS. GALVIN: In the tracking note, would it be expected that all elements are included?

I think that's where it might get into a little bit of difficulty.

DR. J. JACOBS: I think if this were to get implemented, the way I would envision implementing it in the database is that there's going to be database fields for all the structure and process metrics here.

And there's going to be four check boxes here, which there's going to be a check box for each of the four elements. And the database manager will enter yes or no for

whether each of those four elements was done. And if one answers no, there's a list of acceptable reasons why it wasn't done.

There's no acceptable reason why Number 1 wasn't done, ever.

MS. GALVIN: Right.

DR. J. JACOBS: There's potentially some acceptable reasons why Number 2 isn't done, patients getting CPR and you just go to get to work. And there's potentially some acceptable reasons why Number 3 isn't done.

So, if the database could track each of the four elements with a yes or a no, and if no, you have the opportunity to say why it wasn't done with the acceptable reasons, patient instability.

MS. GALVIN: So, one of -- actually, you're right. I mean you could say you did one, two, three and four, however, Number 3 has a lot of information in there.

So, what this is saying is that

there is identification of the operative plan, that if there's any implants -- I'm sorry. Number 2. If there's any implants, any devices, pump requirements and so on that are not often included in a time out.

So, if you have a pre-procedural briefing where the surgeon just says we're doing an ASD closure, does that count as meeting Number 2, or is there a way to capture that all of the elements in that particular section were included?

Do you see what I'm saying?

DR. J. JACOBS: Well, the definition is going to require that it was a proper pre-procedural briefing.

And the other thing I would say about this whole concept is that this is, in a way, an opportunity that we as a group have a way to change practice.

MS. GALVIN: Yes.

DR. J. JACOBS: And not just, you know, if we just listed Number 1 as the only

one that is a conventional pre-procedural time out, well, then every hospital in the country that has JCAHO certification is going to qualify automatically.

So, that's not going to differentiate anything.

MS. GALVIN: Right.

DR. J. JACOBS: But if we put two, three and four in here if we all as a group decide when the discussion is over that these are truly important concepts and practices, we implement those, then not only are we creating a quality indicator, we hope to potentially change the practice.

MS. GALVIN: Well, I think they're important. Don't get me wrong. I'm just wondering in some settings --

DR. MAVROUDIS: How do you measure?

MS. GALVIN: How do you measure it and how do you -- how are you sure that all of those little elements are included, all of the

--

DR. MAVROUDIS: I got dinged. I got dinged, for instance, because I did the time out and then I told a story before I made the incision. And the story lasted more than a minute and I should have made the incision one minute after the time out, but that's a measurable thing, right?

MS. GALVIN: Yes.

DR. MAVROUDIS: And so I think what you're getting at is how are we going to do that for this, right?

MS. GALVIN: Yes. Right.

DR. HINKLE: I assume there will be a development process, a developing checklist for both of these pre and post-procedure that will evolve over time.

And then the nature of that will be kind of what Jeff, I think, was alluding to and that leads to the opportunity for quality improvement.

DR. J. JACOBS: Yes.

DR. HINKLE: But you got to get to the first place first which is what are the standards for pre-procedural -- I mean there may be new ones that are developed and to get some kind of -- eventually it would evolve, I would think, to a checklist.

Like we have in anesthesia, you know, there's a checkoff list before you start --

DR. J. JACOBS: Like what airplane pilots do.

DR. HINKLE: Right. It's the same -- so, that's how I looked at this as the process.

MS. GALVIN: I guess compliance is sort of what, as nurses, we struggle with, that everybody is on the same page.

We have a lot of residents in our programs. And in fact in our institution, they do the time out, but they may not have the answers to all of these.

DR. MAVROUDIS: Well, your points

are probably the most important ones here because the nurses are going to be doing this.

MS. GALVIN: Yes.

DR. MAVROUDIS: They're going to be the ones who are going to have to understand the process and put it into the system.

MS. GALVIN: Yes.

DR. MAVROUDIS: So, if you have some objections to this, we ought to --

MS. GALVIN: It's not an objection. It's just more of a clarification because yes, I know the diagnosis, I know the plan procedure, but I can't say that we're going to use X, Y or Z valve, that we're going to need these grafts in the room, that there's going to be some issues, it's a re-op sternotomy.

I mean that's not for a nurse to say.

DR. J. JACOBS: Right. So, our thoughts were that before you cut a kid open,

that's a discussion the surgeon should have with the nurse.

MS. GALVIN: Right.

DR. J. JACOBS: If I'm going to cut somebody open and put in an aortic valve --

DR. MAVROUDIS: Operate on them.

DR. J. JACOBS: If I'm going to operate on somebody, yes, and put in an aortic valve -- well taken -- and put in an aortic valve, it's probably a good idea that before I make my incision that I make sure that the nurse has the aortic valve that I need somewhere in the room or at least in the hospital.

MS. GALVIN: I would agree.

DR. J. JACOBS: Because if you start that case and you do the standard time out, this is John Smith, date of birth is this, allergies are this, having an aortic valve replacement, great, you keep going, you get going, you dissect everything out. Okay,

I need a 17 millimeter -

MS. GALVIN: St. Jude valve or whatever.

DR. J. JACOBS: I need a 15-millimeter St. Jude valve. Oh, we don't have one.

MS. GALVIN: Right.

DR. J. JACOBS: So, that's the kind of thing that we were trying to get at here where I'm doing the redo sternotomy and I like bilateral rule-tract retractors set up to help me do -- to elevate the sternum when I do it.

And to be honest, if I have to do a redo sternotomy and the rule-tracts aren't in the hospital, it's not going to be a good deal for anybody because I haven't done a redo sternotomy without the rule-tract retractors for a long time.

MS. GALVIN: Yes.

DR. J. JACOBS: So, there's little things that you want to make sure are there

before you make your incision.

MS. GALVIN: Right. And I think --

DR. MAYER: Does this get to the -- just from a mechanic standpoint here, does this get to the usability?

Is this where we -- I mean I don't think there's been much discussion yet about how important this is.

It sounds like everybody agrees it's important, right?

MS. GALVIN: It's important.

DR. MAYER: And it's that there's at least some data to suggest that this is likely to be beneficial, so it's scientifically acceptable.

So, now we're down into the usability/feasibility discussion.

DR. MAVROUDIS: So, what's the difference between the two?

DR. MAYER: Between usability and feasibility?

I think usability has -- at least

if I infer correctly from what was said earlier, it's more like how could somebody from the outside looking in use the information.

I think actually what we're talking about here is mostly feasibility about how we would actually implement this and devise a checklist or do something like that. Is that --

MS. GALVIN: How cumbersome the process might be and would it prevent someone from completing the process because it is cumbersome.

DR. MAYER: Right. But then usability is --

DR. MAVROUDIS: That's what we're getting at now that there may be too many issues here in order to make --

DR. J. JACOBS: If I put my other hat on as the database guy, what I would do is I would have on the database form in the same little place where you have diagnosis,

procedure, bypass time, arrest time, did you do Number 1, Number 2, Number 3 and Number 4, yes or no and check it. And you check those four things.

And if you put the little mouse over what those are, the actual definition pops up. And yes, at some point somebody is going to have to make a judgment call whether or not it's met the definition, but that's true of almost any database field.

And I think then it's just a matter of checking four boxes and making a judgment call that it was actually done.

CO-CHAIR JEFFRIES: So, just thinking of sort of the charge that the group has which is to go through the elements which are importance and then scientific acceptability --

DR. MAVROUDIS: What did you say? Scientific what?

CO-CHAIR JEFFRIES: Acceptability.

DR. MAVROUDIS: Oh.

CO-CHAIR JEFFRIES: So, let's please go through importance because that -- if you read through the valuation criteria if it's not important, we stop right there.

So, let's go through the elements that are listed here. And I think you would -- just go through it just in that fashion.

I think a lot of this discussion has been great. A lot of the talk is about feasibility. But before we get to that, let's go through the importance first.

MS. GALVIN: So, the importance from this conversation, I'm assuming everybody agrees that this is an important thing to have in place specific for cardiac surgery.

DR. HINKLE: Well, can I just make one comment and ask a question, I guess?

MS. GALVIN: Sure.

DR. HINKLE: I see the importance from the cardiac care suite improving the process of care. The importance to the public, I think I'm there too.

So, in other words, this would be reported out to the public potentially and they would look and say wow, a hundred percent.

It's like the airline's on-time arrival. You go a hundred percent time outs achieved.

And so I think that, to me, is how I looked at both of these. There's a public side and then there's an improvement side. I think it does both, but I don't know if I can answer the public looking for cardiac surgery if they're going to go -- I mean I don't know how important this is ultimately to the patient who is going to be selecting unless you go into some database and making a selection of where they're going to go have their cardiac surgery.

I think it's an important element. So, I do, you know, my vote on this -- my view on this is definitely it's in the importance -- it cuts through the importance criteria.

MS. GALVIN: Yes.

CO-CHAIR JEFFRIES: I think this is one of those areas where the public probably expects us to do this.

DR. HINKLE: Yes. Okay.

CO-CHAIR JEFFRIES: The fact that we don't do it is shocking to them sort of like you expect the pilot to know how they're going to land the plane.

DR. HINKLE: Right. Right. Okay.

MS. GALVIN: Right.

DR. HINKLE: Do the checklist before they take off.

DR. J. JACOBS: People go in and operate and they've got the heart dissected out, and they find out the valve that they need isn't there.

And you're right. That is shocking to the public. Because if the plane took off and you found that you didn't have wheels on it to land --

DR. MAVROUDIS: Shocking to

anybody.

DR. J. JACOBS: But it happens, and it happens all the time. So, that's what this is.

DR. MAVROUDIS: Again, if I may, I would ask the -- I want to go back to what you wanted to do, and that is to go by stages.

What stage are we at now?

MS. GALVIN: So, we're still on importance, right?

DR. HINKLE: I think we went through that.

MS. GALVIN: Do we vote?

DR. MAVROUDIS: Are we all saying it's important?

DR. HINKLE: Yes.

DR. MAVROUDIS: I should go to the process and read just to satisfy my -- I think that three is going to be difficult to use. And I'm not sure that's the venue either.

I'm not sure that when we're about ready to move the patient over and everybody's

got their things that they're doing, is the time to stop and say how do did we do, guys and girls? Did we do okay? How did you do? How did I do?

DR. HINKLE: Yes. Increase in the pressures and there's so much going on that --

DR. MAVROUDIS: Yes. I'm not sure that's the venue. I think it's the venue before you do the operation, everybody is you haven't done it yet. It's not started, basically.

Although, the anesthesiologist has done their work and so forth. So, I'm not sure how that's going to play and how that's going to be enforceable because there may be a lot of times people will say well, we don't have enough time, the patient is too unstable, click unstable.

MS. GALVIN: Well, actually what we did to make this work was we took it out of the operating room and brought it to the bedside in the ICU.

We consider that a post-procedural debriefing that includes all of the important people. The operating room nurse goes up and stays with the patient, the anesthesiologist and resident go up, the residents are there.

Then there's a time that the nurse needs to get the patient settled, but there's no discussions that start until that person is ready to take this report, and then the whole thing is gone through.

DR. MAVROUDIS: And who is responsible for doing that? Is it going to be the resident, the attending? Does it have to be the attending and so forth? Who does that?

MS. GALVIN: We have both, actually. I mean sometimes it's the attending, sometimes it's the resident.

DR. MAVROUDIS: Okay.

DR. J. JACOBS: I mean what we were looking at when we wrote this, that for Number 3 it was members of the surgical team and members of the nursing team and profusion

team in the OR.

MS. GALVIN: Yes.

DR. J. JACOBS: And then Number 4 is members of the anesthesia and surgical team with the ICU hand-over team. So, it's two different groups of people.

MS. GALVIN: Yes.

DR. J. JACOBS: And that's why we separated those things out because it's not universal that both groups of people are all in the same place at the same time because the first group may not be in the ICU. They may be setting up for the next case.

MS. GALVIN: Yes.

DR. MAVROUDIS: If you're monitoring this in the operating room, when are you going to be satisfied that all of this stuff was done?

Suppose I tell you oh, it was done, but suppose you don't agree?

MS. GALVIN: Right. I think that using that WHO framework, I think what they

wanted or the goal of that debriefing in the operating room was, was there anything that could have been done better in this venue in the operating room?

Something went wrong. Could something have been done better? And the debriefing of the transition of care happened at the bedside.

What we aren't good about is that in the operating room, discussing how the procedure itself went, what could have been done differently, what went wrong, what can we do better the next time.

DR. MAVROUDIS: There's a list of arguments right there.

MS. GALVIN: Yes.

DR. MAVROUDIS: You made me give blood, I didn't want to give it, what's wrong with you, you didn't read the literature, how stupid. I mean I can see all that developing.

DR. J. JACOBS: Better to talk about it though than just to walk away.

DR. MAVROUDIS: It may very well be, but it breeds for confrontation under those circumstances.

CO-CHAIR JEFFRIES: I think these discussions sort of allow us to get really at two, which is understanding the -- if the measure is well defined and precisely specified, which I think is what you're getting at.

MS. GALVIN: Yes.

CO-CHAIR JEFFRIES: I think what we can do is come up with some recommendations either in this group or in the Committee for some language changes which may make it a little more clear.

Maybe it's -- from what you're saying, it's not taking out the meeting in the operating room or something.

DR. MAVROUDIS: No, I think it's a good idea. I'm getting stuck, and I think appropriately so, on who is going to observe this, who is going to say you did or didn't do

it. That's all.

DR. MAYER: But, I mean presumably you're going to just put it into your -- you're going to put it in as part of your database entry, right?

So, and then how you work that out locally depends on your local environment and whether it's the operating room nurse or the profusionist or the whatever.

But I do think the -- I do think probably the key to the whole thing is the escapes which is we're having trouble, Stage 1 is too much drug, I don't think we ought to stop, let's get to the -- that's got to be a legitimate -- that's got to be a legitimate escape so that people don't feel like they have committed some terrible sin by omitting this.

It's a judgment call.

DR. MAVROUDIS: And this is where your idea about clicking on it gives you --

DR. J. JACOBS: Yes. I mean it's

the same way they track a mammary artery. Yes, we did it or no, we did not because we didn't want to, not good. No, we did not because the patient has subclavian artery stenosis and you can't use the mammary because there is no blood in it.

So, here you would say yes, we did it or no, we did not because of hemodynamic instability of the patient.

DR. LOPEZ: If Number 3 --

DR. J. JACOBS: It's for a legitimate reason.

DR. LOPEZ: If Number 3 were done in a concise and efficient manner, how much time do you envision a debriefing taking?

DR. J. JACOBS: If the case went well, 20 seconds. If the case didn't go well, you'd say a couple of minutes and we'll come back and talk about it later.

I couldn't see spending more than two minutes on this. But it's just to get in the habit of instead of putting that last

stitch in and going and eating lunch, putting that last stitch in, looking at the nurse.

I mean it seems like the very obvious thing that you put your last stitch in, you look at the nurse who has helped you for the last four hours, and you talk to her before you leave.

It seems like it should happen all the time. But you know what? It doesn't. And there's plenty of surgeons who put that last stitch in and they're out of there and they don't say anything to anybody.

And so this could take if it's a perfect case, 30 seconds. Thanks a lot, everything went well, see you next case.

In a case where you had a problem, well, this didn't go so well and we probably can't talk about it now, but let's have a meeting tomorrow and we'll talk about it at lunch. And we'll go over and figure out why we didn't have that valve here or why the retractor is --

DR. MAVROUDIS: No one has said -- no one is indicating that's not a good idea. It's a great idea. Just how it's going to be judged, that's all we're talking about.

DR. HINKLE: Yes, and the reality gets in, I mean you don't expect to conduct a quality improvement session during this moment. It's just to say we had this quick debrief.

But I agree with you. It's going to get into a potential here for emotional -- I mean I can remember when starting the case there was an accidental cut through the RV outlet graft.

Well, you got to at that point, everyone's got to focus and get the job done. And then at the end, that needs to be talked about.

But I think what you're suggesting here that's all at the end of that case, that all you would say is well, we got to talk about what happened here at a later time.

That's a debrief.

DR. J. JACOBS: Or maybe you did talk about it if the opportunity exists, but you don't just move on to the next thing without even --

DR. HINKLE: Yes, you recognize -- you say well, something happened here. And I'm just thinking back to some cases where -- but I can see where you don't want to get into a blame situation at this moment, I guess is the way I would look at it.

I think what you're saying is just have a check -- just have a -- most things maybe it will only be 15 seconds because it's so urgent to move the patient to a -- and so you could still check the box that you had that debrief.

DR. MAYER: Yes, I think --

DR. HINKLE: And recognize the severity of --

DR. MAYER: -- what's written here actually sort of covers it. The actual

debriefing in the operating room is intentionally and importantly brief in recognition of the fact that periods of transition may be times of instability or vulnerability to the patient.

DR. MAVROUDIS: Well, we should just keep that then.

CO-CHAIR JEFFRIES: So, Jeff, questions about the numerator. Is the intensive enumerator a yes-no, or is it number of patients that it's done on over -- so, if it is number of patients, the way that I've seen a lot of these type of measures come out is it's an all or nothing.

So if all four are done, then you get a yes. If you miss one, then you get a no.

DR. J. JACOBS: I think I would agree with that.

And what I would do is on the database, we track all four individually. But then for the quality indicator you did all

four, yes. You forgot to do one, it's a no.

CO-CHAIR JEFFRIES: So, it's meant to be a rating system.

DR. J. JACOBS: Yes. And it's a rate with the denominator being the number of -- the denominator is actually defined in one of the metrics they're talking about over there.

DR. MAVROUDIS: In all of them.

DR. J. JACOBS: Right.

DR. HINKLE: Yes.

CO-CHAIR JEFFRIES: So, I would think we need to change a little language on the numerator because it says whether or not. And I think it's probably whether or not by patient.

DR. J. JACOBS: Yes. I think the two things I've noticed that would need to be changed is that it's got to be all or none by patient, and that we have to specify acceptable forms of noncompliance or, as John said, escapes, which I don't think we

specified in enough detail in this document.

So, that's the two things I think if we could -- the way I would sum it up is the two things this discussion led to so far that needs to be changed is that there needs to be documentation of escapes.

There's probably no escapes for Number 1, but there's probably legitimate escapes for 2 and 3. Probably no escapes for Number 4.

And then we should change it so that it's an all or none phenomena so it's a rating.

CO-CHAIR JEFFRIES: And my only comments on 4 is there are some centers that -- it gets to the floor and not to the ICU.

DR. J. JACOBS: But still even if you go to the floor, you should have to have some type of a handoff of --

CO-CHAIR JEFFRIES: We just need to -- just the language, it says ICU. So, I would just say ICU or wherever the patient --

DR. J. JACOBS: There's actually language we can use in here too. In here, the Anesthesiology Society defined the period of anesthetic care, and they defined it until they turn over care to somebody else.

Then they have sentences that say when that was in the recovery room and how that applies when it's in the ICU. So, the verbiage can be applied here so that it would cover the recovery room or whatever.

So, that's a good idea too. I would agree with all three of those suggestions.

MS. GALVIN: Okay. So, I don't have that in front of me, so what is the next --

CO-CHAIR JEFFRIES: The next thing is measure number two -- reliability.

MS. GALVIN: So, I guess in the area of reliability, if the data collection is as, you know, if we do sort of look at it from a simplistic yes-no, then the data should be

reliable.

We still have a concern about the elements when you say yes, that all of those elements were included.

But the data should -- and other studies have supported the use of a checklist to reduce errors. So that, to me, it seems a reliable measure.

Anybody else have anything to add?

CO-CHAIR JEFFRIES: I mean the one question I have, and I think it's a question for several of the measures, is there's a statement in the forms that were submitted that said reliability, validity testing -- and so how we could get around that.

DR. MAYER: Well, some of them, I mean there is an escape at least in some of the stuff I read that said they have face validity. I think that was the term that was used.

Then I don't know that we need to necessarily say here's the references of how

many we'll require and things like that.

I think there are other situations where clearly we don't know. Right? I mean we don't have -- we're not sure that it has validity or -- and I think we'll just have to recognize that, I mean that's all we can do.

I think one of the later ones is the composite measure of absence of any of the above. Well, I mean it sort of has face validity that if you avoid those complications, it's likely you're going to have better quality of your outcomes. Right?

But do we know that those are exactly the right ones or maybe there should be another one in there or something like that. Have we studied that?

The answer is no, but clinical impression is, is that those are the important ones to measure.

I mean that's the way I'm interpreting it. Is that where you're --

CO-CHAIR JEFFRIES: That's

reasonable for validity. Because again I think with face validity, we sort of have pulling out from --

DR. MAYER: Right.

CO-CHAIR JEFFRIES: -- having things be numerically presented to you.

DR. MAYER: Right.

CO-CHAIR JEFFRIES: For reliability, I mean I think that's unknown.

DR. MAYER: Right.

CO-CHAIR JEFFRIES: I mean I think that's the question. We don't know about the repeatability of these results from, again, center to center, time to time, whether or not over time we will see improvements because of changes that are made.

DR. HINKLE: I would just make a comment that in all of medicine that's practiced, probably only less than 50 percent is evidence-based. Then it goes to consensus.

Consensus sometimes then moves to evidence over time.

DR. JENKINS: An alternative measurement strategy for this is that most hospitals are measuring pathogens as part of their transmission requirement.

Many are actually using observation actually so one could actually not use the check box at all, but actually measure implementation of it.

DR. MAYER: I think the question is going to be the feasibility and how much, you know, do we necessarily want to add another 20 boxes to check or something like that.

I mean or mandate that that be used, which we do have to keep in mind that this is going to have some impact. What we're proposing and recommending is not going to be without impact on how we take care of patients.

And some of the things if we get -- this is definitely one where the enemy of good is better. I mean if we get to too much

data collection, we're going to distract people from taking care of the patients.

DR. J. JACOBS: I don't think this is going to be all that cumbersome. I mean right now we're collecting about 250 fields for every operation. Four yes-no check boxes on top of that isn't going to be a deal buster. So, I think it's pretty feasible from that point of view.

Kathy's idea is a very interesting idea about a way to validate what's going to be collected in the database externally. And once we collect these fields within the database, it's going to use the internal QI process from time to time to check out whether or not it's not just four boxes being checked routinely, but whether it's actually happening.

But I don't think that that really would change the way you would write this. That's just another way to validate or file within the hospital.

DR. JENKINS: The other loophole I saw in the process that they could approve something, but make you come back --

MS. HINES: And that's what all of these measures will become. And, Jeff, I think on the forms that were submitted where you state there was no reliability and validity testing probably thinking in pilot testing or in a national kind of setting, but certainly there was data behind choosing elements of the measures.

DR. J. JACOBS: And that's why I brought all these materials, is because there's hundreds of peer review publications that support these 20 metrics.

MS. HINES: Right. But just to --

DR. J. JACOBS: That question read was there formal reliability and validity testing done.

To be quite honest, I don't know what a formal reliability or validity test is, but I know that we use the stuff in the

database and we use it to track outcomes. And some of the stuff we used in the database for ten or 15 years.

MS. HINES: Right. And I just wanted to make that clear point because certainly there was no reliability or validity testing which I think Howard was trying to get to.

It wouldn't meet scientific acceptability. But there is data and I think it was just the way our form is constructed for our time out.

So, any additional testing or additional information gleaned from the book you probably --

DR. J. JACOBS: But in those forms and other places, all the references that are --

DR. JENKINS: But there's no data in the book about the checklists and --

DR. J. JACOBS: No, but there's other published papers which we went through

by Marc De Laval and by Alan Goldman, that talks about implementing these strategies. And those are referenced in this particular packet for this metric, because I know Marshall Jacobs put together all those publications for that.

So, did the STS database do validity testing of this? No. But is there peer review literature that supports it? Absolutely. Those peer review publications are listed in the materials in --

DR. JENKINS: What they're looking for is if you got -- let's suppose Austin did 80 percent and Tampa did 90 percent. What does that mean?

Does that mean we forgot to check off the boxes, does that mean we interpreted how to check off the boxes differently, does that mean really that Tampa's performance is 10 percent better than Austin? That's what they're looking at.

How would you really know? If

you're going to put that out in a public report card, you're saying that you believe that 90 is better than 80 and it -- I think that's what they're looking at.

DR. J. JACOBS: Yes, but it might be that some of that data never existed. There's no data that would ever be created to tell a guy jumping out of an airplane that it's a good idea to wear a parachute. Right?

DR. JENKINS: You can incorporate it as a structural element Jeff.

DR. J. JACOBS: That's basically what we're doing.

DR. JENKINS: I think that's what you want.

DR. J. JACOBS: Yes.

MS. HINES: And I'm just trying to tease it out and get clarity because those are the type of questions that the CSAC is going to look for.

If they look at a form to, as you all know, and see no reliability and validity,

it's going to be well, why did you even discuss this?

So, I'm just bringing the points out for discussion and --

DR. J. JACOBS: So, the answer is that there's piles of peer review literature that support it and the references are in the packet. That's the best way I can answer it.

MS. HINES: No, no no. That's fine. I'm just trying to make sure that we fairly represent it and have the discussion point --

MR. HARDER: And that's your homework if you get time-limited endorsement.

MS. HINES: Is to kind of --

DR. JENKINS: And is it limited to a year?

MR. HARDER: Two years.

MS. HINES: Two years.

The thing to consider with feasibility, too, that is often brought up, it may be 20 more elements, but the outcome of

those 20 elements, I mean they're truly not looking just at we don't want more burden, but does that outweigh the good? Does the burden outweigh the good?

So again, if it's not being done and equipment is not in the room when it should be, things like that, I think that would totally justify the 20 extra questions just from your standpoint.

DR. J. JACOBS: The trick is for this, you know, I've been thinking about so then we go back and over the next two years we try to do this reliability testing, but we're trying to prevent some pretty rare things.

How we're going to document, I guess that's a discussion for another time, but it's going to be tricky.

DR. MAYER: Well, you know, but there are some -

DR. J. JACOBS: No, I know. But if you can't - I understand you say that's your homework, but if you came back and said all

right, we want to have reliability and validity testing to demonstrate that it's a good idea to wear a parachute when you're jumping out of an airplane, well, where are you going to get the data on outcomes of people who didn't?

So, I mean that's taking this argument to an extreme, but I think it applies to what we're talking about here just a little less extreme.

MS. HINES: Well, and I think with what I'm seeing other STS - I talked to Dave Shahian. He's filled out a ton of these forms and stuff and I think he'll be very helpful and kind of -

DR. J. JACOBS: I had dinner with Dave Shahian 48 hours ago in Vienna and we talked about - that's exactly what we talked about. He was sitting - me, him and his wife in this restaurant, and we spent two hours talking about these forms.

So, I agree. That's the right guy

to talk to.

CO-CHAIR JEFFRIES: So, from a feasibility, just looking through the statements here, this is a little different because this is new. It's not something which currently exists in the data record.

And I think that's something you're really getting at, John.

Are we ready to discuss about recommending this or is there more discussion that we need to have?

DR. MAVROUDIS: If you need a motion, then I make a motion that we recommend it.

DR. HINKLE: Second.

CO-CHAIR JEFFRIES: Is there any dissension?

All right. So, we'll move on to the next one which is 13, mediastinitis.

DR. LOPEZ: I've got that one. Number 13, mediastinitis, that was PS3 in congenital heart surgery. The measure is the

rate of mediastinitis versus re-exploration after pediatric or congenital open heart surgery. It includes the following diagnosis of post-operative mediastinitis to meet the following criteria.

Criteria 1, a patient has organisms cultured for mediastinal fluid or tissue that is obtained during the surgical operation or by needle aspiration.

Number 2, the patient has evidence of mediastinitis by histopathologic examination or visualize evidence of mediastinitis seen during surgical operation.

Number 3, the patient has at least one of the following numbered signs or symptoms with no other recognized cause. That is fever, chest pain, sternal instability and at least one of the following: purulent mediastinal drainage, organisms cultured from mediastinal blood, drainage or tissue, or the widening of the cardiomediastinal silhouette.

Number 4, a patient is less than a

year of age and has at least one of the following: Signs or symptoms with no other recognized cause, fever, hypothermia, apnea, bradycardia or sternal instability, and at least one of the following features, purulent mediastinal drainage, organisms cultured from mediastinal blood, drainage or tissue, or widening of the cardiomediastinal silhouette.

Infections of the sternum, that is osteomyelitis, should be classified as mediastinitis.

Sternal instability that is not associated with a wound infection or mediastinitis, is not mediastinitis.

The time interval begins upon admission to the operating room. Ends 30 days post-op or until the time of discharge, whichever is longer.

DR. MAVROUDIS: So, if I got this right, no positive culture, no mediastinitis, right?

You need a positive culture.

DR. LOPEZ: Well, no.

PARTICIPANT: There could be a positive blood culture, right? As opposed to -

DR. LOPEZ: Yes. Mediastinal fluid. This is mediastinal blood, drainage or -

DR. MAVROUDIS: Oh, okay. I'm sorry. I misheard.

DR. LOPEZ: But you could also just have purulent drainage or widening of the cardiomediastinal --

DR. MAVROUDIS: So, I thought that - I don't have it in front of me.

DR. HINKLE: It doesn't say.

DR. J. JACOBS: This definition is on Page 254 of this big blue book. And it's the CDC definition. So, this is a definition that's developed by the Center for Disease Control.

There's a manuscript in this book that's first authored by Howell Walters from

Children's Hospital in Detroit. Then it goes into the rationale for incorporating this definition and the STS database's compared to other definitions that are out there. And it's basically the CDC definition which is harmonious with the definition in the STS adult cardiac database.

And all the definitions and the rationale behind it in this chapter here.

DR. MAYER: Okay. So, we can't rewrite the definition of mediastinitis

DR. J. JACOBS: Right. I think that's probably beyond - well, I think that's beyond the scope of our task here.

I mean there's a group of people that spent two years working on incorporating this into the STS database and there is good science behind it.

DR. MAVROUDIS: This is pretty straightforward. All I wanted was a clarification, and I got it. This is pretty straightforward. I don't see any problem with

it.

DR. LOPEZ: Yes, the blood culture, I guess, doesn't play a part in the definition.

DR. HINKLE: It could, but it's not sine qua non, I guess.

DR. MAVROUDIS: What else do you have there?

DR. LOPEZ: Do you know how they define fever in infants less than a year of age and apnea?

I mean in the neonatal literature, there is a precise definition for apnea. I'm just wondering how STS is defining it.

CO-CHAIR JEFFRIES: It would be the same.

DR. LOPEZ: It would be the same as the pediatric literature?

CO-CHAIR JEFFRIES: The apnea would be the same definition. Fever is most subjective.

DR. LOPEZ: Yes.

CO-CHAIR JEFFRIES: That's some sort of institution.

Well, where I worked it's anywhere from 38.2 to 38.9. So, I guess it depends on where you work.

DR. LOPEZ: Okay.

CO-CHAIR JEFFRIES: But apnea is, if I remember correctly, it's 20. So, 20 or 30 seconds.

DR. LOPEZ: It's usually 20 in the pediatric literature.

CO-CHAIR JEFFRIES: Yes. And I think that would be similar.

DR. LOPEZ: Okay.

DR. MAVROUDIS: I don't see how you could argue with any part of this. It's a great indicator.

CO-CHAIR JEFFRIES: So, from an importance point of view

DR. LOPEZ: Yes, importance. It is important. And scientific acceptability.

CO-CHAIR JEFFRIES: So, Jeff, one

of the things of importance is demonstrating variation.

Have you seen that when you're looking through the STS data set, that there is variation across centers?

DR. MAVROUDIS: You mean what you call them on -

DR. MAYER: No, no.

DR. HINKLE: The outcomes. The outcomes.

They did mention that you - there was some mention in some of the mortality measures about variation across the STS database, but I assume -

DR. MAVROUDIS: Oh, I see.

DR. HINKLE: - assume all of these could have if you have the data there.

PARTICIPANT: I don't know that we've looked, have we?

DR. J. JACOBS: Well, what I can tell you is that we have not published any papers that show the variation of race,

mediastinitis or stroke or any of those things we're about to talk about.

But from working with the data in the STS database, there's no doubt that different hospitals just looking at the data, different hospitals have different -

DR. MAVROUDIS: Different hospitals report differently.

DR. J. JACOBS: Report different rates of mediastinitis.

Now, the actual, formal study of that had not been done, but it could be done.

DR. HINKLE: But I think you raise one point I was going to raise when we get to the mortality ones, which are probably relevant here. The whole issue of quality improvement is to decrease variation over time.

So, capturing that is important somewhere in, maybe in all of these measures, I'm not sure, but I mean generally trying to get to a new move, the whole process may be to

a new place, but then decrease the variation around it so that the outcome is more highly predictable.

DR. MAVROUDIS: Is there anything there that calls for taking into account gastrostomy, tracheostomy?

DR. JENKINS: Risk adjustment. You're looking at risk adjustment?

DR. MAVROUDIS: Yes, I am.

DR. J. JACOBS: Right. So, nobody that I know of has done a risk adjustment specifically for mediastinitis and created a tool to do that.

DR. MAVROUDIS: Right. So, what I mean is all I'm saying is that if we do measure this, the only way I guess that we could get this is to look at the database and see if there's tracheostomy and gastrostomy.

DR. J. JACOBS: And those are all variables that are tracked in the database.

DR. MAVROUDIS: Right.

DR. JENKINS: You could do it by

exclusion.

DR. HINKLE: Yes. Are you suggesting those would be exclusions in the -

DR. MAVROUDIS: I don't know if I'm suggesting that. What do you think?

DR. HINKLE: I don't know either. I would think that a proximity of a trach -

DR. MAVROUDIS: And the gastrostomy.

DR. HINKLE: - and the gastrostomy, probably - I don't know the answer, but I can see why you're raising the -

DR. MAVROUDIS: I think that that is a reasonable exclusion in my mind, because the chances mediastinitis in most patients is extremely high. 20 percent, 15 percent, something like that.

DR. HINKLE: Well, I don't know. But I mean it would actually before we start making this up, we ought to have the data.

I mean I'd rather include it and then we can figure out how to deal with it,

you know, and maybe that's another project is to try to risk adjust for mediastinitis and the presence of a preexisting trach and gastrostomy, you know.

I mean I think we're still in the developmental stage here. That's what I was sort of getting at before. Cast the net widely, then you figure out what -

(Simultaneous speakers.)

DR. MAVROUDIS: Right.

DR. MAYER: But I mean the issue is this is an important -

CO-CHAIR JEFFRIES: But the point is -

DR. MAYER: This is an important thing.

DR. MAVROUDIS: But that makes it even more important because the next thing is what are the issues that are associated.

DR. HINKLE: yes. Once you look at that variation, you can understand that -

DR. MAVROUDIS: Right.

DR. HINKLE: Exactly. The more complex and the higher volume sidebars.

MS. HINES: And remember you have - one of the things that you need to do is come up with research recommendations as well as -

DR. MAVROUDIS: Well, here's one of them, right?

Yes, those are not easy to come by, those things. So, we've got one. Good.

CO-CHAIR JEFFRIES: Kathy, did you have a comment?

DR. JENKINS: Well, I just thought that if that was such an unanswered question, it would question the scientific integrity that when we go forward with exclusions at this point, feel more confident about the measure and then do that research later to see if we can expand it.

Because it might go further in this process, I think that question about risk adjustment sitting in the background.

DR. MAYER: I'm not sure I totally

follow what you said, Kathy. I mean what you're saying is we ought to collect all the data and then figure out how to risk adjust it once we see what it looks like?

DR. JENKINS: I -

DR. MAYER: Is that -

DR. JENKINS: I'm new to the NQF process, so I thought there was sort of a formal proposal of an actual measure that was going to get endorsed.

So, this is an excellent measure that has a lot of the features that will make it need not very little controversy except for this risk adjustment problem since you don't have the data already.

So, I was just suggesting that conversion of the measures is a place to start so that you can get it through without the factor of risk adjustment or -

DR. J. JACOBS: I think that's an excellent point.

DR. JENKINS: - do it by category

with your categories to get around.

DR. J. JACOBS: I think that's an excellent point because we could start making a list of things that should be excluded like tracheostomy, gastrostomy, enterostomy, colostomy, whatever.

But if we had to say well, where's the data, we're doing that based on well, that's what we think is a risk, and it is a risk. But a better way is let's just track mediastinitis and then we could very easily study from the database.

DR. MAYER: But you're not proposing any of those things as an exclusion, right

DR. J. JACOBS: No, I'm not. No. I'm just saying -

DR. HINKLE: I think we're all saying the same thing.

DR. J. JACOBS: I don't think that the argument on the table is that we want to put those in as exclusions now. We want to

put - let's capture - we'll get to mediastinitis and let's study what a risk -

DR. MAYER: Right.

DR. JENKINS: But then that means - but if the centers have different variation in rates, are you adjusting them for quality difference or could it just be a case mix?

DR. HINKLE: Right. Could be a case mix. I think I would just say that it's proven that it's a trach, then you hope there's a quality improvement initiative to prevent it from happening.

I mean I don't know if it's silver trachs or something that would -

DR. JENKINS: I agree it's all important.

DR. HINKLE: - drive the -

DR. JENKINS: I'm not suggesting that trachs aren't important.

DR. HINKLE: No, I know you're not.

DR. JENKINS: I'm trying to make it into a performance measure without the -

CO-CHAIR JEFFRIES: And I think you're indicating that one of the rationales that you use are a basket of measures and you can't look at just one measure for a sample. But this measure and also looking at the case mix suggested measure will help you get some understanding.

At least you understand what case mix that institution holds. So, it makes some sense of some of these are good measures which aren't case mix suggested.

DR. JENKINS: The mediastinitis project is an excellent project.

DR. MAYER: Well, we're not under any gun here to publicly report for at least a few years, right? Didn't I hear that? Somebody say that? I mean I think we got time to figure this stuff out a little bit, you know.

DR. JENKINS: But it did say that you had to believe that these measures are ineligible to be performance measures now.

DR. MAYER: Then we should toss the whole lot of them out.

DR. J. JACOBS: No, I think they are, I mean as far as they spent two years developing their performance measures.

DR. MAVROUDIS: It's okay the way it is. It's okay the way it is. What you're saying is this is the incidence. You're not saying that this is the incidence in clean ones, it's just the incidence in all of them.

That's it, right? That's the definition right there.

DR. MAYER: I think what I'm - you can correct me if I'm wrong or if I'm mishearing this, because I don't want to get us down any garden paths here, but I think there's a recognition that we're going to propose a measure now, but we're gong to come back and revisit it in two years and refine it, right?

I mean this is an iterative process, not that we have - we've got stuff

perfectly established and all we're trying to do is figure out if you're adhering to the perfectly established ironclad evidence.

MS. HINES: Right.

DR. MAYER: Do I understand that right?

MS. HINES: Because I mean as you go back and you start looking at testing results, we've had stroke measures that had stroke/atrial fib flutter. Well, you start doing testing and you realize that - or TIEs. You realize TIEs are noise. So, they take it out and they refine it and just leave it as strokes.

So, that's part of the testing that you will find those things and make the revisions and the data will lock them in.

DR. MAYER: All right.

DR. HINKLE: I mean at NCQA, that's the same process.

DR. JENKINS: Intended use. So, does the intended use of the measure include

both public reporting and quality improvement? Yes. If no, do not submit.

DR. HINKLE: When, right.

DR. JENKINS: If not, will you finish in 24 months?

DR. MAYER: I think the operative word there is "Intended," right?

DR. HINKLE: Yes. Right.

MS. HINES: And the quality improvement versus the public reporting. I mean we truly did just used to look at quality improvement in metrics. We won't endorse just quality improvement. It has to be used.

And as you say, there's a timeline to public reporting, but it has to -

CO-CHAIR JEFFRIES: Can you give me an example of a metric that you did endorse that would suggest a quality improvement metric?

MS. HINES: In the old days. In the old days.

CO-CHAIR JEFFRIES: Can you give me

an example of one?

MS. HINES: Oh, sure. Home health, we just - there were some original measures that came through that said improvement and ability to do upper body dressing.

It may be perfectly relevant as a quality improvement measure, you know, certainly within a larger set. Do you want it for public reporting? No.

So, it's great to know so that you can prepare, but you really didn't want that to be published on a website, what does that mean to the consumers, what does that really show when we had broader functional status measures that weren't all encompassing.

So, that's the closest thing that comes to mind.

CO-CHAIR JEFFRIES: So, we went through the importance and the scientific acceptability.

Any other elements of discussion there?

DR. MAYER: Well, only what we just said. STS will need to develop new statistic models for associated variable - for variables associated with this complication.

DR. J. JACOBS: Such as severity of disease or anatomic problems like tracheostomy or gastrostomy.

DR. MAYER: Or immune deficiency or -

DR. J. JACOBS: But none of that prevents this from being something that should be part of this bucket of metrics, in my mind.

DR. MAYER: Right.

CO-CHAIR JEFFRIES: And usability. It seemed that there was an adult measure, but it's been pretty focused on damages.

DR. LOPEZ: Right.

CO-CHAIR JEFFRIES: And then any comments about feasibility?

DR. MAYER: I think it's pretty easily trackable.

CO-CHAIR JEFFRIES: Actually in

Washington State starting in, I think it's January, there's going to be a public reporting measure of a cardiac surgical nature. Cardiac surgery. Washington State.

DR. JENKINS: In kids too?

CO-CHAIR JEFFRIES: Everything. Yes, kids and adults.

DR. HINKLE: And hospital infections are becoming a requirement. A lot of Department of Public Health, State Department of Health.

CO-CHAIR JEFFRIES: Okay. So, our recommendation?

DR. MAVROUDIS: I move it.

CO-CHAIR JEFFRIES: All right. So, the next measure is 14, which is stroke after pediatric cardiac surgery.

The measure is the rate of new onset stroke rate after pediatric and general heart surgery.

The numerator is the number of patients who undergo pediatric and general

heart surgery and develop postoperative stroke/CVAs defined by the following definition.

The rude definition of stroke is any confirmed neurological deficit of abrupt onset caused by a disturbance in blood flow to the brain or when the neurologic deficit does not resolve in 24 hours. And the temporal elements incorporated in the definition allow for a distinction between stroke and a transient ischemic attack wherein there is a temporary loss of neurologic function resulting from a temporary alteration in cerebral blood flow, but not resulting in permanent brain injury and with symptoms of that resolve within 24 hours. A RIND or reversible ischemic neurologic deficit is a sub-type of stroke with a neurologic function and symptoms resolve within 72 hours.

The numerator is - excuse me. The denominator is patients who undergo pediatric and general heart operations. And the

exclusions are operations which are not of the above type.

DR. J. JACOBS: So, that definition is out of the chapter that's on - I think it's on Page 234 in this book. And the definition is on Page 237.

This chapter was authored by a group of cardiologists and cardiac surgeons with substantial input from neurology. And Dan Link is the pediatric neurologist at Children's Hospital in Philadelphia who is very involved in stroke research.

The definition must harmonize with the definitions used for stroke in the STS adult cardiac database along with the American College of Cardiology, NCDR.

So, by using that definition we're going to call a stroke the same thing, and ACC NCDR call a stroke the same thing, STS adult cardiac database called a stroke. Plus, that's harmonized with the definition used by several neurologists and scientists.

So, the strengths and weaknesses of that definition and the arguments for and for not using it and the reason why it was ultimately chosen are spelled out in great detail in this paper.

I think based on that definition it's pretty trackable. It's pretty important. And the science behind it is in the paper. That's just like the last one. Just like there's a tracheostomy is probably a pre-operative risk factor. For mediastinitis there's probably certain variables that are preoperative risk factors for stroke.

And the next step is going to be the same exact thing, just like we can use this to study what's high and low risk, we can use this the same way with the STS database to say which variables are associated with more or less strokes.

CO-CHAIR JEFFRIES: Right. I mean I think you have started on that discussion in the data that you submitted and the range for

stroke after an ASD was only one percent.

Again, it indicates some sort of complexity adjustment.

DR. J. JACOBS: No doubt.

CO-CHAIR JEFFRIES: Is something you should consider. But I think that that is going to be similar for all of these.

DR. J. JACOBS: Yes.

CO-CHAIR JEFFRIES: I mean if all you do is ASDs, you're going to have a low incidence of most of these complications.

Jeff, I have one question, enumerator question. So, the definition talks about the difference between an RIND -

DR. J. JACOBS: Right.

CO-CHAIR JEFFRIES: - and a stroke. So in the numerator, are you including RINDs?

DR. J. JACOBS: Yes. We - that was the hardest part of this whole paper. And the average - the most common definition utilized by neurologists, say that a reversible

ischemic neurologic deficit is some type of a stroke.

So, therefore, yes, we are because they say it's a type of stroke.

CO-CHAIR JEFFRIES: Adults use 72 hours after CABG.

DR. J. JACOBS: No.

CO-CHAIR JEFFRIES: I think they did. I have to look, but I think that's what I remember seeing.

DR. J. JACOBS: The STS definition -

CO-CHAIR JEFFRIES: Well, in the NQF measure.

DR. J. JACOBS: This whole thing with stroke and reversible ischemic neurologic deficit is quite a topic, discussed topics.

CO-CHAIR JEFFRIES: The adult measure was after 72 hours. Postoperative neurologic deficit which has been greater than 72 hours.

DR. J. JACOBS: That's very

interesting because the STS definition of a stroke is greater than 24 hours. So, then they're tracking a stroke exclusive of the subtype of stroke defines neurologic deficit in that metric.

CO-CHAIR JEFFRIES: Right.

DR. J. JACOBS: So, I think we could do it either way.

DR. HINKLE: Well, it may be in the adult, the prevalence of carotid artery disease, TIEs. I mean there's probably a difference from that perspective, I would think, that might lead to more branching.

So, the data is probably dictating a difference already in 72 versus -

CO-CHAIR JEFFRIES: It's also, I guess, in some ways, what is important to the person who's being impacted, I guess.

DR. HINKLE: Yes.

CO-CHAIR JEFFRIES: If you have a deficit that resolves in three days or is resolved in one day, it's not going to.

DR. J. JACOBS: So, why 72 and not 96? We're dichotomizing it between this variable, right?

CO-CHAIR JEFFRIES: Exactly.

DR. J. JACOBS: I certainly don't feel strongly either way. If the adult metric is 72 hours, what they're doing then is they're tracking in the STS database, a stroke as defined as greater than 24 hours. And they're just defining whether that stroke was a reversible ischemic neurologic deficit and excluding those. And this metric now tracks strokes inclusive of reversible ischemic neurologic deficits.

And I think this metric could be written to be harmonious with the adult database and say a stroke with symptoms that last more than 72 hours, I think that we would have no problem with that.

DR. MAVROUDIS: Except you don't really know where the big symptoms of a child is a seizure and it gets treated. If you

don't treat it, then you know that it persists and you may have some issues whether it persists or it doesn't persist.

And a stroke - I mean and a procedure after an operation is no small matter. And so clearly this is a very important metric without question.

DR. J. JACOBS: Yes.

DR. MAVROUDIS: And then the other subtypes here as I think you're basing it mostly on physical examination, aren't you? Because if you do EEGs on every kid, every child, you're going to get some spikes there that you won't see when grandma seizures, that it looks like a seizure on the EEG and then you treat it.

And so then we really don't know what the - and then the problem with that is not everybody does EEGs across the board.

And so, this is becoming a little bit more difficult especially since some people are actually getting CT scans before

and after. And then your stroke rate may be 30 percent if you look for it, and two percent if you don't.

So if I've got this right here, you and all the colleagues decided that this is going to be on physical exam, right?

DR. J. JACOBS: Right.

DR. MAVROUDIS: And then supported by something else.

DR. J. JACOBS: Right. In other words, if you have a finding on CT scan with a normal physical exam, that's not going to count for this.

DR. MAVROUDIS: Right. Right.

DR. J. JACOBS: And what that does is it creates a level playing field for variations in institutional practice between CT scanning everybody who has heart surgery and nobody.

DR. MAVROUDIS: So, you've already thought about that, clearly.

DR. J. JACOBS: Yes. And quite a

bit of this paper talks about that.

DR. MAVROUDIS: So, the point is that we're talking about physical exam or other signs associated with stroke like seizure and so forth and so on, right?

DR. J. JACOBS: Right.

DR. JENKINS: Physical exam by a neurologist or a pediatric neurologist?

DR. J. JACOBS: We said any confirmed neurologic deficit. We didn't get into that detail about who does the physical exam.

DR. JENKINS: I'm just thinking of FET babies and global injury and anesthesia and -

DR. MAVROUDIS: But, I mean, that's a good one though. Confirmed, right? So, in your hospital, the confirmation might be different than my hospital, but it's confirmed.

DR. MAYER: So, can I -

DR. J. JACOBS: Yes, let's -

DR. MAYER: Can I just make sure I understand what's in this neurologic injury or stroke definition?

Are patients who seize going to be counted here?

DR. J. JACOBS: Yes.

DR. MAYER: Because it's sort of in the chapter, it's in the controversies. What section is it? The way I read it, it's on -

DR. HINKLE: I mean the measure is titled "Stroke or Cerebrovascular Accident."

DR. J. JACOBS: If the answer is in this chapter. I don't want to -

DR. MAYER: Is it? Maybe I misread it.

DR. J. JACOBS: On Page 237, Number 9.

CO-CHAIR JEFFRIES: I don't think a seizure in and of itself implies neurologic deficit.

DR. HINKLE: It says - the definition says rate of new onset of stroke or

cerebrovascular accident. It doesn't say anything about seizures. Seizures could be a secondary manifestation of a stroke, but -

DR. MAVROUDIS: Seizures mean something down the road, doesn't it?

DR. MAYER: Most likely. But not always.

DR. HINKLE: Right.

DR. MAYER: But just forget that part. Is it in or out, the seizure -

DR. J. JACOBS: If you have a seizure without any confirmed neurologic deficit, it's out. If you have a seizure with confirmed neurologic deficit, it's in.

DR. MAYER: Fine. Okay. So, the issue is the neurologic deficit, not the seizure.

DR. J. JACOBS: Right.

DR. MAYER: And then the neurologic deficit may be any of a variety of things -

DR. J. JACOBS: Right.

DR. MAYER: - from hemiparesis to

aphasia -

DR. J. JACOBS: Yes.

DR. MAYER: - to whatever, right?

DR. J. JACOBS: Yes.

DR. MAYER: Okay.

DR. J. JACOBS: Yes.

DR. JENKINS: Could it be global or not?

DR. J. JACOBS: Yes.

DR. JENKINS: Does it have to be focal?

DR. J. JACOBS: It could be focal or global.

DR. JENKINS: Global too.

DR. J. JACOBS: Yes.

DR. HINKLE: So, now you're confusing me a little bit because I'm going to protect my anesthesia colleagues which is, you know, there's a lot of regional anesthesia done now if there's a complication from a thoracic epidural, is that all excluded here?

DR. J. JACOBS: You have to read

the whole definition.

DR. HINKLE: Okay.

DR. J. JACOBS: Stroke is any confirmed neurologic deficit of abrupt onset caused by a disturbance of blood flow to the brain.

DR. HINKLE: Right.

DR. J. JACOBS: So, if you have a neurologic deficit from - disturbance of blood flow to the brain -

DR. HINKLE: Great. Just checking.

DR. J. JACOBS: - when the neurologic deficit does not resolve within 24 hours.

And this is a pretty power-packed six pages that really answers every question that's come up so far.

DR. JENKINS: And I just don't understand the 24 hours, and that's the type of patients who are often paralyzed. I just don't understand that.

DR. J. JACOBS: That's the

definition that the American Society -

DR. JENKINS: But in the context of pediatric heart surgery.

DR. HINKLE: Right. I was thinking of even other anesthetics that can cause myoclonus and things that look like seizures. It has to be a cerebrovascular - but to me, it's going to be confirmed on an MRI or something, I would guess. But I mean you raise a really good point. They're all on -

DR. JENKINS: If it's there at 72, I guess, not -

CO-CHAIR JEFFRIES: It's not saying it's 24 hours if you have a deficit, but it says you have a stroke that doesn't resolve within 24 hours and it becomes apparent -

DR. J. JACOBS: Right. Exactly. That's the answer -

DR. JENKINS: And if it was there at 24 and it resolved by a week.

CO-CHAIR JEFFRIES: You won't know. I mean some of them you won't know. I mean I

think you're right. There's going to be some things you won't know.

DR. J. JACOBS: But if you merge normal, there are things are okay, and then it should be counted as a stroke.

What you're missing -

DR. HINKLE: Plus, there's cognitive dysfunction.

DR. J. JACOBS: The incidence of - the amount of time that you're going to miss somebody who's been paralyzed and sedated for four days and they wake up normal, but they actually had a stroke that resolved after 61 or 78 hours, that's probably not the most common scenario.

So, I don't think I would lose too much sleep over that one.

DR. MAYER: I mean this is a clinical definition, right?

DR. J. JACOBS: It is. And it's a clinical definition that was intensely wordsmithed with guys that are real experts in

this stuff.

I'm doing my best to claim what we came up with, but I'm certainly not the expert. I was a facilitator.

CO-CHAIR JEFFRIES: So, just the language about RIND and health risks, I'm confused.

DR. J. JACOBS: Well, what an RIND is, is some type of stroke. And it's one that is completely resolved in 72 hours.

So, the only question is if you wanted to make - the options we have as a group is to say we're going to harmonize with what the adult metric is which means we're going to say a stroke with symptoms that persist beyond 72 hours, which is okay, or we're going to do it with cutoff of 24.

I don't feel strongly about either one of those.

DR. MAVROUDIS: I think the way it is, is okay. I think our discussion was a

clarification of things. And if further clarification needs to be done, we can add a pop-up to it like you're talking about.

MS. HINES: Just a question because this measure is 18 and under. The adult measure started at over 20. What happened to the 19?

DR. J. JACOBS: This is an interesting question that the scope goes beyond just this group. The STS congenital heart surgery database has stratified patients into four age groups; neonates, infants, children and adults. And we've said that an adult is somebody who's over 18.

I recently learned that the CDC defines an adult as somebody who's over 21.

MR. HARDER: And that's what congress said.

DR. J. JACOBS: Right.

DR. JENKINS: And the FDA.

DR. MAYER: That must make it right.

(Laughter.)

PARTICIPANT: Maybe between the two measures, the adult measure -

MS. HINES: Define 16. That was the first one.

PARTICIPANT: I mean these are only - this is probably a handful of patients we're talking about.

MS. HINES: I'm sure. It's just somebody's got to look at it.

DR. J. JACOBS: But we've got to get this right.

(Off-the-record comments.)

DR. J. JACOBS: The ones it will turn out to be is if you're stabbed in the heart and you're 19, you don't have anywhere to go right now.

(Laughter.)

DR. J. JACOBS: So, we in our database, said a child is under 18, but I don't know that that might not be something down the road we might have to revise, but I

think we'd have to study it a little bit and find out what everybody else is saying.

And I think we came up with 18 because that's kind of like an average compared to what we heard from different people.

Kathy just said the FDA is 16, CDC is 21, so I would think for now we should keep it at 18 with the possibility of potentially revising it down the road realizing that if you have an acquired cardiac lesion between 18 and 20, there's no NQF metrics that are going to cover you.

MR. HARDER: But congress said, Jeff, the age is 21.

DR. J. JACOBS: Okay.

MR. HARDER: Just so you know. I know that for sure. Just so you know. And that's what the Impact Registry is going to be too. It's 21, just so you know.

DR. J. JACOBS: Right. And that's where I heard about this. The Impact

is doing 21.

MR. HARDER: That's because I raised the issue.

DR. J. JACOBS: Was this in Vegas? There was a meeting in Vegas where the impact guys were telling me about 21.

DR. HARDER: Yes.

DR. HINKLE: What is it in Europe?

DR. J. JACOBS: Well, you can drink beer in London when you're 12.

DR. HINKLE: I know that, but the definition that - there's an international database that might define it.

DR. J. JACOBS: No, no. In the STS and EACTS databases right now it's 18.

DR. HINKLE: It's 18.

DR. J. JACOBS: Everything in the STS database is done in the EACTS, and vice-versa. So, it's 18.

DR. HINKLE: Okay.

DR. J. JACOBS: But I was actually thinking that we might need to revisit the

issue because Impact is saying it's 21 based on what congress told the FDA.

DR. HINKLE: Okay.

DR. JENKINS: The Impact is ultimately going to hit adults.

DR. J. JACOBS: Right. But I know that we made the decision in Impact to make the cutoff between children and adults at 21.

And that's one of the few differences right now between Impact and STS database, and it might be that the STS database needs to make that change too.

It's really not that many patients, but it's something we need to revisit.

CO-CHAIR JEFFRIES: So, the only other comment I had here I think I already brought up, which is about the potential in the future to think about risk adjustment or complexity adjustment.

DR. J. JACOBS: And I think that's going to apply for every complication we're

tracking right now.

CO-CHAIR JEFFRIES: Okay.

DR. J. JACOBS: And it's probably most relevant for mediastinitis and stroke, but it's also going to be relevant for heart block and other things as well.

CO-CHAIR JEFFRIES: And is this like mediastinitis when you've looked at the data set in an unpublished manner? There's a variation among centers?

DR. J. JACOBS: Yes, I think there is for every one of these, but I don't have a reference that I can provide for that.

That's just me looking at the data.

CO-CHAIR JEFFRIES: Sure. I don't have any other comments.

DR. MAVROUDIS: I move.

CO-CHAIR JEFFRIES: So, why don't we -

PARTICIPANT: Second.

CO-CHAIR JEFFRIES: So, why don't

we break for lunch.

(Whereupon, the above-entitled matter went off the record at 12:23 p.m. and resumed at 1:12 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:12 p.m.

CO-CHAIR JEFFRIES: Why don't we skip 15. We'll just come back to that one.

DR. MAVROUDIS: I know. Let's go to the most controversial one. Just kidding.

CO-CHAIR JEFFRIES: So, that wouldn't be 16, but we'll go to 16. So, 16 is my measure as primary, and you're the secondary. And that is arrhythmia necessitating permanent pacemaker insertion.

So, the brief description is percentage of pediatric and congenital heart surgery patients with a new onset arrhythmia that requires postoperative permanent pacemaker insertion.

The numerator, a stated number of pediatric and congenital heart patients with new onset arrhythmia or prior insertion of a permanent pacemaker after heart surgery. And then there's some definitions. And that implantation and utilization of a permanent

pacemaker for treatment of any arrhythmia, including heart block.

And the time window is 30 days post-op or until time of discharge, whichever is longer. And the denominator is number of pediatric and general heart surgery operations with the exclusions, as we said before - well, actually the one other set of exclusions are patients with implanted pacemakers before surgery. And then the other set of exclusion are patients who don't have pediatric or congenital cardiac operations.

DR. MAVROUDIS: The only thing that I have to comment on is whether it was clear enough that this thing occurred, this occurrence, this arrhythmia occurred after open heart surgery or after any kind of surgery during that hospitalization.

I think it's fairly clear. The thing that we have to be careful of is that patients, and we talked about this before, that some patients come to the operating room

with an arrhythmia who will get pacemaker intentionally for that purpose. But I think this is clear that it eliminates those patients just by the wording.

If it's not clear to everyone, then we should change the wording. I think it's clear to me.

DR. J. JACOBS: Where we said new onset arrhythmia.

DR. HINKLE: Yes, new onset.

DR. MAVROUDIS: Right.

CO-CHAIR JEFFRIES: And I think the exclusion for that has spelled that out.

DR. HINKLE: It does say begins on admission to the operating room. So, my only thought about it is I think that's fair, but I think it's rarely there could be arrhythmias from the anesthesia or that those would be self limited and not caused by the surgery necessarily. But surgery and anesthesia are together in this process, so -

DR. MAVROUDIS: I mean you can also

say that measuring pressures afterwards you put the needle to the wrong place and then -

DR. J. JACOBS: But you could have a stroke because of the way the anesthesia is being administered, also.

DR. HINKLE: Right.

DR. J. JACOBS: You can get mediastinitis if the anesthesiologist doesn't use good sterile technique.

So, this isn't to judge the performance of the surgeon. This is to judge the performance of the surgical team.

CO-CHAIR JEFFRIES: Absolutely.

DR. HINKLE: Yes. Right.

DR. MAVROUDIS: This is a very important issue, clearly, because it's an enduring complication. And the sad thing is that we really don't know the impact of pacemaker insertion in a two-year-old child for the rest of his or her life.

I mean there are some scattered reports about it, but we don't know what that

does to their lifestyle - not lifestyle, but for the longevity of that patient.

My guess is that it's significantly less. I would say on the order of ten to 15 years, but we're going to find out.

DR. JENKINS: Did you ask people about variation and indication for pacemaker? I mean, is it standardized?

DR. J. JACOBS: Yes, there is a variation when one would put in a pacemaker and when one would not. But the postoperative indications for putting in a pacemaker, I think, are a little bit tighter.

DR. JENKINS: My worry about this measure was potential unintended consequences.

DR. MAVROUDIS: Like what?

DR. JENKINS: Well, people chose not to put pacemakers -- to not to have pacemakers implanted and patients --

DR. MAVROUDIS: They'll go to hell.

DR. JENKINS: What?

DR. MAVROUDIS: They'll go to hell.

DR. JENKINS: They'll go to hell. Okay. Could be, but the baby would have first.

DR. MAVROUDIS: No, that's what I'm saying. I mean if they're doing it because of that, then they're really missing out on why they became a physician.

DR. JENKINS: I'm with you, but I'm just saying that when you put P for measures out there, you do have to worry about unintended consequences.

And when you're not at iron-clad indication territory --

DR. J. JACOBS: But there are some things that are iron-clad indications, and that's the one we're trying to keep track of. I mean if you've got a little one with heart block after a VSD closure, you're going to get a pacemaker.

DR. JENKINS: But that's not what you're asking.

DR. J. JACOBS: Right.

(Simultaneous speakers.)

DR. J. JACOBS: There was a fair amount of discussion that went into that because the original written out version was the third degree. And then, in the final analysis, that's probably 90 percent of them. And the remaining ten percent, I guess you get sick sinus syndrome and other things.

But the reason it was left in after that postoperative sick sinus syndrome is also in some ways the manifestation of poor surgical technique.

DR. MAVROUDIS: As long as we're in good shape, Mr. Chairman, are we continuing or do we - can we make a motion or -

CO-CHAIR JEFFRIES: Well, let's just go through this.

DR. MAVROUDIS: Okay.

CO-CHAIR JEFFRIES: So, from an importance point of view --

DR. MAVROUDIS: Way important.

Highly important.

CO-CHAIR JEFFRIES: And again I think it's, you know, my comment was similar to the things you've already stated that we didn't have the -- I think there was some assumption there's variation.

I mean it was listed there was one to three percent incidence, but that there are variation across centers.

DR. J. JACOBS: Oh, there's no doubt.

CO-CHAIR JEFFRIES: And that there's opportunity for improvement.

DR. J. JACOBS: Yes, it should be zero patient. I mean I've had patients I've closed a VSD on and put a pacemaker in and -

DR. MAVROUDIS: I don't think it should be zero percent.

DR. J. JACOBS: In a perfect world.

DR. MAVROUDIS: It shouldn't be zero percent because the anatomy isn't as consistent. And that's why it shouldn't be

zero.

DR. J. JACOBS: Yes. But there's definitely variation.

DR. MAVROUDIS: You'd like it to be zero.

DR. J. JACOBS: You'd like it to be zero, but there's definitely variation.

CO-CHAIR JEFFRIES: And do you track pre-existing pacemakers currently in the STS data set?

DR. MAVROUDIS: If it's a pre-operative pacemaker -- if it's a pre-operative pacemaker, it's in the --

DR. MAYER: I think it's a pre-operative arrhythmia is what's in the current version right at this minute, and then --

DR. MAVROUDIS: Yes. The answer is yes.

CO-CHAIR JEFFRIES: So, if someone has a pacemaker, they would track pre-op arrhythmia.

DR. J. JACOBS: Yes.

CO-CHAIR JEFFRIES: But that doesn't necessarily mean it's a pacemaker.

DR. J. JACOBS: But they're not going to have -- if they have a pacemaker, their operation isn't going to include pacemaker implantation within 30 days of surgery because they've already got one.

Their operation might be a battery change or a lead change.

CO-CHAIR JEFFRIES: Okay. But that's a separate code.

DR. J. JACOBS: Separate code.

CO-CHAIR JEFFRIES: I don't have any other thing from what I've reviewed.

Do we need to have any more discussion about -

DR. HINKLE: Well, I would like - I'm going to ask a question that will clarify questions that I would have asked on all the others, you know?

CO-CHAIR JEFFRIES: Okay.

Dr. Hinkle: So, it has to do with

the code. The litany of CPT codes and ICD-9s, I guess.

So, the question to you is that we're in ICD-9 world, the United States. Congress has said on October the 20th, 2013 we're going to go to ICD-10. You made some comment about ICD-11.

Europe, the rest of the world is all in ICD-10 now. That's a huge transformation that's going to take place.

So, I'm trying to understand the cross -- sounds like you guys already maybe have the ICD-9, ICD-10, 11 crosswalk done. I'm not sure, but the rest of the healthcare in the United States does not.

It's going to be like a Y2K issue, we think, going forward. So, my question has really to do with the timing and when this two-year window we're talking about, is it 2011 and 2012?

You're talking about -- it won't even be because ICD-9 is not supposed to --

it's not mandated until October 20th, 2013 right now at least. So, that's one of my -

DR. J. JACOBS: So, those are CPT codes there.

DR. HINKLE: Yes, I know, but -

DR. J. JACOBS: Which is a totally separate issue.

DR. HINKLE: Yes.

DR. J. JACOBS: And CPT gets updated every single year.

DR. HINKLE: Right.

DR. J. JACOBS: And these are reported based on a denominator and numerator CPT codes.

DR. HINKLE: Yes.

DR. J. JACOBS: But I don't think that really --

DR. HINKLE: Pertains to this one.

DR. J. JACOBS: Right.

DR. HINKLE: Maybe because I'm thinking --

DR. J. JACOBS: I don't think it

pertains to any of these.

DR. HINKLE: Oh, even when you get into the subsets of --

DR. J. JACOBS: I think everything here --

DR. HINKLE: -- cardiac mortality?

DR. J. JACOBS: This is all CPT code based, but --

DR. HINKLE: So, it's not --

DR. J. JACOBS: But to answer a couple of your questions about ICD-9, 10 and 11, Europe has used ICD-10, you're correct, for over a decade. When I trained there in 1995, we recorded in ICD-10. And the United States theoretically is maybe going to start doing that soon.

ICD-11 is just an idea. And there's an international committee in our -- and members of our nomenclature committee sit on the international committee that's developing ICD-11, but that's not going to be implemented for, I would think, at least a

decade.

So, ICD-11 is a non-issue. It's a decade away from being functional. It's just a bunch of people sitting in a room putting ideas on paper right now.

DR. HINKLE: So, my question is really more do you see the ICD-10 conversion as it takes place, which may be very messy in America because every hospital has got to do it, the doctor, I mean everyone's got to -- being messy, impinging your ability to measure this?

DR. J. JACOBS: No.

DR. HINKLE: No. Okay.

DR. J. JACOBS: No, because the numerators and the denominators are written based on CPT codes.

DR. HINKLE: Yes. Okay.

DR. J. JACOBS: The complexity stratification tools are all made based on procedures and the associated diagnosis of those procedures. And they can be cross-

mapped to any ICD system that exists pretty quickly.

DR. MAYER: When we entered in the codes into the STS database, your local version that you download then to the central database, you're not loading it by code numbers. You're loading it by STS code.

DR. HINKLE: Yes. Okay. So, you've got to crosswalk the STS from ICD-9, I assume.

DR. J. JACOBS: Yes, we do.

DR. HINKLE: So, there's going to be -- we're going to go from 25,000, roughly, ICD-9 codes to 160,000.

I've already done the crosswalk for pediatric surgical procedures to see what happens to them, and there's an expansion. There's more granularity and stuff and it's -- I'm not trying to belabor the issue, but it's -- as I was looking through all of this stuff, it sort of was in the back of my mind.

I'm going like okay, we're all

going to be affected by it as we try to report publically.

DR. J. JACOBS: I think you're absolutely right. It's a huge issue. None of these metrics were written based on ICD-9.

DR. HINKLE: Okay. Yes. That sounds like you're going to be --

DR. HARDER: And just in general about registries, when you go in for a version upgrade and you change data elements, they go through a verification of remapping.

So, this is an exercise that normally happens in registry land, just so you know.

DR. HINKLE: Yes.

MR. HARDER: It's not like it's going to be something new.

DR. HINKLE: No, I'm aware of that. It's a huge project for us. Okay. I'm fine otherwise.

DR. MAVROUDIS: What was your concern? Was that leading up to the ICD-9s?

Is that what the issue was?

DR. HINKLE: The ICD-10 conversion.

DR. MAVROUDIS: Okay. All right.

DR. HINKLE: Which we're getting ready to do right now in our health plan. We've started the process and we don't have to do it until 2013. We're seeing it as a significant issue both from the standpoint of payment, and as well as tracking quality because the whole -- everyone has to do this and no one is going to do it together and whether Congress is going to be forced to move the date from 2013. There's a lot of unknowns.

I was just asking the question. I think I got the answer which is STS, you have your own identifier sort of coding in there, so that can be mapped to whatever.

DR. JENKINS: It's actually an international code.

DR. HINKLE: Yes. Right. So, that helped clarify the question I have. Great.

Thanks.

DR. MAVROUDIS: Do you need a motion then?

DR. LOPEZ: Second.

CO-CHAIR JEFFRIES: Any other comments?

DR. MAYER: Is there anything I should write down here?

CO-CHAIR JEFFRIES: I think that our main discussion was around the indications that pacemakers and some variability in that, but the feeling of the measure developer was that this really is looking at postoperative arrhythmias and the indications are more -- are not as varied.

DR. J. JACOBS: I would agree with that. Gus is like a world leader on this. It's his thing.

CO-CHAIR JEFFRIES: So, we're going to go back a measure since we skipped 15, post-op renal failure.

DR. LOPEZ: Post-op renal failure

is 15. The measure of percentage of pediatric and congenital heart surgery patients that require dialysis at hospital discharge due to new onset of post-op renal failure.

Numerator, the number of pediatric and congenital patients with new onset renal failure requiring dialysis after heart surgery.

And then these are new post-op, post-procedural requirements for dialysis including peritoneal dialysis and/or hemodialysis. Patient requires dialysis at the time of hospital discharge or death in the hospital.

Renal failure is defined as new onset oliguria with sustained urine less than .5 cc's per kilo per hour for 24 hours and/or a rise in creatinine greater than 1.5 times upper limit of normal for age or twice the most recent pre-op, pre-procedural value that this is, with eventual need for dialysis including peritoneal dialysis and/or

hemodialysis or hemofiltration.

Acute renal failure will be counted as an operative or procedural complication that must occur prior to hospital discharge or after hospital discharge, but within 30 days of the procedure.

Time window begins on admission to the operating room. It ends 30 days post-op or until time of discharge, whichever is longer.

Denominator is the number of pediatric and congenital heart surgery operations. There are some exclusions, and that is those requiring dialysis prior to the procedure or surgery.

Seems to be an important measure.

DR. MAVROUDIS: Just for the record, these definitions come right out of a certain book, right?

DR. J. JACOBS: Yes. So, just like the other ones there's a chapter here on Page 222 to 225 that describes the rationale for

this definition, where it came from and the references that support it. And it's a harmonized definition that's been harmonized across multiple databases.

DR. MAVROUDIS: We were writing -- we still are writing a paper on trying to do the metrics for morbidity like we did for mortality. And we approached this very difficult problem with these kinds of definitions which are extremely important. It seems like it's done extremely well here. It's pretty clear what is renal failure and what isn't. Nothing nebulous about it.

DR. LOPEZ: The importance to measure seems to be met.

CO-CHAIR JEFFRIES: Jeff, do you have a sense of what the incidence is?

DR. J. JACOBS: Very low.

DR. HINKLE: Under one percent?

DR. J. JACOBS: Very low. And it's extremely low in survivors because most patients -- most little babies with renal

failure, it's pretty unlikely they're getting out of the hospital on dialysis.

But it's an important metric to track because we're not just talking about neonates or infants here. And if you're a teenager that develops postoperative renal failure, you still have hemodialysis.

So, the incidence is less than one percent, but it's an important indicator to track.

CO-CHAIR JEFFRIES: I'm sorry. Maybe I missed it. So, if they die on dialysis --

DR. MAYER: It counts.

CO-CHAIR JEFFRIES: -- it counts.

DR. MAYER: What about if they are still on dialysis at 30 days, but recover while they're still in the hospital?

Which is the operative --

DR. J. JACOBS: Yes. You'd have to -- the period of data collection in the STS database, ends when two criteria have been

met. 30 days past, and you're out of the hospital.

So, if you're on dialysis on Day 31, but you go home off dialysis on Day 55 --

DR. MAYER: You went home off dialysis.

DR. J. JACOBS: You went home off dialysis and you do not meet renal failure.

DR. MAYER: Okay. All right. Got it.

So, I mean what this will not capture is the patients who have renal failure severe enough to require dialysis, but who had recovered --

DR. J. JACOBS: Correct.

DR. MAYER: -- before they go home?

DR. J. JACOBS: Correct. Because that's not going to be counted as postoperative renal failure in the STS database.

DR. MAYER: Right. I understand.

CO-CHAIR JEFFRIES: So, this is going to be -- your sense is, is this around .1 percent, .01 percent?

DR. MAYER: I think it's pretty low. I mean it's really low.

DR. J. JACOBS: My sense is it's less than one percent. I don't want to begin to guess after that.

DR. HINKLE: Is there any exclusion for any other -- I mean I suppose at 30 days you could have renal failure from some other cause, you know, reaction to a drug or something.

DR. LOPEZ: Sepsis.

DR. HINKLE: Yes. So, is that an exclusion?

DR. J. JACOBS: No.

DR. HINKLE: No exclusion, right. Not at this point.

DR. J. JACOBS: I don't think there should be. Because if you're in the hospital for a VSD repair tetralogy and then you

develop a postoperative infection and you require aminoglycosides and you develop renal failure --

DR. HINKLE: Chances are the drug or whatever happens to you is a byproduct of having to have the VSD repair.

DR. MAYER: It's thinking about the whole hospitalization for the cardi0thoracic surgery with whatever came after it.

DR. HINKLE: Yes. Right.

DR. MAYER: Rather than just thinking about the procedure.

DR. HINKLE: Yes.

DR. MAYER: Which I think is probably --

DR. HINKLE: I think it's the right thing.

DR. MAYER: -- the right thing to do, I would think.

DR. HINKLE: The right place to begin, yes.

CO-CHAIR JEFFRIES: Jeff, how do we

think about someone who's on hemofiltration on ECMO?

DR. J. JACOBS: Right.

CO-CHAIR JEFFRIES: And dies on ECMO.

DR. J. JACOBS: So, it depends on the indication. If you're put on peritoneal drainage or hemofiltration to remove volume, but you don't have the element of the oliguria, that doesn't meet this definition.

So, you have to have two things. You have to have the therapy, peritoneal or hemodialysis, but you also have to have oliguria and azotemia.

So, if you're put on that just to take volume off whether it's with the routine use of a peritoneal drain after a Norwood like Roger Mee used to do, or whether it's like hemodialysis because you've got a kids that's all swollen on ECMO and you hemofiltrate them, that would inquire as renal failure. That's something that requires renal -- that's

something that meets the requirements of renal failure requiring dialysis. That's simply bio overload using a mechanical device to remove the volume.

But if that's associated with a creatinine of three, that's different.

CO-CHAIR JEFFRIES: I mean the creatinine level here is 1.5 times. So I mean that's .6 for a baby. That's most, I would say, postoperative babies are .8. I'm looking at the Norwood. I mean, they don't usually come out.

DR. J. JACOBS: Hold on, 1.5 times --

CO-CHAIR JEFFRIES: Times the normal. The normal range is .3, .4 for a neonate. So, you're really getting to .6.

DR. J. JACOBS: But that has to be associated with a sustained urine output of less than 0.5 cc's per kilogram per hour over a 24-hour period.

CO-CHAIR JEFFRIES: It says or.

DR. J. JACOBS: Or. Okay. Yes. Right.

CO-CHAIR JEFFRIES: So, I'm just thinking that you're going to get to that -- I would say -- I don't know what the percentage are, but I would say probably all, or close to all, I would think on the babies who --

DR. MAYER: But they don't go home with that. That's why the issue is the discharge, is the status of discharge which I think is really -- I was hanging up on the same kind of problem. That's why I asked that question before.

CO-CHAIR JEFFRIES: I guess I was just relating that to the hemofiltration. If you're going to filter someone, are they going to meet the criteria? Because most of the creatinines are going to be above .6.

DR. J. JACOBS: Yes, I agree.

CO-CHAIR JEFFRIES: I'm not saying it's not unheard of. I'm just saying it's --

DR. J. JACOBS: Well, actually, the task I have is that these are definitions that have been developed over a three-year period by a large committee that are implemented in about seven different databases.

CO-CHAIR JEFFRIES: Sure.

DR. J. JACOBS: So, we can decide that we're not going to use them here, but I can't really make any statement whatsoever about that we're going to change the definition.

CO-CHAIR JEFFRIES: Yes.

DR. J. JACOBS: There was nephrologists and representatives of the Nephrology Society that got involved in this stuff. A lot of experts were called in to create these definitions.

And I'm certainly not the guy that can solely defend them all because I wasn't the one who developed them all.

CO-CHAIR JEFFRIES: And I guess I'm not asking for a change. I'm just thinking

about what are some of the --

DR. J. JACOBS: It seems to me that if you're on hemofiltration and you've got a creatinine that's .6 and you're not making urine, that kind of meets the definition of renal failure to me.

Not the most common kind of renal failure, but I mean that's different from the kid who's just having volume taken off, but he's still making urine, but you want to take off more volume.

Now, one way to fix it is to exclude patients who are on mechanical circulatory devices.

CO-CHAIR JEFFRIES: I would say just as part of the review, just take a look at that. As this review is over those two years, take a look at how many patients are on --

DR. J. JACOBS: Versus not on mechanical support.

CO-CHAIR JEFFRIES: -- support who

are labeled as having renal failure when they die.

DR. J. JACOBS: I think that's good because that's analogous to the way we dealt with the gastrostomy for mediastinitis.

So, a research question is does the utilization of mechanical circulatory support or corrupt this indicator? That's a good question.

CO-CHAIR JEFFRIES: I'm not sure it does, but I --

DR. J. JACOBS: It might. No, it might. You're absolutely right. It might.

DR. MAYER: Okay. This should be pretty easy to figure out. There shouldn't be a usability issue here. And it certainly is feasible because it's not very common and --

CO-CHAIR JEFFRIES: I mean the only thing in my mind that just comes is just the small numbers and comparability of the small numbers and what that -- because, again, I can't imagine it happens very frequently.

CO-CHAIR JEFFRIES: You think it's more or less common than -- I guess it's probably less common than mediastinitis.

DR. MAYER: Yes, by a lot.

CO-CHAIR JEFFRIES: And it's probably less common than pacemakers.

DR. MAYER: Yes.

DR. J. JACOBS: But it's a big deal.

DR. MAYER: I mean if you count -- if you count in there, and that's again why I was trying to ask you that, you know, the patients who die who were still getting dialyzed or something like that, now you've got a little, you know, that cranks the end up because I think the only question will be how much added information there is from just looking at the patients who died, you know.

I mean, to get out of the hospital, I mean I'm struggling in my head to remember a patient that we sent out of the hospital on dialysis.

DR. J. JACOBS: You've got to think outside the neonatal period, though.

DR. MAYER: No, but even in older patients.

DR. J. JACOBS: You don't have any heart transplant kids that are 16 years old that their kidneys shut down and they left the hospital on a peritoneal dialysis?

DR. MAYER: I don't think so.

DR. JENKINS: Even then, it is a question of qualification.

DR. MAYER: Well, but if it's a system issue writ large, I mean, whether it's antibiotics, preexisting -- I don't know. I don't know.

DR. JENKINS: It'd be difficult, going into the operation on the borderline.

DR. MAYER Right.

DR. JENKINS: There more likely to come out the other side.

DR. MAYER: I'm just trying to think back to the transplant population which,

you're right, is one where you might see it, but I don't know that we sent any of our transplants out on dialysis.

DR. J. JACOBS: I just know of one who --

DR. MAYER: That's indelibly burned into your memory.

CO-CHAIR JEFFRIES: Jeff, is that implantation? Is that a CPT code here?

DR. J. JACOBS: No.

CO-CHAIR JEFFRIES: Okay. And what about patients who leave with no kidney transplant?

DR. J. JACOBS: Do you know of anybody that had their heart surgery and got a kidney transplant in the same hospitalization?

MS. GALVIN: Yes, we had one.

DR. J. JACOBS: I'm not counting that. I'm talking about, do you know of a patient who came in with normal renal function, had heart surgery, developed

postoperative renal failure and stuck around to get a kidney transplant?

That, I don't think, is going to happen.

DR. MAYER: Not unless you have a double transplant.

DR. J. JACOBS: I mean, if it's somebody who had a double transplant that --

DR. MAYER: No, I understand. That wasn't a serious comment. Sorry.

CO-CHAIR JEFFRIES: But the reason I ask about that is because we had someone like that who had heart failure, got a VAD, developed renal failure, had a heart/kidney transplant.

DR. J. JACOBS: Right. So, we're not discussing -- if they approve what I'm counting Marshall on to make them approve, one of the things is the structure indicators that talk about denominators.

And the denominator for -- the denominator that they track is pediatric

congenital heart operations. There's a whole, big definition of what's included and excluded which the STS has published in peer review literature in the Annals of Thoracic Surgery.

And that includes open heart surgery on bypass, it includes cardiac operations on off bypass, and other operations based off bypass like coarc.

It excludes ECMO and VAD. And the only way ECMO and VAD plays a role in is if it's done in a patient who's already had an operation, can't come off bypass and who's put on ECMO or VAD.

But primary ECMO or primary VAD are not included in this denominator according to the definitions that they'll discuss over there and the structure indicators.

Now, what the STS does, and you know this, it approves operations, CPT/no CPT in cardiovascular, ECMO, VAD, thoracic minor procedure and others. And all it included here is CPT/no CPT in cardiovascular. And

that's where those codes came from.

CO-CHAIR JEFFRIES: So, any recommendation?

DR. MAYER: Approved.

DR. LOPEZ: Second.

CO-CHAIR JEFFRIES: So, we went through 16. And so the next one is 17.

DR. MAYER: That's me, I think.

CO-CHAIR JEFFRIES: Yes. Surgical re-exploration.

DR. MAYER: Let me just -- okay.

We voted yes on the pacemaker, right?

DR. MAVROUDIS: Yes, we did.

DR. MAYER: The arrhythmia measure?

DR. MAVROUDIS: Yes, we did. Yes. Yes, we did.

DR. MAYER: Okay. Seventeen, that's me, right?

CO-CHAIR JEFFRIES: Yes.

DR. MAYER: Okay. So, this measure is to determine the percentage of patients

undergoing pediatric and congenital heart surgery who require postoperative unplanned surgical re-operation excluding re-exploration rate for bleeding and delayed sternal closure.

The numerator is simply that. The denominator is the denominator of all the patients having the described operations.

The exclusion is for -- probably the most common of the things that would require patients going back to the operating room without a so-called structural defect is bleeding after the operation requiring re-exploration. And that's been proposed to be excluded from this measure, so that this measure is directed at trying to measure the number of patients who have to go back to the operating room for a residual defect for a previously unidentified defect prior to their operation that requires surgical re-intervention.

I think this is, again, an important variable. It sort of assesses, if

you will, technical performance of the operation. Although, it also assesses whether a complete preoperative diagnosis has been made as well, since that can certainly be an indication for re-operation.

I think you could have an argument about whether going back for bleeding fits in this category or not. It is tracked certainly within the database, so -- but I think the implications might be a little bit different particularly since -- particularly in small children, you know, we induce coagulopathy just by going on bypass. And particularly as the time on bypass gets longer, the bleeding in general tends to be worse.

So, I think I understand the rationale and would be in agreement that that's okay to exclude the re-ops for bleeding and one could consider, I suppose, proposing that as an additional measure although I'm not sure that that's necessarily that valuable.

This is certainly, I think, easy

to track, would be easy to report. I don't think it's hard to acquire the data. It's pretty obvious when you have an event that takes you back to the operating room.

And the only other issue that came to my mind was whether -- and I don't -- and this is -- I don't quite know how to deal with this, to be honest with you: the patients who after their initial operation might have something else done in the catheterization laboratory to deal with a problem that was not adequately dealt with at the time of surgery or not understood prior to surgery. That certainly has happened.

So, I'm not trying to rewrite the thing, but there probably would be someplace, maybe in the future, for trying to get at this issue about sort of broadening this to make re-intervention during the same hospitalization because then it would include both the things that were done in the cath lab as well as in the operating room.

DR. MAVROUDIS: You raise a very good point, and that is closing a residual VSD through the catheter or through an operation.

Let me think about that.

DR. MAYER: I think I'm going to look something up before I speak.

CO-CHAIR JEFFRIES: I agree. I think it's important. I think if you have this sort of measurement and in some ways that encourages people to use interventional techniques to deal with problems which may or may not be the right way to --

DR. MAVROUDIS: Correct.

DR. MAYER: Although, to be honest with you, I'm not sure that that would actually -- I have a hard time imaging that that would influence my decision making, but, you know, I've tilted at windmills many times in my life here.

So, I may not be the right reality check on this.

DR. JENKINS: Guys, what about the

opposite, the paper that you and I wrote where you actually explain the terms rescue procedures for going back to the operating room just to try to salvage something minor that we found out in our death series was not that uncommon in the lab, but also in the OR.

DR. MAVROUDIS: Yes.

DR. JENKINS: Are you giving credit, bad credit --

DR. MAVROUDIS: Yes.

PARTICIPANT: You know, you could argue that hey, this kid has got a residual two-and-a-half-long shot, go back and fix it. No, let's give him a cath probe.

DR. MAYER: Right. Well, that's the other possibility is, what do you do with residual problems?

I mean some of the work that Emile has done is sort of looking at these technical outcomes. Scores, if you will.

Might be something to consider in the future. I think, given what we have now

here though, I don't know how to -- I'm not sure I know how to clean this up.

DR. MAVROUDIS: Given what we have now and what we can track at least in the database, because we don't have catheter dimension, I'm not sure that I would include this as an indicator.

DR. J. JACOBS: So, now I've got enough information in front of me that I can respond.

DR. MAVROUDIS: Okay.

DR. J. JACOBS: First of all, the STS database does track both unplanned cardiac re-operation during a postoperative or post-procedural time period and unplanned interventional cardiac catheterization procedure during the postoperative and post-procedural time period.

So, both of those are in the STS database. Okay. And we can use our database to track both operations and interventions.

This metric, as it stands now, was

written just to track unplanned re-operations. That may or may not be the best thing.

For some reason, we made that decision to just track the unplanned re-operations and not unplanned interventions, but the database does track them both.

The other interesting point that I'd raise here is that clearly an unplanned cardiac re-operation or an unplanned re-intervention adds morbidity.

And if one was trying to come up with how much morbidity postoperatively did the patient suffer from, these would be things that would contribute that.

But that doesn't necessarily mean it's going to be the best-quality indicator because if we put the --

DR. MAYER: No, I think it more reflects on the initial operation and the pre-operative understanding of what's --

DR. J. JACOBS: That's all agreed. And, therefore, tracking it to keep track of

how much postoperative morbidity a patient has after an operation makes sense, because it depends on exactly what you just said.

Making it a quality indicator, though, may be associated with a problem that it disincentivizes people to intervene on things that need to be intervened upon.

DR. MAYER: Well, but you can make that argument really about all of the outcomes measures, right?

DR. J. JACOBS: You can, yes.

DR. MAYER: I'm not taking this case on because the risk is too high and it's going to make me look bad.

DR. J. JACOBS: Right.

DR. MAYER: I mean it's the same thing.

DR. J. JACOBS: So if we can swallow that, I don't see any problem with it with the exception of the fact that -- do we want to make it say unplanned re-operation in interventional cardiac catheterization

procedure, or do we just want to make it unplanned re-operation.

The database can handle both of those without modifying the database at all. And I don't feel strongly either way, but whatever the group would go with, we would be able to support from the database.

DR. MAYER: And I think they're both important.

DR. J. JACOBS: And that's the reason why we --

DR. JENKINS: Calling one collateral.

DR. J. JACOBS: Right.

DR. MAYER: No, no. But the question would be why they got to the cath lab.

DR. JENKINS: You're saying the fact they went is not good news.

DR. MAYER: Right. I mean there was usually --

DR. JENKINS: You were the one who

taught me about rescue procedures. Re-ops for technical difficulty. I mean we spent a year working that out because we found a lot of them.

DR. MAVROUDIS: You can't possibly leave this the way it is for just surgery and expect that to be a good indicator. Can't possibly. It has to include surgery and cath intervention. It has to.

DR. J. JACOBS: And that's doable with the database.

DR. MAVROUDIS: Has to.

CO-CHAIR JEFFRIES: Do you mean it needs to be in the same measure or two measures?

DR. MAVROUDIS: Well, two measures would be better because then you can weed it out. You can tease it out.

But you can't have just one.

CO-CHAIR JEFFRIES: Because I think the morbidity is associated with a different one

DR. MAVROUDIS: Well, maybe.

CO-CHAIR JEFFRIES: Or we don't know if they're different.

DR. MAVROUDIS: I mean just for the uninitiated here, I would give my little sermonette, right, that the best predictor of a smooth, postoperative course is the anatomic integrity in the repair.

And so I mean it's as simple and as complicated as that.

DR. MAVROUDIS: And he went to Yale.

(Laughter.)

DR. MAYER: So, I do think that these going-backs whether it's to the cath lab or to the -- I mean, that's really what we're testing here is both how good were the pre-operative processes to identify everything that needed to be dealt with, and the intraoperative processes of dealing what it is that we -- did we deal with what we're supposed to deal with in the operation.

So, I mean I don't know. I think either way is fine. And whether it's one measure or two, I'm not sure the -

DR. MAVROUDIS: We need them both.

DR. MAYBE: Yes. But I think we should capture them both, to be honest with you.

CO-CHAIR JEFFRIES: I think I'd like to capture them together.

DR. MAYER: Okay. I don't --

DR. MAVROUDIS: No, wait. Why did you change your mind?

CO-CHAIR JEFFRIES: Because taking what's stated here, I think my natural inclination, my experience, has been to say that going to the cath lab is better, but I don't think that's -- I don't think that's true.

And I think if you put a measure which says cath and surgery re-operation, then the people who feel like cath is better, they say oh, well, look, we don't do any re-op

surgical, we do all interventional.

But I don't think we know enough to know which is better. So, I think at this point until we know which is better, we shouldn't have it alone.

DR. HINKLE: Cast a broader net. I would agree at this point.

DR. MAVROUDIS: If you put them both -- if you capture them both, you'll know which one is which anyway.

CO-CHAIR JEFFRIES: I mean you can talk. This discussion --

MS. GALVIN: I just have one question. So, what about the patient who goes back to the cath lab or the OR multiple times? Is it one even or is it multiple?

CO-CHAIR JEFFRIES: That's a good question.

DR. J. JACOBS: So, just like in Indicator 12, we said it was an all or none phenomenon, here we said percentage of patients, not --

DR. MAYER: Yes, I agree.

DR. J. JACOBS: Either you have a smooth postoperative course, or you got some badness and you go back and you get credit for it. And then after that, go back as many times as you want. Just get it right.

(Laughter.)

CO-CHAIR JEFFRIES: And so, what are we going to do? Are we all --

DR. J. JACOBS: Add re-intervention and keep it as one metric.

DR. MAYER: So, we'll put in here under the scientific acceptability part, right, this would be the --

DR. J. JACOBS: The committee felt that it would be important to make this re-operation and re-intervention and the metric developer agreed.

DR. MAVROUDIS: Does that end this discussion? Should I make a motion? I'm the motion maker here.

DR. HINKLE: Second.

DR. MAVROUDIS: I didn't make it yet.

DR. HINKLE: You said you were the motion maker.

DR. MAVROUDIS: Well, okay. I make a motion.

DR. HINKLE: We're in Washington, you know.

DR. MAYER: Those were my thoughts.

CO-CHAIR JEFFRIES: And usability?

DR. MAYER: I think these are easily countable and interpretable events, it seems to me. So, I think it's fine. It's certainly feasible to capture the data. There's no question about that.

All right. So, let me just see if I can translate this into something that makes sense.

CO-CHAIR JEFFRIES: So, there was going to be a suggestion that intervention is added? Is that --

DR. MAYER: Yes.

DR. MAVROUDIS: And he has acknowledged that.

DR. MAYER: Yes. I think that that's a good idea.

DR. J. JACOBS: I'm honestly not sure why it wasn't there.

DR. JENKINS: You're the chair.

DR. MAVROUDIS: I'm not.

DR. JENKINS: No, I know.

DR. J. JACOBS: That's why I love this guy.

DR. MAVROUDIS: I make the motion.

DR. HINKLE: Second.

CO-CHAIR JEFFRIES: Eighteen.

DR. MAVROUDIS: Now, this is the STS -- this is the --

DR. J. JACOBS: This is the STS' metric of stratification.

DR. MAVROUDIS: Yes. So, this metric of stratification is basically allows for the stratification method to be picked out by -- or to be selected by the program to be

one of three.

And that is RACHS, Aristotle or the STS-EACTS morality levels. So, it doesn't say that the test has to be one of them, it just says it has to be one of the three, and then you comply with that part of it. It doesn't say that it had to be one -- specifically one in exclusion of any other.

The numerator is the number of patients who undergo pediatric and congenital heart surgery. And the --

DR. J. JACOBS: And died.

DR. MAVROUDIS: And died, yes. And it's prior to hospital discharge or within 30 days of the date of surgery, whichever is longer.

The denominator is the number of cardiac index operations at each level of complexity stratification.

Of some note here is that the STS database gives in a report the stratification model for both RACHS and Aristotle in its

system with the corollary that it does not include the RACHS expanded function, shall we say -- if I'm saying this wrong, please let me know. Okay.

The STS database does not include the expanded RACHS, which I call the mini-comprehensive score by adding prematurity, age and multiple operations.

Is that correct? Did I get that right?

DR. JENKINS: What's in the STS database now with the high categories of RACHS.

DR. MAVROUDIS: Right. And it's not the one that --

DR. JENKINS: It's not a risk model.

DR. MAVROUDIS: Yes, it's not a risk model. Right.

Now, what this does, what this indicator does is that it allows for a broad scope of what people want to use.

And the reality of the world is that different programs use different risk stratification models or complexity stratification models.

And it's no secret or it shouldn't be any secret to anyone. This debate has been a hot and heavy debate in the literature, multiple papers have been written on it.

It's not my intention to say which is better, which isn't. That's not the purpose of this discussion.

The purpose of this discussion is to determine whether it's okay to have one of three models that would satisfy the compliance with this indicator.

DR. JENKINS: Three types of categories. They're just different categories.

DR. MAVROUDIS: Different categories, yes.

DR. JENKINS: None of them are really models.

DR. MAVROUDIS: Okay. They're not --

DR. JENKINS: In a mathematical sense.

DR. MAVROUDIS: In other words, you're talking about Aristotle, RACHS and STS-EACTS.

DR. JENKINS: They're just categories.

DR. J. JACOBS: Three methods of risk adjustment, none of which are formal risk models.

DR. JENKINS: They're all fine category.

DR. MAVROUDIS: Okay.

DR. JENKINS: By the Aristotle category, by the new STS categories or by RACHS.

DR. MAVROUDIS: I think that this discussion we're having is an important one because it's not my intention to skew one thing to another.

DR. JENKINS: It was just the term model. Where to me, that means a mathematical --

DR. J. JACOBS: It's a stratification.

DR. JENKINS: Stratification.

DR. J. JACOBS: Three tools of complexity stratification.

DR. MAVROUDIS: Right.

DR. JENKINS: Yes. That was the only point I was making.

DR. MAVROUDIS: And going further, I guess we can take it a step at a time that the first one is to say whether this is an important issue or not, correct? Importance.

CO-CHAIR JEFFRIES: Correct.

DR. MAVROUDIS: And so what they -- from my point of view, the important part of this is that it takes advantage of the status quo. The reality of the world is that some centers report one way, other centers report in another way.

Against that is the idea that there are people out there, users out there, industry, et cetera, et cetera, who would rather have one model. That is to say one - not model. Excuse me. One way of risk stratification.

I think that's probably premature because already we have Aristotle developing Aristotle complexity score, RACHS going from RACHS-1 to RACHS-2, and now we have the EACTS-STS - or the STS-EACTS risk stratification scheme which is based on actual empiric data, where the other two are still, in some respects, based on the Delphian principles of expert opinion.

So, I think that -

DR. JENKINS: Actually, RACHS was based on both; adjustment and empirical data.

DR. MAVROUDIS: Okay. And that empirical data comes from what?

DR. JENKINS: The two large data sets that were used to derive RACHS. One

administrative and one prospective --

DR. MAVROUDIS: Which ones are the administrative? Tell us about that.

DR. JENKINS: In the derivative of RACHS, the empirical data to inform the process came from two large administrative data sets in two states and from the Pediatric Cardiac Care Consortium prospectively collected data over a several-year period.

DR. MAVROUDIS: Okay.

DR. JENKINS: So it was derived both by judgment and empirical data.

DR. MAVROUDIS: Thank you.

And so the point here is, is that do we as a committee say okay, we're going to pick one of these, or do we say let the development continue and that we would use as an indicator that it's okay to use one of these three systems as long as you are tracking some kind of risk adjustment?

DR. HINKLE: All right, so let me ask, I was the secondary on this. Let me ask

a question. I think it might be on the usability standard here. It sounds like what you're describing, these three different risk adjusters, you've got vanilla, to some extent, chocolate, and strawberry.

DR. MAVROUDIS: Except the strawberry, which is the last one, the STS-EACTS, is based on 80,000 cases and it -

DR. HINKLE: That's important now.

DR. MAVROUDIS: Yes.

DR. HINKLE: So I don't know if we can debate the value of each of those three risk adjusters, but you know where I'm going with this is that I would say operative mortality is probably of all the standards we've talked to today, probably the most important to the outside world.

And so now we've got - so we take that and now we have confused it with three different - unless they cross talk to each other, you can kind of be almost silent on it and just say well, believe us. These

complexities are all the same at all the different children's hospitals.

I would argue that the usability is one of the weaknesses of this standard is that that nuance - but I have to say that across the world of medicine as long as there's risk adjustment, then people get into what tool did you use to risk adjust it?

We say DxCG, somebody else says something else, and people are happy that it's at least risk adjusted. But this is such a complex area that you're into, you're not into general medicine or general surgery, that it seems like it might be important to have one, but I don't know what the gold standard is.

And then you'd have to - somebody -- the experts would have to go down to it - if you say there's 80,000 in one and 10,000 in the other, I'd pick the 80 -

DR. MAYER: I think, you know, there are several problems. Number one, even though there's a lot of cases, there - and

what I'm going to do is draw the contrast with the adult cardiac database.

The adult cardiac database, you've got three and a half million -

DR. HINKLE: That's your denominator.

DR. MAYER: - you've got maybe ten procedures, more or less, that are in there; coronary bypass, coronary plus valve, you know.

We got 80 or 90, so you take that -

DR. JENKINS: 200, actually. We have 200.

DR. MAYER: Well, anyway. It's a lot, right?

It's a bigger - the smaller number of cases is spread over a much larger thing. So just that all by itself makes it much more difficult to come to a strictly data-driven risk model.

And that's why in at least two of

the iterations of trying to get some handle on how to risk adjust this, this element of expert opinion, general consensus stuff, that sort of crept into - not crept. I mean it was intentionally added because it had to be added. There was no other way to get at this.

So I think - I don't know. I mean Kathy and others know more about this than I do, but I'm not quite sure we're all the way there that we know what the gold standard is.

DR. HINKLE: Right.

DR. MAYER: And so in the absence of - so then the question becomes do we pick the best of the lot knowing that it's probably going to change anyway, or do we allow a couple of, two or three different ways, each of which has been tested?

There have been a few comparisons. There's a comparison between the Aristotle and the RACHS system. The area -

DR. MAVROUDIS: So each time we're getting better and better.

DR. HINKLE: There's a sense - if one is picked, is there a sense that - right now I think what I read somewhere, that only out of 122 programs, 80 something reported to the STS.

And I assume that's - my assumption is that may be 90 percent of the patients. So we've got most of the patients. So the ones that aren't reporting, aren't reporting for some reason.

What you've alluded to here is the reason we have these three risk adjusters is the local environment probably just grew up with a particular -

DR. MAVROUDIS: Not exactly.

DR. HINKLE: Okay.

DR. MAVROUDIS: This is virtuous in every way. All three -

DR. HINKLE: No, I'm not saying it wasn't. I'm just saying for whatever reason. That's what you answered my question to is if you picked one, would you lose compliance with

- or would everyone just follow one? What is your thought on, you know, picking one would seem to make the most sense to me, but I don't know enough about the details of -

DR. MAVROUDIS: Well, first of all, let's just leave the idea of how you would pick it. Let's just leave that alone.

The STS allows now for the risk stratification, if you will, of both RACHS and of Aristotle. If you get that report back from STS, you have it. It's right there. So you use either one or use them both.

DR. HINKLE: Okay.

DR. MAVROUDIS: Now, soon we're going to have the new risk stratification scheme which is the STS-EACTS, which is based on empiric data. And when there's not enough empiric data in those small N groups, then Bayesian methods are used to give a reasonable statistic. And the C-statistic is the best from that in any of the - than both the other two.

So how are you going to pick it? Secondly, if you have it all together, why not keep it all and have it all? There's no reason to make the choice at the moment because what you really want is each center, you want them to be able to risk adjust their data with volumetrics as well. And the STS database does that for you.

Now, I don't know, for instance, and this goes back, this will go to 21 now, how much extra - what you have proposed, will the STS database the way it is right now be able to arrive at that without any further update -

DR. JENKINS: Are you talking about the SMR measure?

DR. MAVROUDIS: Yes, yes. The SMR, yes. Whatever you want.

DR. JENKINS: Maybe I could just give my perspective because this is -

DR. MAVROUDIS: Because it's all the same anyway.

DR. JENKINS: - a very important topic. I think that as already stated and I showed up here today, that I do believe that the SMR with the full models is actually -- has advantages over the bicategorical adjustment in various ways to give an overall measure to improve the risk adjustment.

Having said that, in terms of these categories, they all work nearly about the same as the five categorical core procedure adjustments. And they have various strengths and weaknesses. The biggest strength of the Aristotle system is it's the standard in Europe that all the European systems have really gone to. When you're looking at comparability between Europe to the US, that's the clear one that is really to be used to make those empirical.

RACHS has the advantage of being by far the most flexible. It has that advantage.

The STS empirical categories are

the best empirical evidence coming from one data source, the STS, which is not a population-based data source. It's a voluntary data reporting system.

And those are the strengths and weaknesses, and that's why the world isn't picking one or another or another. There's a variety of reasons why, depending on your study, you choose one or the other.

So I actually think that the STS developers in their wisdom are trying to get into this game and get people into this game saying use one, okay, and not trying to put a line in the sand now that really forces a winner for the bicategorical. So that's my personal opinion.

DR. MAVROUDIS: Well, that was very good up until the STS wanting to choose one.

CO-CHAIR JEFFRIES: That's not what she said.

DR. JENKINS: I didn't -

DR. MAVROUDIS: Well -

DR. JENKINS: I'm saying that the advantage --

DR. MAVROUDIS: Oh, oh. I see.

DR. JENKINS: What did I say? An individual center may have a reason for choosing RACHS or choosing Aristotle or choosing the empirical evidence from STS if that's their core base for -

DR. MAVROUDIS: This is what I wanted to come to conclusion to that in fact that each center may want to choose one or the other and that this indicator, this one over here, this 18, allows for that. Allows for each one.

But if we choose 18, then by conclusion or by necessity you would have to reject 21 because 21 says that we will now use the RACHS SMR system exclusively.

DR. MAYER: That's not what -

DR. JENKINS: Any more than I might not choose renal failure in Boston because I think -

DR. MAVROUDIS: But maybe you could explain that then because -

CO-CHAIR JEFFRIES: This one is really looking at unadjusted mortality, but then stratified by particular levels of complexity. 21 is risk adjusted mortality.

DR. JENKINS: It's giving an SMR for a center.

CO-CHAIR JEFFRIES: Right. So, it's risk adjusted mortality.

DR. JENKINS: You could do an SMR with Aristotle or with the empirical categories. You just haven't yet, so that's why RACHS has been used as an SMR. That's what we're proposing.

DR. J. JACOBS: So the last version of the STS database report produced an SMR with observed and expected mortality and a risk adjusted mortality with a model that was created fusing information from both RACHS and Aristotle, and also adding in the patient's weight and age and length of pre-operative

hospital stay. And that proved that, A, we could do it, and, B, that we could do it using RACHS and Aristotle.

I would think having looked at all this, somehow we have to come up with well, what are we going to do and how are we going to operationalize this? It seems to me that first of all, 18 is a good indicator in that it gives people the choice of using any of the three metrics and reporting it stratified in the categories. So that's a form of risk adjustment through complexity stratification, but it doesn't create for report any risk adjusted mortality.

My solution to this dilemma that we're faced here is that we would implement Number 18, and then we would also implement Number 21, but we would make this slight revision that the adjusted ratio of observed to expected in-hospital mortality can be done with any of the three systems because the STS can do that with any of the three systems

within the database, so you can make 21 apply to all three systems just like you apply 18 to all three systems.

What that would then allow is that Number 18 would mean you report your results using complexity stratification through any of the three ways, and Number 21 would mean that in addition to that you would report using any of the three complexity stratification tools or risk adjusted mortality from that.

When we do that, it would be very easy then to go back to the program which is DCRI and say okay, we want you to spit out adjusted ratio of observed to expected mortality by not only RACHS, but RACHS by Aristotle and by the new tool they created, and to do it utilizing the full model of RACHS when they do it for RACHS, and utilizing the other variables when they do it for Aristotle.

DR. MAVROUDIS: Can that be done?

DR. J. JACOBS: That can be done easy. Easy.

DR. JENKINS: Yes. The only counterpoint that I would make to that, Jeff, and this is being a little bit of a measurement nudge, whatever the word is, being tight on measurement, is that the first model, the RACHS model has been used and validated to be done that way, and there are seven years of experience doing it that way, and the other ones are new. So you just have less information about their validity and reliability, but methodologically they're just multi-variant models incorporating additional variables, and that's what they are.

DR. J. JACOBS: So I think my biggest principle is that when it's all said and done, we leave here treating these three systems the same way within the STS database and within the quality indicators. I don't think that our group should be the group that tries to legislate which one is better or worse. There's piles of publications that argue on either way, and I don't think that

there's any solid evidence one way or another.

We could talk about the timeline of how things have been around and Kathy is correct that RACHS has been around longer than Aristotle. But it's also correct that Aristotle has been in the STS database for six years more than RACHS.

DR. JENKINS: No, I'm just talking about the application --

DR. J. JACOBS: Understood. Understood.

DR. JENKINS: If the question is does STS want to propose an SMR model for Aristotle and empirical data, I certainly don't have any problem with that. That's not something I'm going to propose, but it's certainly something one could --

DR. J. JACOBS: Right. So my proposal would be that Metric 18 allows the utilization of all three stratification tools. Metric 21 should just say that you need to report an adjusted ratio observed to expected

mortality using any of the three stratification tools.

DR. HINKLE: So I'd like to ask a simple question again. So it sounds like what I've heard from all of you is that the three tools will in no way mislead the public. They're equal across the mortality rates that you're looking at by complexity.

DR. MAVROUDIS: No, they're not equal because - they're not equal because some of them are better than this than others, and others are better than this than others. So they're not equal.

Where we are - give us credit. We're being nice to one another. We don't want any bad feelings about this or anything like that, and that's why we are trying to find the common ground. So they're not equal.

DR. HINKLE: I mean if they're publically available, is it going to do any harm, you know?

DR. MAVROUDIS: No, no.

DR. HINKLE: I mean the variation in those is probably minuscule -

(Simultaneous speakers.)

DR. HINKLE: Okay.

DR. JENKINS: For the categories, for sure, no, because everybody's seen that and they've seen the areas under the ROC curves based on that, and they're all in the same range -- for adding the additional variables, they're in various stages.

DR. HINKLE: Yes.

CO-CHAIR JEFFRIES: No one is going to be able to game the system by picking one versus -

DR. HINKLE: Right. That's what I was trying - I'm trying to be polite to get there, but -

DR. JENKINS: You won't be able to compare an SMR with one compared to the other.

DR. J. JACOBS: I don't think that that would be the goal of - that's just like we can't compare the mortality of RACHS-1

versus Aristotle 1 -

DR. JENKINS: That's correct.

DR. J. JACOBS: - within that level. That's not the purpose of it.

I think Kathy could make a strong argument that use of adjusted ratios of observed to expected mortalities has been around longer with the RACHS system than it has with the Aristotle system, which is true.

The other argument could be made that the number of operations classified with the RACHS system is 86 percent in the STS database where there's - I'm sorry, 84 percent compared to 96 percent with Aristotle.

So, like I said, you can argue strengths and weaknesses of each system, and we can sit here and do that for hours. But the truth is, I think, as long as we create a set of indicators that allows for the utilization of all of these, I think we're supporting - what my ultimate goal is that eventually they're all going to end up as the

same tool not by a group of people around the table saying that's the way it has to be, but by eventually that's where the science will lead us.

CO-CHAIR JEFFRIES: So if someone wants to -

MS. HINES: I just want to get a clarification because these are being considered for public reporting. I've heard, and maybe I misunderstood, that RACHS and Aristotle and STS cannot be compared.

DR. JENKINS: To each other.

MS. HINES: Right. But I mean -

DR. JENKINS: -- compared if there were ten centers that all reported and either of those --

MS. HINES: That's not what would happen. When we're talking public reporting, we're talking -

DR. HINKLE: Public reporting.

MS. HINES: - public reporting.

DR. HINKLE: I think what they're

saying if I can maybe elaborate -

MS. HINES: Okay.

DR. HINKLE: - I think where I'm at, what they're saying is if it's Seattle - let's say Seattle Children's is using a risk adjustment. And the public goes in and says wow, look at that one. And then they go look at the Boston Children's Hospital maybe using a different method. And I think what I'm hearing is there's probably not much difference across - I mean it's not going to be -- the mortality rate -- because of the tool that's being used.

DR. J. JACOBS: But you have to do it within the tool that you're talking about. So what the STS does -- participation in the STS database means that your outcomes are analyzed with all three tools because -

MS. HINES: But only one should be used for reporting.

DR. J. JACOBS: But how do you -

DR. HINKLE: Why is that?

DR. J. JACOBS: Why is that?

MS. HINES: Well, I'm just saying if you -

DR. JENKINS: You're saying any of the three could be used.

CO-CHAIR JEFFRIES: But then they have to be able to be compared against each other.

MS. HINES: Right, right. If it's apples, oranges and grapes, they're not -

DR. JENKINS: - the whole group doing apples, and then you --

MS. HINES: Public reporting is not going to be apples to apples. Then in my mind, that makes this a quality improvement measure that can be used within a facility but couldn't be looked at at CMS or -

DR. JENKINS: If CMS came in and they just said pick one, and they randomly picked one of the three -

MS. HINES: Then that's what the measure would -

DR. JENKINS: Then that would be the measure.

MS. HINES: That's right. But that measure would not have three choices, they would just come in and say Aristotle, RACHS. And I understand what you're trying to do with giving someone three choices just to get them -

DR. MAVROUDIS: You're not giving them three choices, you know. We're not doing that. They've already made their choices.

MS. HINES: Well, to get -

DR. MAVROUDIS: We're not giving -

DR. JENKINS: You're saying any of the three are fine.

DR. MAVROUDIS: They're using them. It's different.

MS. HINES: But not for public reporting.

DR. MAVROUDIS: It's different. It's different. We are complying to them rather than them complying to us.

MS. HINES: But if it's public reporting -

DR. J. JACOBS: There's no scientific way to choose which one is better to use right now.

MS. HINES: Then in my mind it's not a public reported measure because -

DR. MAYER: But yet this is the measure that the parents are going to want to know more than anything else.

MS. HINES: But again -

DR. JENKINS: And this is the one the centers are using. This is the number one thing coming out of -

MS. HINES: But again, not apples to - I mean you've got -

DR. JENKINS: I'm not sure I agree with that.

MS. HINES: But that's what I'm hearing from you all. You're telling me that -

DR. JENKINS: No. We're talking

about two different things.

DR. J. JACOBS: So the STS I have been fairly involved with are public reporting efforts up until this point in time. Which as you probably know, were initially adult cardiac based on the coronary artery bypass grafting part.

And the task force that's doing that I happen to chair, so we've had a lot of talk about once that gets done, and our goal is to have that public reporting piece on the internet by May 15th, and I think we will.

Then we're going to try to look at well, what are we going to publicly report for adult thoracic and for congenital. And the discussions we've had for adult thoracic and congenital are preliminary but pretty good.

And what we're thinking about for the congenital database is that the outcomes from any given program can be reported in a very easily understood graph on the internet where you could go and say okay, here's

hospital A, and here's how they do with the RACHS system. Then you click it. And here's how they do with the Aristotle system, and you click it. And here's how they do with the STS system.

So our public reporting system would have a scenario in place where the parent or the referring doctor would be able to actually go to the internet and look and see how that hospital or how that surgeon, right now hospital, performs using any of those three systems. And then that guy could decide which one he wants to use to make his decision, but the public reporting metric will actually get any of the three.

And you just click one, two, three, and you see them all. That's why I think you need to treat them all as equals, and then the public actually gets more information.

MS. HINES: Well, and that's fine, and I'm playing devil's advocate because I'm

looking for holes in what you're saying because they will come up. And that's going to be something that you're going to have to be very clear about when you're writing because it's not - if this was a typical, say, CMS reporting, you can't do that. It has to be one thing. But if that's what your - if that's going to be a capability, then the -

DR. J. JACOBS: Well, that's our intent.

DR. JENKINS: It may change over time.

DR. MAYER: If I may say, we may not have found the holy grail in any one of these three.

DR. HINKLE: What you just described is a complex, I think, expectation to ask of a parent sitting in the pediatrician's office, you know, just looking and saying look at these three risk adjusters, these are the different performance around them and you need to be aware of how this

hospital -

DR. MAVROUDIS: They're so close.

DR. HINKLE: Well, maybe. So I'm just asking.

DR. JENKINS: So you're just saying that all of this is just one variable, the type of procedure, but we're talking about - that's why I was objecting to Gus talking about models because you guys were mentioning multi-variant models or something complicated.

It's one variable. What kind of procedure do you have? And it's a way of grouping together those procedures, grouping them together in one system. There's four categories in one, there's five in another, there's six which is functionally almost always used as five because there's very few in one category.

Okay. And so that's all it is. It's not adjusting for age or any other factors or complicated model. It's just that. So if you had a mother and you had a baby with

tetralogy of fallot, you would look up whatever category that's in in Aristotle and probably be focused in on that.

If you were looking at RACHS, it would be in Category 2. If you were looking at STS, I assume it would also be in Category 2, right?

DR. J. JACOBS: Correct.

DR. JENKINS: And in the fine print of the smaller volume procedures based on how and when they were derived, there may be some variation about where your more unusual procedures fell.

Okay. But a general distribution of cases, how many are in each category, is it across the bar, so the categories would be relatively standard.

DR. HINKLE: So one other question. You said Europe went with Aristotle. Is that all through Europe?

DR. MAVROUDIS: One of the things about - Aristotle was developed by - not by a

Greek, but by a Frenchman. And he was very influential and he's moved here to - he moved here to Denver, now he's in New York.

Anyway, he was the sort of vision behind this kind of Delphian system, you know, based on experts' opinion.

DR. JENKINS: And that was purely by judgment.

DR. MAVROUDIS: Yes.

DR. HINKLE: So was there a process in the European Union they went through -

DR. J. JACOBS: What happened was -

DR. HINKLE: I'm just trying to figure was science -

DR. J. JACOBS: So there was a panel of experts of North Americans that developed RACHS with 11 people. And then there was a panel of experts that was set up to develop Aristotle.

DR. JENKINS: In two large data sets.

DR. J. JACOBS: Right. And then

the panel of experts that developed Aristotle had 50 people which were from Asia, Europe, North and South America. So that's why I think that got a little more buy-in in Europe because they were involved in the development of it, as were the Americans. But they're both valuable tools, and I don't think that there's any realistic way that we could choose one over the other.

DR. MAYER: I think the other thing that Jeff said that sort of might have gone by here a little bit is that since ICD - since RACHS is based on ICD-9 diagnosis and procedure codes, you know, it's hard -- because the ICD system hasn't kept up, to be honest with you. There's a population that doesn't fit very well in -

DR. JENKINS: That's not true though, John. Actually, RACHS includes all of the coding frameworks, it just can be used in an ICD-9 framework. It wasn't only for an ICD-9 framework.

DR. MAYER: Well, then help me understand what -

DR. JENKINS: So that's where there's -

DR. MAYER: Is what Jeff said -

DR. JENKINS: - been a real misunderstanding here. The idea that RACHS can only be applied and was derived from ICD-9 codes is not true and was never true.

MS. HINES: You know, I think one thing - we don't' have to choose one or the other.

DR. MAVROUDIS: That's what we're trying to say.

MS. HINES: Okay. Well, it sounds like -

DR. MAVROUDIS: Actually, to be fair, this came up because of you.

DR. HINKLE: I mean you made a statement which is a goal in the United States to have a national standard. Otherwise -

DR. JENKINS: And quite frankly --

is because AHRQ came forward with a RACHS-like model and it's exclusively an ICD-9 application and did not use the original RACHS methodology. And that's what in your PDI -- whatever it is.

MS. HINES: Well, it sounded like -

DR. JENKINS: And we actually like the real RACHS. I personally like the real RACHS better than what AHRQ came up with in their application.

MS. HINES: It sounded like you were trying to -

MR. HARDER: I think what Lisa is saying, Lisa is saying that there's councils. There's a consumer council, there's these other councils that are going to have to grasp this discussion.

DR. J. JACOBS: Right.

MR. HARDER: So just be prepared.

DR. MAYER: No, no. But I think the -

MR. HARDER: But this is the -

DR. MAYER: Although I recognize that that's the issue, right, the question is, is how much does that drive this versus how much does the people who actually know a lot about this drive what happens. And I think that's the tension that's in effect here right now.

DR. J. JACOBS: And I think the people who have published the most about this and researched the most about this would agree that we should not try to choose one over the other and just include them all in these metrics and treat them as equals. But the problem is selling that to everybody else, I think.

DR. HINKLE: Yes, so help me with the process here. So we wouldn't want operative mortality removed.

DR. J. JACOBS: Right.

DR. MAVROUDIS: Well, we're not going to remove operative mortality. What we're debating here is stratification.

DR. HINKLE: Well, I know. But if this is going to move -

DR. MAVROUDIS: Yes.

DR. HINKLE: Let's say we approve this, it moves on to another process up the chain here at NQF where it's going to start bumping more against consumers, and, I mean, that's where it could be. We would not want to lose this.

DR. J. JACOBS: A consumer group that's not as literate in these topics as we are, just like we're not as literate in consumer topics as they are, comes back and says well, we have to choose one, we can't have three.

DR. HINKLE: No, I don't think they'll say that. My guess is -

DR. MAVROUDIS: Well, you'll have trouble with compliance then. You'll have trouble with compliance.

MS. HINES: No, I think what you're going to - the consumers -- are going to want

outcomes and they're going to want what's good for the kids. So that's in both favors.

Sitting back here and listening at you all go - you know what you're talking about. It very much sounded like it was going to be one or the other. So what I'm trying to do is message if you want to put or if you surely put both of these through, then what we need to do when we do the comments for it to move forward is to say why each is important in its own right.

CO-CHAIR JEFFRIES: Why each measure is?

MS. HINES: Yes.

CO-CHAIR JEFFRIES: So -

MS. HINES: So you could - both could go through, they're both going to be time limited.

DR. JENKINS: Are you talking now about the SMR and the categories or the three kinds of -

DR. HINKLE: 18 and 21.

MS. HINES: 18 and 21. The measures.

CO-CHAIR JEFFRIES: So I think that's what we should actually --

DR. HINKLE: Move for that.

MS. HINES: So I think that could be important to show why both should go forward in the testing -- we'll remove the time limited, if that's what you're truly saying.

CO-CHAIR JEFFRIES: I don't think we should - I guess I wouldn't - I don't think we should spend time comparing 18 and 21. Let's just talk about the merits of each one and then we'll report on the merits and move forward that way.

So I think -- so for 18, Gus, did you have anything else you wanted to -

DR. MAVROUDIS: No. I think that you can all remember what I said. I'm comfortable with making that motion. I think that it's inclusive. To use the word, I think

it's ecumenical.

So I think that that will work. And further, it will allow all the people who are using them now to continue to use them and without any acrimony of any kind and so forth. So the STS will give the reports out. And in the reports there will be the RACHS stratification and the Aristotle stratification. And sooner or later the STS-EACTS stratification as well.

And so I think that if we treat this as an ongoing development - as a motion, a plan in motion, then what Jeff said is going to happen. Sooner or later one of these will go forward and then there will be some kind of a meeting of the minds of one thing or another. And then in a year or two, three, they'll have one probably. And then that will be a good one, it will be a great one. It will be based on good data and the rest.

So I'd like to make that motion that we approve this, 18. Yes, and we can

have discussion

DR. HINKLE: Second.

DR. MAVROUDIS: You know what I'd like to do? I would actually love to hear you two. You may not be voting, but I certainly would like to hear your opinion.

DR. JENKINS: I already stated mine.

DR. MAVROUDIS: Yes. Okay. Motion made.

DR. HINKLE: I second. I think the conversation was good. It helped me at least move to a place I was stuck on.

And I think the measure, the operative mortality is so critical to the public going forward and the nuances within. And people are just all over the internet. Maybe these patients are going to be driven to find granular and more granular information.

They're going to be probably looking to figure out these three things, what do you think, and they're going to have to

search out the pediatric cardiac surgeon in their community to help them, maybe, with this, and that's healthy.

That's sort of where I've - so I think I'm in favor.

DR. MAVROUDIS: So motion made and seconded.

CO-CHAIR JEFFRIES: Okay. All right.

DR. MAVROUDIS: Sylvia, you don't have anything to say?

DR. LOPEZ: No, I agree.

CO-CHAIR JEFFRIES: Why don't we talk about 21 since we're well into that discussions?

DR. MAVROUDIS: Well, unfortunately I'm the lead on that as well.

CO-CHAIR JEFFRIES: Yes.

DR. MAVROUDIS: What I did was I tried to prepare all three with as much information as I had. All three meaning the SMR associated with RACHS or the RACHS SMR,

Aristotle and STS-EACTS system.

And there have been papers written about this. And I looked at the C score. What is it called?

DR. MAYER: C statistic.

DR. MAVROUDIS: C statistic. And the C statistic you can - they're very close. All three of them are very close. It turns out that the EACTS-STS seems to do better because it's based on 80,000 patients - not 80,000, is that right?

DR. JENKINS: Gus, can I just ask for a clarification?

DR. MAVROUDIS: Well, you could even do more than that.

DR. JENKINS: When you say you're comparing all three, I don't know what that means.

DR. MAVROUDIS: Right, right.

DR. JENKINS: Because the measure we proposed was the SMR based on RACHS.

DR. MAVROUDIS: I'm not comparing

the SMR in this one. I made a chart, and it did not compare the RACHS SMR. And 21 is about the RACHS SMR.

DR. JENKINS: I thought you were discussing 21.

DR. MAVROUDIS: We are.

DR. JENKINS: That's why I -

DR. MAVROUDIS: I know, but what I'm trying to say is that to try to get some understanding -

DR. JENKINS: But when you said you compared all three, I just don't understand what you compared it with.

DR. MAVROUDIS: I compared the C statistic on all three for their risk stratification.

DR. JENKINS: For the categories only.

DR. MAVROUDIS: Yes.

DR. JENKINS: Okay.

DR. MAVROUDIS: Yes, that's what I did.

DR. JENKINS: I just want to point out that the SMR that we proposed -

DR. MAVROUDIS: Is different.

DR. JENKINS: - is different.

DR. MAVROUDIS: No question.

DR. JENKINS: Okay.

DR. MAVROUDIS: No question. And I tried to make that known, too.

DR. JENKINS: Okay.

DR. MAVROUDIS: But what we're talking about for the SMR is comparing observed mortality and expected mortality.

DR. JENKINS: Based on five factors.

DR. MAVROUDIS: Right.

DR. JENKINS: Category across the four other variables.

DR. MAVROUDIS: Exactly. And those four other variables are part of another program, right, that you've -

DR. JENKINS: They're part of 21.

DR. MAVROUDIS: Right.

DR. JENKINS: They're the measure that we're proposing.

DR. MAVROUDIS: Correct.

DR. JENKINS: Those four other variables in the SMR.

DR. MAVROUDIS: Correct. We've talked about the pros and cons of all three so far. And this - if we put this in with just - just for RACHS SMR, then it excludes others - the other system which can be done. And it strikes me as not moving in the same direction as 18 insofar that it allows - that 18 allows all programs - the program to do whatever - pick whatever they wanted or to emphasize whatever they want.

And this one you're going to get dinged if you're a program, you're going to get dinged if you don't use 21. That is it say RACHS SMR calculation. So I would like to see 21 move in the direction - I actually would love to see that 21 be melded into 18 with the SMR being reported by all three

categories and not just RACHS.

In other words, make 18 not only risk stratification mortality, but also for SMR. And then each program would be allowed to use one of those three classifications or one of those three metrics.

DR. J. JACOBS: Or better yet the STS could calculate an SMR with each of the three metrics.

DR. MAVROUDIS: Yes. Right.

DR. J. JACOBS: Because it's been very hard for an individual program to calculate that unless they have their own biostatistician, and most of us aren't lucky enough to have that.

DR. MAVROUDIS: That was one of the things. That was one of the problems that I saw as a viewer, that -- let's just say, I don't know. Let's pick a place in California, a small place in California. They may not have the wherewithal to do it.

If Duke and the STS can get that

program and figure it out in that family of data, then it can be done there for all three categories and it will be there. And for the price of what you would pay for to have the STS database, you can have everything there at once.

And I welcome any discussion. I would welcome that we take 21 and instead of having it there all by itself and having it sort of in a pregnant pause elsewhere, to move that into 18. And then have the STS calculate the SMR for all three categories.

MS. HINES: That could be a research recommendation, but that leads us then to changing the measure.

DR. MAVROUDIS: I see. That's a problem, isn't it?

MS. HINES: And what we're doing is we're supposed to be looking at the submission form as it's submitted.

DR. MAVROUDIS: Okay. So, what you're saying is, is that -

MS. HINES: So you could -

DR. MAVROUDIS: - you either accept or reject it; is that what you're saying?

MS. HINES: Right.

DR. MAVROUDIS: Didn't we amend the one about interventional cath?

DR. J. JACOBS: Yes, we did.

DR. MAVROUDIS: Adding interventional cath into the re-operation?

MS. HINES: That was because you've got one measure developer that agreed to do it. You're crossing two measure developers in the -

DR. MAVROUDIS: Well, I don't know if we can agree to do it then.

DR. J. JACOBS: I would agree to add adjusted ratio observed to expected mortalities to Metric 18, doing it for all three, doing it exactly as described within Measure 21 for RACHS, and then doing it the same way, basically, for Aristotle and STS

Score. So that would be easy for us to do and that would make all of this work together.

MS. HINES: I'm just afraid -

DR. J. JACOBS: So I would support that.

MS. HINES: Right.

DR. JENKINS: I guess the issue that I would have - my understanding, Jeff, is that we don't right now have the additional variables in STS although they will be coming in soon.

DR. J. JACOBS: They'll be coming in in -

DR. JENKINS: So I don't think you can actually -

DR. J. JACOBS: They'll be coming in in five weeks.

DR. JENKINS: Right. And I think the reason the comparative papers did not compare the full RACHS model is because you didn't actually have the variables in the current version to do it that way, which is

why it was done differently with part of it, but not all of it.

DR. J. JACOBS: Right. So starting five weeks from now we're going to have all those variables and we're going to be able to do that. And the one thing I have to be fairly strong about is that it's very important to the STS that whatever we adopt, we adopt with the ability of the STS database to be able to do it.

And that's why all 20 of these variables were written so that participation in the STS database allows one to do these 20 things.

DR. JENKINS: Right, but we're at the -

DR. J. JACOBS: And I think that we can make number -

DR. JENKINS: - NQF so centers that are not part of STS -

MS. HINES: We're not driving toward making everything STS.

DR. J. JACOBS: I understand.

MS. HINES: So, I mean, we need to be really careful because we have 20 STS measures and -

DR. J. JACOBS: Right. No, I'm not saying -

MS. HINES: - one additional measure.

DR. J. JACOBS: I'm not saying that we should make a metric come into existence, that the only way to do it is to participate in the STS database. That's absolutely not what I'm saying. But what I am saying is that I don't want to put a metric into play that the STS database can't do.

MS. HINES: Well, and you're a measure developer.

DR. J. JACOBS: Right.

MS. HINES: And you're speaking as that.

DR. JENKINS: And I'm just saying that we have been able to do our measures in

various ways with various tools.

DR. J. JACOBS: From administrative data sets.

MS. HINES: Well -

DR. JENKINS: And other data sets, too. So my perspective would be that it would be wonderful if STS could be incorporated to do the full RACHS model.

What I'm objecting to and the reason I'm here is that AHRQ did this as a partial implementation of RACHS. Okay. And then saying it's RACHS, but it's not. It's something a little bit like RACHS. It's not the full RACHS.

They use different age categories. They use only the admin data application, not the broader uses and other kind of data and some other quirky things that were harmonized with something AHRQ was doing, but it wasn't the real RACHS.

I'm agnostic as to whether the models using Aristotle or the new STS

categories with the additional variables that are part of RACHS will work better or worse because I haven't' seen that analysis.

But I'm assuming it will probably be reasonable in which case SMRs derived as a result of adjusting is probably very reasonable.

But having never seen it, it's hard to endorse it. That's all I'm saying. I've never seen the validity, whether the changes in categories do or don't require the additional variables.

I've just never seen it because it's not -- I'm agnostic about an opinion about it.

DR. J. JACOBS: Where would a given hospital get this from?

DR. JENKINS: Where would a given hospital --

DR. J. JACOBS: Where would a hospital that doesn't have their own biostatistician be able to come up with an

adjusted ratio observed to expected in-hospital mortality?

DR. JENKINS: Jeff, we get calls all the time from people who use RACHS with biostatisticians who can use the coefficients from the model because people do it on pencil and paper. The database can do it. People have cranked it out with their kid. The algorithms are in the public domain.

DR. J. JACOBS: Administrative datasets.

DR. JENKINS: So, believe it or not, other people really actually are doing it with something other than their STS report.

DR. MAYER: So, wasn't there as proposed in one of the -- I mean didn't we hear about this a month or so ago where there was actually an intent to compare the data that was collected through these two different mechanisms?

I mean one of the underlying issues here is that the data that gets into

the administrative claims data gets acquired and entered by an entirely different mechanism than what happens with the STS data.

DR. JENKINS: Yes.

DR. MAYER: And there is a paper in the adult world from Massachusetts that suggests that there are significant discrepancies in exactly the same time period, three-year time period, between the data that went in and from the administrative claim side, and the clinical data that went into the STS database.

MS. HINES: Happens all the time in the ambulatory measures and hospital measures according to whatever --

DR. MAYER: Right.

DR. JENKINS: So, the validity of the administrative approach is simply based on the fact that the administrative codes are sufficient to categorize the patients well enough for about 85 percent of the case mix to yield an area under the ROC curve of

approximately .8 or seven years.

So, it's not saying it's the same or making a claim and saying that that's a validity claim about the use of the model as developed.

DR. J. JACOBS: The problem with that though is that that assumes that the classification was correct from the beginning using the ICD-9 codes. And what John is talking about is a very big issue that the CDC, Center for Disease Control, did a study comparing clinical and administrative coding. And that's also in this book here.

And unfortunately, their conclusion is analysis based on ICD-9 diagnostic codes of cardiac disease may have substantial mis-classification of congenital heart disease. Isolating the major defect is difficult and certain codes do not differentiate between variants that are clinically and developmentally different.

So, that's why the whole purpose

of pushing to use the clinical database like the STS database exists.

DR. JENKINS: Could be. Could be, Jeff. But it turns out there's sufficiently good to generate an area under the ROC curve that's actually quite reasonable.

DR. J. JACOBS: Right. If you assume that the actual diagnosis that that's been based on is correct.

DR. JENKINS: We're just using the big dataset. And that's what the mortality discrimination is coming out.

So, that's an admin database versus prospective database argument. But at the end of the day, those databases are more informative than one would imagine.

That although subject to repeated audits, actually at Children's Hospital of Boston there's ten to fifteen two source document audits of that database per month for the pairs.

So, your point is well taken. I

actually agree with you that prospective data is probably better. But at the end of the day, the codes are sufficiently robust to be discriminated.

And we're not proposing an SMR based on that. That's what AHRQ did last year. We're proposing it based on a variety of data sources.

CO-CHAIR JEFFRIES: Okay. Let's go through this measure by the points. So, go through the importance, which I think we sort of got through that. Mortality is clearly important here.

So, next is the scientific evidence.

DR. MAVROUDIS: Well, I'm supposed to be leading this. And if I'm supposed to lead on the scientific evidence of how good the measure is, I'm not so sure I -- I mean I've looked at this. I'm not so sure I can make a good statement on it because it requires a total understanding of

administrative data and how accurate it is.

It also requires a knowledge of the program that was used to include the four expanded metrics, which I don't think is going to be hard to understand, but there are papers that talk about mis-coding in administrative databases and how important this is.

Now, we probably use administrative databases all the time and that there are metrics to say that we might have one percent or three percent mis-coded, but the vast majority are appropriate and we can make inferences from that based on this statistic and that statistic.

And I, you know, quite frankly I'm not a statistician, so I can't really comment on that and I look, actually, for the rest of you to make comment on that.

I think administrative data, I've read some papers and actually had my own experience where I said let's take a look at all the truncus arterials, just connect them

up with transposition, let's take a look at all the tetralogies that come up with transposition after transposition, I come up with single ventricles a lot.

And so the people who are putting in data in the STS are trained data managers, et cetera, et cetera. The database is verified ten percent per year, which is a pretty good number.

I don't know how the administrative database will allow an important measure like this to be verified. You know, I just don't know.

And I think that, you know, I really -- I'm not sure it's for us to figure that out.

MS. HINES: I think it's really tough for this group because it does keep getting back to the STS database.

DR. MAVROUDIS: No, it doesn't. It doesn't for me.

MS. HINES: Well, that's what you -

-

DR. MAVROUDIS: No, it doesn't.

MS. HINES: But as far as administrative data just from an NQF perspective, we just did a huge administrative data project looking at tiers of clinically-enriched data, pure administrative, administrative plus pharmacy data or x-ray data, whatever, and then registry data.

So, I mean they've just gone through 270 measures and I think 74 or something like that are getting voted through.

There's a bunch of harmonization. So, I just -- if it's -- if there's no --

DR. MAVROUDIS: Let me interrupt for a moment. I'm sorry. I'm being rude, but I doubt that radiology and other sub-specialties have double outlet right ventricle tetralogy type, transposition type, single ventricle type. I doubt that they're listed under that. I doubt it very much and, you know, it's the norm for us. It's the norm for

us.

Again, we're getting into the debate on how good administrative data are and so forth and so on, and I didn't want to do that.

I think that this is a premature thing that we're doing here. We're edging towards deciding that one metric is better than another. It's way premature for that.

I think these metrics have to be put into the system and they have to be -- go their normal and their natural way, and eventually we'll find one.

And I think to say like you want to do, like EMS wants to do, what everyone wants to do is to choose one now and --

MS. HINES: No, no, no.

DR. MAVROUDIS: -- that's wrong.

MS. HINES: My - I shouldn't say this: My preference is to put them both through and see what the comments are that come through.

DR. MAVROUDIS: But I was supposed to do this and now we're just basically saying that I didn't know. And that's what I just said. I don't' know about this stuff, and so I can't make a comment about it if it's any good or not.

DR. JENKINS: I guess you could propose an SMR based on the other two systems.

DR. MAVROUDIS: So, in other words, would you like to see --

DR. JENKINS: Just separate it from 21 so that I'm not in a position of having to --

DR. MAVROUDIS: You're playing an important part here.

DR. JENKINS: Why don't you just make a 22 and propose an SMR using -

DR. MAVROUDIS: Oh, I see.

DR. JENKINS: -- just the two that you are involved with so that I can keep my paper trail for validity of the one that was derived differently than the others and have,

in my mind, more of a history. Just propose an SMR and I won't object to that.

DR. MAVROUDIS: But you see, the problem with that is, is that then if you have one Metric 21 and Metric 22, if you don't use Metric 21 and you use Metric 22, you get dinged.

DR. JENKINS: I don't know where we're getting dinged in the story.

My understanding is at the end of the day centers will choose I'm going to do 2, 4 and 7. I'm not going to do 1, because I decided I don't --

DR. MAVROUDIS: Oh, is that how it is?

MS. HINES: It won't be a whole set necessarily.

DR. JENKINS: There's no dinging.

DR. MAVROUDIS: Oh.

DR. JENKINS: There's no dinging.

DR. J. JACOBS: Well, there is when Blue Cross and Blue Shield chooses one.

DR. JENKINS: That's different.

DR. J. JACOBS: There is a major difference.

DR. JENKINS: But they're going to choose for a reason and that's a long conversation with them. Actually, the Tufts health plan is a very long conversation with them.

DR. MAVROUDIS: Well, you know --

DR. JENKINS: This is what we do. We argue over --

DR. MAVROUDIS: If Blue Cross/Blue Shield comes in and picks 21 and other people are doing 22, that's going to be a big pain in the neck to try to get to all the stuff --

DR. JENKINS: If they're working in a system where their Blue Cross and Blue Shield for whatever reason chooses 21, they're probably going to end up choosing 21.

DR. J. JACOBS: Of course. So, then we're going to have the decision on which complexity stratification tool to be used made

by the insurance companies.

DR. JENKINS: But you'll have given them a laundry list of ones that are approved by NQF.

DR. J. JACOBS: But not the ones that should be making that decision.

DR. JENKINS: They do. So anyway, that's my suggestion, Gus. Make your proposal to --

DR. MAVROUDIS: Oh, I don't --

DR. JENKINS: -- for the other two.

DR. MAVROUDIS: I could make --

DR. J. JACOBS: So, modifying yours is a non-option?

DR. JENKINS: You're putting us in a hard situation.

DR. J. JACOBS: I'm just asking would you consider modifying yours to consider all three?

DR. JENKINS: No. I'm agnostic on that because I have never seen evidence of how

it works. That's all I'm saying.

MS. HINES: The other thing is you guys want to take this offline. I mean we're not held to a hard fast end point. And instead of somebody having to make a decision, you could table.

DR. HINKLE: Well, let me ask -- tomorrow morning we're going to meet again.

MS. HINES: Right, but Kathy is only here today.

DR. JENKINS: That's all right.

DR. HINKLE: But my suggestion is whether we should sleep on this. And we all know, we've beat it up enough and what I'm struggling with, just to put it on the table, is 18 we decided that we would pick -- allow all three.

DR. MAVROUDIS: We would accept 18 as is.

DR. HINKLE: Yes, accept it as is.

Now, when we get to 21 I'm looking at all of the statistical data. It looks

pretty darn good.

And the whole idea -- I think you'll always criticize the claims database, but the fact of the matter is it's getting better and better and better every year. We use it tremendously in healthcare already with the 42 HEDIS. We are using it quite extensively.

And I know it has holes in it, but it's much better than most physicians give it credit for. And it's going to get -- it gets better and better over time and it's a way to move the country forward on some of these things.

So, I'm stuck because I see both sides of it here and I'm trying to wrestle with that and saying okay, you know. So, it's tough to come to a clean conclusion on this one, I think.

DR. MAYER: I don't disagree with most of what you said. I think the problem is we probably will have an answer to this

question in two years when this comes around again. And we will know whether or not -- I mean there as I mentioned before, I think there is a study that's actually either being contemplated or has already been proposed and funded to compare the two datasets. I mean that would help us understand that.

There will be the ability to do -- take the same standardized mortality ratio approach that has been taken in RACHS with other complexity or risk stratification mechanisms.

The concern I guess that I have is that I'm a little worried that we're going to get into a rush to judgment here which I don't think is wise.

I think we ought to be basing this as much as we can going forward, on data. Right? I mean that's something we can all salute.

And I think the notion that we are going to be picking winners and losers here is

one that I think we've all agreed is probably not wise. Right?

So, now the question is how do we try as best we can to keep this process from preventing the real process which is important to all of us, which is the acquisition of data and the comparison of things when we have the ability to do it. And then picking the best or maybe the newest one that evolves as some merger of these things, then that becomes the sort of gold standard.

I'm not sure we want to be in the gold standard picking business right now. And so I'm -- I mean we've got a -- I think what we have to be careful of is we're not going to do Heisenberg Uncertainty Principle here. We're going to screw this up by trying to get too close.

So, I understand your -- I mean some of us have sort of been more or less tightly involved in this. Obviously we've got two people or three people around here who

thought a lot about it. I thought a little bit about it.

So, let's think about this maybe from a tactical rather than picking losers and winners. I mean how can we do this through the NQF process that accomplishes both of those goals? That it doesn't preclude us getting to the point where we can continue to evolve and determine with more data, what works well, what doesn't work well?

How can we do that within this context, but still allow us to get to that end goal. Which I suspect we probably haven't seen the ideal end goal yet, to be honest with you.

DR. MAVROUDIS: So in terms of process, what do we do with this proposal?

Do we approve it, disapprove it or table it?

CO-CHAIR JEFFRIES: So, can we propose a Measure 22?

MS. HINES: I'm sorry?

CO-CHAIR JEFFRIES: Can we propose Measure 22?

DR. MAVROUDIS: We can propose Measure 22 if there's someone to propose a Measure 22.

CO-CHAIR JEFFRIES: Can we ask Jeff to --

MS. HINES: Jeff is right there. I mean --

DR. J. JACOBS: I'm not going to propose it where there are two separate measures. I don't think that that's right.

DR. JENKINS: Why does it matter if it's like 21A or 21B?

So, the only way we can do this is if I propose it? Is that what you're saying?

DR. J. JACOBS: No. I think it would be easy if you would agree to modify yours so that it would work for all three systems.

I'm not going to create a system where we have two different metrics that --

DR. JENKINS: I don't know how to fill out the answers to these questions for that model.

MS. HINES: I think we need to -- you kind of -- it's kind of, I'm going to say strawman it, but we're not really voting, voting here.

This needs to go back to the broader Steering Committee, I think for everybody's -- because it's just going to go -- and, really, all of the discussions, you're kind of making preliminary suggestions that are all going to be discussed at the broader steering committee, but there is diversity and there are some different votes and stuff like that.

I don't know that we're going to get any further than this right now with the workgroup. You've got two more measures to go.

CO-CHAIR JEFFRIES: Okay.

DR. MAVROUDIS: I want to make sure

that you get -- you have your say in this at least from my point of view.

What do you think about tabling it and then talking about it some more? What do you think about that?

DR. JENKINS: You mean for right now?

DR. MAVROUDIS: Yes.

DR. JENKINS: I'm not sure I understand the NQF process enough to know what that means. I mean I think I've been clear I'm more than happy to amend my proposal with the other measures. I just -- I'm agnostic. I'm agnostic on its properties or its value because I just haven't seen it.

And just modifying my measure, I think, reduces the validity of my measure, quite frankly.

MS. HINES: So, that kind of take tabling off because I just didn't want you to feel pressure that you had to do something, make a modification without looking at other

data.

But if you want yours to stand as is, then that --

DR. MAYER: Well, Kathy, can I understand why would that undercut or diminish the validity of what this measure is proposing?

DR. JENKINS: Because I think that when this goes to the science committee, they're going to ask questions about reliability and validity and tests, re-tests and use and variations, and that's going to be the basis of the final approval decision and I have a paper trail of using this one.

I mean I know I can show you this variation, I cans how you how it's used, I can tell you the area under the ROC curve, I can show you -- use it in admin data and non-admin data. I can do all that so it's like a full proposal.

So, that's why I am proposing it. I can do that. And I realize that some of the

measures you guys are proposing are much less well-developed than that. Some of them you don't even know what the deal looks like and you're putting them through this process.

So, maybe we can do 21b, and 21b will require further evaluation over a 24-month period or something. Maybe that's true.

But you need to put the Aristotle categories and add the mixed variable and see what the area of the ROC curve is, then put the next variable and put the next one and make your decisions that make your final model and then it would probably look great. It's just that you haven't done it.

So, if you need me to agree to something, I'm willing to agree in spirit, but both models should be built and looked at and might be equally valid.

That would be more -- I'm more than happy to do that, if that helps.

DR. J. JACOBS: Well, I cannot propose a measure.

MS. HINES: I don't mean to be rude, but the workgroup -- I've got to distinguish who has a vote and you're here as a developer, so the discussion has to kind of stay at the table. I don't want it going back.

DR. MAVROUDIS: Yes, but we do want to hear what they have to say because they know more about it than we do. I mean they are the experts in this and we are responding to their understanding of what the two processes are.

DR. J. JACOBS: I wasn't critical of a lot of input we had from them on the other 19 metrics we discussed, and I welcomed it and --

MS. HINES: No, no, no, no, but I just --

DR. JENKINS: That's true.

MS. HINES: But I'm just making --

DR. J. JACOBS: I think it would be sub-optimal if we would have -- first of all,

I understand why Kathy doesn't want to incorporate this into her proposal because she has the data on the RACHS system and she can write a very strong proposal based on that system only. So, I understand why she would not want to incorporate the other systems into her proposal, and I think that's reasonable.

I would not want to put forth a proposal that is another metric so that anybody who then chooses to use these metrics could be in a position where they could choose using one or using the other for an insurance company or a governmental agency or anybody because I think that that's problematic.

We all acknowledge that each system has its strengths and weaknesses within the system. Kathy is right that she's going to have more years of data on this particular application of RACHS than we will have on Aristotle, because RACHS is older and been around longer.

That also means, though, that

because of those more years of data we would favor implementing a system that allows for coding of 84 percent of the operations instead of 96 percent of the operations. So, we would miss four times higher the number of operations and I find that problematic.

I also find it problematic that by putting two competing measures, that means that anybody, another group other than the group that's here, would be the one that would decide which measure should be used when they don't have the knowledge base about those measures that we do.

So, I certainly wouldn't propose a competing measure to Kathy.

MS. HINES: It happens all the time with NQF and AMA and, I mean that's not our -- while we're concerned with harmonization, that -- we can't control for that.

And I hear what you're saying and I think it makes sense to try to make a judgment here and choose one, but if the

measure stands --

DR. MAYER: If you just look at this, the C statistic number that it seems like we're working around is .8, right?

I mean the data that Kathy has is .8, the data from the latest thing when STS and EACTS data were merged together and stuff, the C statistic is still the same. It's in exactly the same range.

I mean I'm just concerned about -- but I can't think of a way out of this little box here that we're in. And I'm a little concerned fundamentally about this picking one business because I don't think we're there.

The science isn't there, the information isn't there.

DR. JENKINS: I'm not understanding why if you accepted this measure as a valid measure, it's picking one.

DR. MAYER: Well, I'm picking up on what you said when you used the word, "picking one." So, that's what I'm trying to

figure out is how we're --

DR. HINKLE: I mean I think that what he's --

DR. MAYER: I think Allen raised the same question.

DR. HINKLE: I think what he's raising is there's no question in the -- you mentioned you want to the insurance companies picking these things for us.

And so I think if I read into you, one of your fears is that if a singular measure gets out in methodology like this, it could be. Because NQF measures do find their way into pay for performance programs.

DR. MAYER: And then reimbursement is going to be tied to it.

DR. HINKLE: And the problem with that is now in that previous one in 18, we say you can pick all three methods. And there are hospitals which I don't understand which I'm still missing -- I mean I wish I knew which was the superior methodology because this

would make this much easier, but no one knows.

So, it seems like what you're saying is that the hospital might be using Aristotle, then using this methodology for this calculation would be problematic to that hospital, for instance.

Have I got that right?

DR. J. JACOBS: You got that right. And then if all of a sudden the insurance company says they have to do it, that means that there's -- now reimbursement is tied to which complexity stratification tool you use.

DR. JENKINS: Jeff, just explain to me why if it's 21 or 22 you call that different. That's all I --

DR. J. JACOBS: Because we've been very careful within all 20 methods that we proposed to treat all of these systems as complete equals so that anyone could choose which one they use for their own purposes.

And to propose two competing

measures where then you could choose to use RACHS or choose to use Aristotle as competing measures --

DR. JENKINS: But I don't understand how that's different than 18 where it was all in one. I really don't understand.

So if you could explain to me why just having to do that --

DR. MAVROUDIS: Because in 18, you have the choice of all three. And if you pick 21, you don't, and if you pick 22, you don't.

DR. J. JACOBS: Right. If you comply with metric number 18 --

DR. JENKINS: I really don't get it. My center might choose RACHS, and yours might choose Aristotle --

DR. HINKLE: It leaves it up to --

DR. J. JACOBS: You're going to meet the requirements of Metric 18 by choosing any of them.

CO-CHAIR JEFFRIES: I think we need to move on because I don't think we're

going to get anymore closer than --

DR. JENKINS: If I could understand the interest of this I might be able to agree to what they're proposing.

CO-CHAIR JEFFRIES: So, can I ask --

DR. JENKINS: I just really don't understand.

CO-CHAIR JEFFRIES: Can I ask you and Jeff to talk? Why don't you guys get together and talk so that way we can finish up the last two measures.

DR. J. JACOBS: So, we're going to table it and do the last two measures and then --

CO-CHAIR JEFFRIES: Well, I think we're going to bring it up to the larger group. I think that's the next step with it.

So, Number 19.

DR. HINKLE: Okay. 19, that's me. I think we've covered in so many other measures, we've covered a lot of this one. I

think it will be straightforward.

DR. J. JACOBS: This one builds on everything.

DR. HINKLE: It builds on everything that we've had. So, let me remind everybody what it is. I'll find the right page here.

Okay. The title of this measure is Operative Mortality for Six Benchmark Operations.

DR. MAYER: Where are we now?

DR. HINKLE: Number 19.

DR. MAYER: Okay. Sorry. Just trying to catch up.

DR. HINKLE: Okay. So, the description of the measure is operative mortality for six benchmark pediatric and congenital heart surgery operations.

The denominator is the number of index cardiac operations to each of the six procedures. And they are as follows: Number 1, VSD repair; 2, tetralogy of fallot repair

excluding TOF with pulmonary atresia, TOF with atrial ventricular septal defect and TOF with absent pulmonary valve syndrome, 3, AV septal defect repair excluding TOF with AVSD, 4, arterial switch operation excluding arterial switch with VSD closure and/or aortic arch repair, 5, primary or completion Fontan operation excluding Fontan revision or conversion, i.e., redo Fontan; and 6, Norwood Stage 1 uni-ventricular operation.

And the numerator, obviously, is deaths from those procedures. Let's see. Comments along -- so, I think first of all there's no question of the importance of this measure. It has high impact.

These are, you know, obviously it's a high resource intensify need in hospitals to conduct these surgical procedures.

Parents who go through this operation have a high need to know going into it, what the expected mortality may be.

And the opportunity for improvement my read on what the literature that we had is that even though the overall mortality for congenital heart disease is going down, it's something like four percent or something -- going down, that that's not a good enough measure now and there's a need for more granularity with regards to both morbidity, but then mortality by procedure types and trying to get at that is the way -- one of the attempts here.

So, let me see if I've got some notes here. I'm going to walk through this pretty quickly, but I'm going to try to hesitate on the places that I had questions.

One of my questions was around -- let me just put this one on the table first. I've struggled with these because of the size issue.

So, I'm thinking of it from the standpoint of going back to the public looking at mortality rates when there's ten cases.

So, I went through the math and John helped correct me with it. Okay. One in 125 live births have congenital heart disease, right? That's the statistic. About 4 million births in the United States a year. 32,000 cases a year in the United States.

And then John tells me only half of those go to surgery, roughly, because I guess the PDAs or ASDs that close or whatever --

DR. MAYER: Yes. I mean it's probably the most common thing they close is these --

DR. J. JACOBS: All those numbers are pretty reasonable so far.

DR. HINKLE: So, then you go down to -- so, you got 122 centers. So, I divided that and they said okay, I'm still using the 32,000 figure. 262 per year at each center with under 22 centers.

And then I divided that by six figuring we got these six procedures and we

come up with 43 at each hospital at each year. And then I have to cut that somewhere in half, I guess, because only half the kids -- so, we're talking about potentially small volumes, but I know that the network is skewed towards high-volume centers, right?

So, what I was struggling with is the denominator for mortality around a Norwood, for instance.

DR. J. JACOBS: That's a good question.

DR. HINKLE: So, you're going to have one death out of 10 or even one out of 20. You got the overall mortality of four percent, and now you've got that hospital -- my only question was the usability I guess of this because the public kind of --

DR. J. JACOBS: We said this should be recorded in one and four-year intervals. And if it's reported in a four-year rolling time window --

DR. MAVROUDIS: Okay. You know

Marc De Laval wrote a paper out about this.

DR. J. JACOBS: Yes.

DR. HINKLE: So, you thought through those.

DR. J. JACOBS: And you're absolutely right. It won't work if you do this just for one year.

DR. MAVROUDIS: No.

DR. J. JACOBS: But if you do it in a four-year rolling window, it will work. And we chose lesions that were not of sufficient volumes and most program are a four-year window to do a reasonable analysis.

DR. HINKLE: Okay.

DR. MAVROUDIS: I just want to -- may I interrupt you for a moment?

DR. HINKLE: I think you're my secondary, aren't you?

DR. MAVROUDIS: Well, I think the issue here is, Jeff, do you want to include in the exclusionary TOFs you have to appropriately, I think, put down pulmonary

atresia, AV canal and absent pulmonary valve.

Do you want to put anomalous coronary thrust through right ventricle output?

DR. J. JACOBS: That's just part of the deal. If you get in there, you have got to fix it.

DR. MAVROUDIS: So, you tell me if you take a hundred cases, if you take a hundred cases with an anomalous coronary artery and cross the right ventricle output, and a hundred cases without both tests, you think the results are going to be the same?

DR. MAYER: Short term.

DR. MAVROUDIS: They won't be the same. But if you guys vote that way, that's fine with me.

DR. J. JACOBS: I think you should e able to --

DR. MAVROUDIS: They're not going to be the same. You're going to have a complication like coronary arteries, if you do

a hundred of them, you're going to have a complication. But anyway --

DR. J. JACOBS: Well, isn't there all these strategies that you can implement to avoid that like RV to PA conduit and all that stuff.

DR. MAVROUDIS: Sure. But what's going to happen is that you're going to be in the middle of it. You already have injured the right coronary artery.

DR. J. JACOBS: Well, that's what we want to find out.

DR. MAVROUDIS: That's fine. Okay.

DR. HINKLE: So, you're okay with --

DR. MAVROUDIS: I'm okay with this especially when I have these overwhelming --

DR. HINKLE: So, my other question was around the unit of measurement. I know that most of these were measuring -- were looking at the group level. So, I assume that

the group is pediatric cardiac surgeons at practice.

I mean there's no question if you're -- I mean I think the numbers -- I think I've answered my own question. You can't do it at the individual clinician level.

DR. J. JACOBS: None of these are proposed to be done at the individual clinician level at this point. These are team measures.

DR. HINKLE: So, I was wondering about this comment. I think this is something you submitted, you guys submitted here, summary of evidence around does the measure have a high impact aspect on healthcare.

And there was something in here that said the six benchmark operations identified in this measure are among the most common procedures performed by pediatric and congenital heart surgeons spanning a spectrum from simple to complex outcomes. The easiest operations have often been used as benchmarks

for surgeon and programmatic performance.

I think to make sure I understand, what you're saying is you use it to improve the individual surgeon.

DR. J. JACOBS: No.

DR. HINKLE: What is meant by that?

DR. J. JACOBS: What that has meant was that there's previous publications that have used these lesions to benchmark both surgeon and programmatic performance.

Our proposal here is just on uses to benchmark programmatic performance because we believe that this is a team sport and that you don't tie it down to an individual clinician, but to the whole team.

CO-CHAIR JEFFRIES: Some of these were part of the US News and World report when they were looking across centers and they wanted to know mortality from TETs.

DR. HINKLE: Yes.

DR. J. JACOBS: And beyond that

there's peer review papers by some pretty good surgeons like Stark and De Laval that did that.

So, the did this on individual surgeons, and we were just referencing that, but we're not advocating doing that ourselves.

DR. HINKLE: Okay. That was just for clarification.

DR. J. JACOBS: It's a good point though.

CO-CHAIR JEFFRIES: I had a question.

The CPT codes that you have listed in this, do those have the exclusions built within them, or does somebody have to then go and figure out that separately?

DR. J. JACOBS: CPT codes are not granular enough to do that.

CO-CHAIR JEFFRIES: So, they're just going to say tetralogy repair?

DR. MAYER: No. There are three different -- sorry. I happen to know this.

DR. J. JACOBS: Right. From a tetralogy standpoint, John is absolutely right. But for the other examples, that's where --

DR. MAYER: But for instance, tetralogy with AV canal you can't report with a single CPT code. You have to report two. Tetralogy with absent pulmonary valve you would essentially never report as a single code because you'd miss all the pulmonary artery reconstruction work.

So, I think that the, you know, I mean the point is we can distinguish these things in the database.

DR. J. JACOBS: Right. But we can't with CPT codes always.

DR. MAYER: Right.

DR. J. JACOBS: Some of them we can with CPT codes, but certainly not all of them.

DR. MAYER: You can distinguish between a -- I mean the way the CPT goes is

there's non-transannular patch, transannular patch and RV to PA conduit. Those are the three CPT codes -- individual codes.

And then if you had tetralogy with AV canal, then you'd have to add a secondary code with a 51 modifier. That's --

CO-CHAIR JEFFRIES: Do, if you're not doing STS, you have to do is measure this from the data.

DR. MAYER: You're right about that.

DR. J. JACOBS: I mean you can track what type of tetralogy repair you did with any database in the world. And with any database in the world, the CPT codes will not be granule enough to tell you that all.

So, it's absolutely not STS database dependant. Any clinical database can do it. It's just that most administrative databases won't allow this level of differentiation.

CO-CHAIR JEFFRIES: Okay.

DR. HINKLE: I think this one is straightforward, the rest of it. I mean I have no other questions or comments about the rest. It seems fairly --

CO-CHAIR JEFFRIES: What's your sense of relative importance of this measure versus the --

DR. J. JACOBS: The RACHS and Aristotle?

CO-CHAIR JEFFRIES: Versus 18.

DR. J. JACOBS: So, when we had our phone conference of the group of people that developed these, there was a feeling that a substantially important denominator, increased information could be gained by looking at the benchmark operations and not just using complexity stratification.

And to support that, they referenced papers by De Laval and Stark who have used that approach and presented that at the STS and the AATS as a good approach for benchmarking programs.

It's used by the United Kingdom Central Cardiac Audit Database and it's been published in other papers.

So, our group felt that it added additional information above and beyond the information we would get from complexity stratification alone because these are common operations, they're benchmark operations.

CO-CHAIR JEFFRIES: I mean I think from a family point of view --

DR. J. JACOBS: Yes, my kid's got a TET.

CO-CHAIR JEFFRIES: -- this is what they're going to want to see.

DR. J. JACOBS: Yes. They're going to know my kid's got a tet, not my kid's got a RACHS-1.

CO-CHAIR JEFFRIES: Exactly. These are the most common things.

DR. J. JACOBS: So, I think it adds -- it just adds more information and it adds information in a more digestible format

toward families who happen to have a kid with one of these six problems.

DR. HINKLE: I only have one other question. It's a crazy question, probably going to be. Maybe I've thought too much about this.

But when you get into the 30-day death, it says prior to hospital discharge or within 30 days of the date of surgery.

DR. J. JACOBS: Yes.

DR. HINKLE: Do any of these procedures, will they get out before 30 days? Is it possible?

DR. J. JACOBS: Yes, a lot of them. Most of them.

DR. HINKLE: Right. That's what I thought. So, they get out and they get hit by a car.

DR. J. JACOBS: Great question.

DR. HINKLE: Or they go back into the hospital because they have appendicitis, and they die during surgery.

DR. MAVROUDIS: So, it's an operative mortality.

DR. HINKLE: Yes. Okay.

DR. MAYER: This has been dealt with.

DR. MAVROUDIS: It's operative mortality.

DR. HINKLE: Okay. That's enough said.

DR. J. JACOBS: That's what this paper talks about.

DR. MAVROUDIS: You get shot by the Taliban. Operative mortality.

DR. HINKLE: Thought it was a crazy thought, but --

DR. J. JACOBS: Well, there's less likelihood of having that happen than there is having gaming the system that gets it or not related to the heart or excluded.

DR. HINKLE: That's what I figured. Okay.

So, my recommendation is for this

to be accepted and proceed.

DR. MAVROUDIS: I make a motion that we accept the measure is that what you're asking?

DR. HINKLE: Yes. I can't make the motion. I put it on the table.

DR. MAVROUDIS: I move that we accept it.

DR. LOPEZ: I'll second.

CO-CHAIR JEFFRIES: We're going to skip 20 in this group.

DR. MAVROUDIS: Let's go back to 21.

(Laughter.)

CO-CHAIR JEFFRIES: John, we'll have you do 20.

DR. MAYER: In the big group?

CO-CHAIR JEFFRIES: In the meeting.

DR. MAYER: All right.

CO-CHAIR JEFFRIES: Okay.

DR. MAYER: Yes, that's fine.

CO-CHAIR JEFFRIES: I mean I think it's sort of a good mix. I think you know what's discussed.

DR. J. JACOBS: Yes, there's nothing new there. That's just taking pieces of all the previous ones and gluing them together as something new.

DR. MAYER: Do I understand correctly that mortality is not in 20?

CO-CHAIR JEFFRIES: That's a good question.

DR. J. JACOBS: Right.

DR. MAYER: It's everything but.

DR. J. JACOBS: Correct.

DR. MAYER: Or not everything but, but it's the defined complications? Is it? I mean I wasn't clear when I read it, and I may have been a little foggy on it.

DR. J. JACOBS: The intent was that you take -- I think the denominator is probably written wrong. It's supposed to be a percentage of your survivors that are free

of these complications.

DR. MAYER: Okay.

DR. J. JACOBS: So, the title says that operative survival free of major complications, but I think that the denominator may actually say all pediatric and congenital heart surgery, but it should say all surviving pediatric and congenital heart surgery, and then it will work.

So, that's a technical flaw in the proposal as written that needs to be corrected.

DR. MAYER: All right. That was --

DR. J. JACOBS: Good pickup.

DR. MAYER: -- a source of a little confusion.

DR. J. JACOBS: So, you're not just typing, are you?

Sorry. I couldn't resist that.

DR. MAYER: Not just another pretty face, right?

DR. J. JACOBS: That's what I

started to say, and then I said I better not say that.

(The above-entitled matter went off the record at 3:29 p.m.)

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