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Medicare Evidence Development & Coverage

Advisory Committee

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7500 Security Boulevard

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CMS Liaison
Daniel Arthur Canos, PhD, MPH

Executive Secretary
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PANEL PROCEEDINGS

(The meeting was called to order at 8:10 a.m., Wednesday, July 25, 2018.)

MS. ELLIS: Good morning and welcome, committee chairperson, vice chairperson, members and guests. I am Maria Ellis, the executive secretary for the Medicare Evidence Development and Coverage Advisory Committee, MedCAC. The committee is here today to discuss their appraisal and recommendations regarding the state of evidence for procedural volume requirements, especially pertaining to surgical aortic valve replacement (SAVR), transcatheter aortic valve replacement (TAVR), and percutaneous coronary interventions (PCIs) for hospitals to begin and maintain TAVR programs.

The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record.

The conflict of interest statutes prohibit special government employees from participating in matters that can affect their or their employer's financial interests. Each member will be asked to disclose any financial conflicts of interest during their

introduction. We ask in the interest of fairness that all persons making statements or presentations disclose if you or any member of your immediate family owns stock or has another formal financial interest in any company, including an Internet or E-commerce organization, that develops, manufactures, distributes and/or markets consulting, evidence reviews or analyses, or other services related to transcatheter or surgical aortic valve replacement procedures. This includes direct financial investments, consulting fees and significant institutional support. If you have not already received a disclosure statement, they are available on the table outside of this room.

We ask that all presenters please adhere to their time limits. We have numerous

presenters to hear from today and a very tight agenda, and therefore, cannot allow extra time. There is a timer at the podium that you should follow. The light will begin flashing when there are two minutes remaining and then turn red when your time is up. Please note that there is a chair for the next speaker and

please proceed to that chair when it is your turn. We ask that all speakers addressing the panel please speak directly into the mic and state your name.

For the record, voting members present for today's meeting are Dr. Aloysius Cuyjet, Dr. Michael Cinquegrani, Dr. Gregory Dehmer, Dr. Anita Fernander, Mr. Naftali Frankel, Dr. Smadar Kort, Dr. Sandra Lewis, Dr. Daniel Ollendorf and Dr. Zoltan Turi. A quorum is present and no one has been recused because of conflicts of interest.

The entire panel, including nonvoting members, will participate in the voting. The voting results will be available on our website following the meeting.

I ask that all panel members please speak directly into the mic. This meeting is being webcast via CMS in addition to the transcriptionist. By your attendance you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may

disclose about you during today's meeting. Please do not disclose personal health information.

In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask that the advisory committee members take heed that their conversations about the topic at hand take place in open forum of the meeting. We are aware that members of the audience, including the media, are anxious to speak with the panel about these proceedings. However, CMS and the committee will refrain from discussing the details of this meeting with the media until its conclusion.

Also, the committee is reminded to please refrain from discussing the meeting topics during breaks or lunch.

If you require a taxicab, there are telephone numbers to local cab companies at the desk outside of the auditorium.

Please remember to discard your trash in the trash cans located outside of the room.

And lastly, all CMS guests attending today's MedCAC meeting are only permitted in

the following areas of CMS single site: The main lobby, the auditorium, the lower level lobby and the cafeteria. Any person found in any area other than those mentioned will be asked to leave the conference and will not be allowed back on CMS property again.

And now, I would like to turn the meeting over to Dr. Daniel Canos.

DR. CANOS: Thank you, Maria. I just wanted to publicly thank the panel for coming today, and the public who showed up as well. This is a very important topic for the Medicare program and for the Coverage and Analysis

Group.

Currently we do have a national coverage analysis open on transcatheter aortic valve replacement. One part of that analysis is the reason for this meeting, which is really to see the state of the evidence on procedural volume requirements, and then based on what we hear today, the Coverage and Analysis Group will go back and will take a look at it and make decisions on what we'll do next policy-wise. So really, the focus of the day is about the evidence, which is the key for us

and what we want to hear about, the basis of the evidence and the panel input is what we will use to decide our next steps and what they might be.

And again, I'd like to thank everyone and the panel for traveling, and I'll hand it over to Dr. Peter Bach.

DR. BACH: Good morning. I'm the chair and non-voting member of the MedCAC today. My job is to help the panel focus on the questions, review the evidence in an open format. My other job, which fails to bring

much glory, is to keep everyone on time, so I'll apologize now for my future rudeness, which will inevitably crop up. To the extent that we go off time, no one will be penalized, if you will, so if you have a half hour, you have two minutes, whatever it is, you will get that time, but I will insist that we keep things moving for the benefit of everyone involved.

DR. CUYJET: Good morning. I'm Dr. Al Cuyjet, I have the pleasure of serving as vice chair for the committee today, and I have no financial disclosures.

DR. CINQUEGRANI: Michael Cinquegrani, I have no financial disclosures.

DR. DEHMER: I'm Greg Dehmer, I have no financial disclosures.

DR. FERNANDER: Anita Fernander, I have no financial disclosures.

MR. FRANKEL: Naftali Frankel, and I have no financial disclosures.

DR. KORT: Smadar Kort, and no financial disclosures.

DR. LEWIS: Sandra Lewis, I have no financial disclosures.

DR. OLLENDORF: Dan Ollendorf, I have no financial disclosures.

DR. TURI: Zoltan Turi, I have no disclosures.

DR. CARLSON: Mark Carlson, I am the industry rep and I have financial disclosures. I am an employee of Abbott and I have Abbott stock.

DR. DESVIGNE-NICKENS: Patrice Nickens, and I have no financial disclosures.

DR. BACH: All right. We're going to get the day started now. The opening remarks will come from Sarah Fulton from CMS.

MS. FULTON: Good morning, thank you for joining today's MedCAC meeting. My name is Sarah Fulton, I work in the Coverage and Analysis Group here at CMS and we're really happy to have such a full room today, and thanks for joining us.

The purpose of today's meeting is to obtain the MedCAC panel's recommendations on the appraisal of the state of the evidence for

TAVR, surgical aortic valve replacement, percutaneous coronary interventions and other relevant structural heart disease procedural volumes, for heart teams and hospitals to begin TAVR programs, and for heart teams and hospitals to maintain TAVR programs. The panel's recommendations will be based on scientific evidence assessing procedural volume requirements for hospitals and heart teams both beginning and maintaining programs, that treat Medicare beneficiaries.

It is important to note that today's meeting focus is on whether having minimum volume requirements for these procedures is supported by scientific evidence. We are not discussing what the actual numbers for these

volume requirements should be.

TAVR procedures are used for the treatment of aortic stenosis. The procedure involves a bioprosthetic, inserting a bioprosthetic valve using a catheter via transfemoral, transapical and transaortic approaches. The valve is implanted in the

orifice of the native aortic valve or a failed surgical bioprosthetic valve.

The FDA first approved TAVR in November of 2011 and within six months CMS established the current national coverage determination. To date CMS has approved 24 clinical trials under the NCD to cover TAVR in investigational studies that have led to FDA approval of expanded indications. As expanded indications are approved by the FDA, the NCD provides for concurrent Medicare coverage without the need to reopen the policy or adjust claims processing instructions.

The clinical trials CMS covers continue to explore these and other uses for TAVR, including in patients at low risk for SAVR, in asymptomatic patients, and for the treatment of severe aortic stenosis or, I'm

sorry, regurgitation.

This slide kindly prepared by our colleagues at FDA shows the progression of FDA approval since initial approval in 2011. As noted in my previous slide, Medicare coverage has been concurrent with each expanded

indication.

The current NCD is a coverage with evidence development or CED NCD.

Section A addresses coverage of TAVR for treatment of symptomatic aortic valve stenosis when furnished according to FDA-approved indications. Hospital and heart team requirements are included here, and pertain to both infrastructure and procedural volume requirements. Hospitals and heart teams must also participate in a CMS-approved prospective national audited registry. CMS has approved the STS/ACC Transcatheter Valve Therapy or TVT registry.

Section B addresses coverage of TAVR for uses that are not expressly listed as FDA-approved indications. Procedures must be performed in CMS-approved clinical trials, and these trials are listed on our website, which

is provided here. The NCD specifically non-covers TAVR in patients who have existing comorbidities that would preclude the expected benefit from correction of the aortic stenosis.

On June 27th we opened a reconsideration of the current TAVR NCD, which resulted from a complete formal request. The request challenges the inclusion of procedural volume requirement, recommends coverage be based on quality outcomes instead of non-TAVR procedure volumes, and program qualifications be based on physician operator education, training and skill. The analysis process for the reconsideration began with a 30-day comment period which closes this Friday, July 27th. The proposed decision is due on March 27th, 2019, and posting the proposed decision initiates the second 30-day public comment period. The final decision is due 90 days after the proposed decision is posted. To follow the analysis, please periodically check the tracking link listed on the website, or the website as listed up here. You can access public comments here, and both the decisions, proposed and final, will be available as well.

Thank you.

DR. BACH: Thank you very much, Sarah. We'll have our first speaker, who's Peter

Pelikan, Dr. Peter Pelikan is medical director of the Cardiac Cath Lab and Structural Heart Program at the Pacific Heart Institute and Providence Saint Johns Health Center. Thank you for coming.

DR. PELIKAN: Thank you for having me. Ms. Ellis, Ms. Fulton, Dr. Canos, Dr. Bach, committee members, colleagues, this has been a long journey for me here and I'm very happy to be here. I have no financial conflicts. I am the medical director of the cardiac catheterization lab at Saint Johns Hospital in Santa Monica, California.

About five or six years ago, one of my patients had a TAVR at an outside hospital, she happened to be a nun, and as I watched this sick heart become a healthy heart in about five heartbeats, it was literally a religious epiphany for me and I fell in love with this procedure and decided I had to learn how to do it, which I've done, and I've been doing it for the past five years.

During that period of time, I drive an

hour to an hour and a half to another hospital that met the NCD volume requirements, and then I drive an hour to an hour and a half back. It's about 15 miles, but in Los Angeles that's the time frame. And my patients' families have to do the same, or they have to stay in a hotel at this hospital. So today we're here to discuss why that is and whether we are ripe for a change, so that other hospitals then, high volume hospitals can perform TAVR.

When the NCD was issued, there were a variety of requirements, I'll just review them briefly, I'm sure most of you are aware of them, but two surgeons needed to approve the procedure, a heart team model needed to be in place which included cardiology and multidisciplinary members, and appropriate infrastructure in the hospital had to be present such as onsite cardiac surgery, cardiac cath lab or hybrid room, echo and ICU, and procedural volume requirements were mandated.

So for a hospital without prior TAVR experience, they had to do 50 surgical aortic valve replacements, 1,000 cardiac

catheterizations including 400 or more percutaneous coronary interventions, I'll refer to those as PCIs, during the prior year. Two cardiac surgeons with a hundred career surgical aortic valve replacements, ten of them at high risk, and 25 aortic valves in the prior year or 50 in the past two years were required.

For the interventional cardiologists, the requirement was 100 or more lifetime structural cases, or 30 or more left-sided structural cases per year, at least 60 percent of which were balloon aortic valvuloplasty. At the time of the NCD, ASD and PF closure were not counted, Watchman or left atrial appendage implant procedures were not counted in terms of the cardiologist's structural experience because Watchman was not FDA-approved at the time outside of a research setting. As mentioned, the participating hospitals must enter data into the national registry as a team, with the cardiologists and cardiac surgeons working together.

For hospitals with prior TAVR experience, there were similar requirements. They had to have two cardiovascular surgeons on

active staff, maintain a surgical volume of 20 surgical aortic valves per year or 40 in the last two years, and continued for the hospital to perform a thousand cath's and a minimum of 400 percutaneous coronary interventions to remain a TAVR center.

Today we are here to discuss revision of the NCD, and I submit that the time is right to modernize the NCD. Initially, TAVR was a major foray, a new, an experimental procedure carrying significant risks, and some of the physicians who really started that off and accepted those risks are here in the room today, you will be hearing from them later. However, now the procedure has become commonplace and incredibly safer.

For ethical reasons the procedure was restricted to patients at high risk for surgical aortic valve replacement. Now it's approved for intermediate risk patients, meaning a three percent or greater risk of death during open surgery, and as you heard, low risk patient cohort trials are in progress, and it is expected by all that TAVR will be open to low risk patients when those trials are

completed.

The TAVR NCD in an attempt to maintain patient safety was based on several presumptions. First is that the volume of a procedure predicts the quality outcome of that procedure, for example, PCI volume predicts PCI quality.

The second, which is a leap, is that the volume of a cath lab procedure predicts outcome of a different procedure. In other words, if you do a lot of coronary interventions, you're going to be a good TAVR center.

Third, the presumption was that TAVR was a minor modification of surgical aortic valve replacement requiring active cardiovascular surgical non-catheter-based intervention, and that it was a high risk procedure with a significant risk of crash or thoracotomy in the cath lab.

So in the next part of this talk, let's examine these presumptions and see if they're still ethical now. Does volume predict quality for cath, PCI, CABG, and for example,

25 left ventricular assist device or LVAD

1 implantation? Does volume of non-TAVR
2 procedures such as cath, PCI and surgical AVR
3 predict TAVR quality?
4 For cardiac catheterizations simply
5 stated, volume does not predict quality
6 outcomes. The 2012 American College of
7 Cardiology, Society of Cardiovascular
8 Angiography and Intervention, and you're going
9 to be hearing from leaders of these
10 organizations later today, but ACCF and SCAI
11 consensus documents stated, because of the low
12 risk of diagnostic catheterization, it is
13 difficult to come to a consensus as to what
14 would constitute a minimum caseload. They go
15 on to say that using, and I'm quoting, using
16 minimum case volume as a surrogate for quality
17 presumes that a high procedural volume equates
18 to a high skill level. The relationship
19 between procedural volume and outcome remains
20 controversial. They recommend quality
21 assurance, not volume criteria, to maintain a
22 safe and effective catheterization program.

Turning to PCI, we are going to find a weak or an absent correlation with quality. Here's a paper by Moscucci in 2002 showing

volume and quality in 14 hospitals in Michigan entailing 18,504 patients. I stress, this paper was 16 years ago. In that study, no correlation between operator volume and mortality was found during the hospital stay. They did find a correlation between volume and MACE, major adverse cardiac events; however, let's look at the actual data.

So, this is a graph from Moscucci's paper. On the X axis is operator yearly volume and on the Y axis is MACE. Each circle on this graph is an individual physician. There's a regression analysis showing a mild correlation of volume and quality.

Do I have a pointer on here? Is there a pointer on this, or no? No, okay.

Well, the line is a regression line and you can see there is a correlation, but it's a very slightly tapered slope down to the right. But making the point, and you will see other graphs like this, at least from me today.

In the lower left-hand quadrant of this graph lie numerous high quality low volume operators. This paper from 16 years ago was in the early stent era. Stents, as I'm sure you all know,

have made the coronary intervention procedures safer.

A more contemporary study from the United Kingdom between 2007 and 2013, this is more into the stent era, showed no correlation of hospital volume and quality outcome, meaning mortality for coronary intervention.

As PCI has become safer, the organizations that you're going to be hearing from today, ACC, AHA, you won't hear from the AHA, and SCAI, have altered their position papers. So in 2007 the position statement which was based on registry data from New York and Michigan hospitals performing less than 400 PCIs a year showing a higher mortality. I suspect that this position statement from 2007 is where the current NCD 400 case per year requirement came from.

This paper was from data from 1998 and

1999, only really five years into the stent era. Even then the authors commented that procedural volume was only one factor contributing to outcome and that technological advancements might level the field.

Six years later the update from these

organizations now using data from 1995 to 2013 showed, quote-unquote, moderate heterogeneity in the volume-quality relationship. They noted that studies for angioplasty before the stent era showed some relationship between volume and quality, but stenting had dramatically improved safety outcomes. They at the time, and again, this is five years ago based on data from more than five years ago, suggested a possible threshold of 200 coronary interventions a year. So, the large cardiology organizations have gone with the data and changed their outlook and recommendations.

When looking at individual operator volume and quality, the society suggests that there may be a volume-quality correlation, but they also again note the significant heterogeneity. And look at this graph, again

from the ACC/SCAI update, quite similar to the other graph I showed you. These are procedural volume by physician and in-hospital mortality, and the R-squared value of .0057 shows sort of somewhat of a correlation. The red line tapering downward towards the right is data suggesting that there may be a volume-quality

correlation, but as on the other graph, in the lower left-hand quadrant of this paper's graph, there are numerous high volume -- I'm sorry -- low volume high quality operators, again arguing that volume does not confer quality.

The conclusion of the committee, overall, it is the opinion of the writing committee that the available evidence does not send a loud signal supporting a consistently strong relationship between operator caseload and mortality.

When reviewing the volume-quality question, it is also seen that statistics can mislead and I'd like to just show you an example of that. This is a paper from the INTERMACS registry, 7,419 patients were studied

and hospitals doing ten or less LVAD, left ventricular assist device implants, 11 to 30, 31 to 50, and greater than 50 implants per year were studied. If you look at the curves, the blue line, which is one to ten implants per year, and the green line, which is greater than 50 implants per year, are almost superimposable. If there was truly a volume-quality relationship, the greater than

50 curve should be the highest curve there, not almost identical with the lowest volume center.

I had one of the statisticians from Providence at their medical data center review the data available from this article, and Dr. Chiu's conclusion to me was that there really is no statistical difference between the highest volume and lowest volume center. Yet, the conclusion of the paper was volume implies quality. So again, I ask everybody to keep in mind that these statements are made but they're not necessarily supported by the data.

For cardiac surgery, there are numerous papers showing that the correlation of volume and outcome does not really exist. I

just show you one graph here from multiple hospitals in the state of California published by Carey. Similar to all the other graphs I've shown you looking at volume and quality, there is a mild downward slope to the regression line, suggesting there's some relationship between volume and quality, but as with the other graphs I've shown you, the lower left-hand quadrant shows numerous hospitals who are low volume but high quality. And if you

look closely at this graph, numerous hospitals in the lower left quadrant who do less than 50 surgical aortic valve replacements per year will not by the current NCD be able to start doing TAVR, even though their quality is high.

So -- sorry -- looking at volume-quality relationship for a procedure, I hope I've debunked it.

The second question is, does volume of a procedure confer quality on another procedure? I did several PubMed searches, this one looks at the correlation between cath lab volume and TAVR quality. I've never had a zero

hit PubMed search in my life, but I got zero hits on this. If you look at the correlation between -- in the upper line there you can see what I searched on. If you look at the correlation between PCI quality and TAVR outcome, there are zero hits. And if you look at the correlation between cardiovascular surgical volume and TAVR outcome, there are zero hits. And to be fair, I searched using numerous terms, not just outcome, but mortality, et cetera. I got zero hits on all of them.

Now, since I've shown here that volume of procedure is not predictive of quality -- I'm sorry, I lost my slides here.

As we saw with PCI becoming safer over the years, we see the same sort of thing with TAVR, and I initially said TAVR has become safer. I just show you this graph from one paper showing that the process matures. This is a paper from Israel on 1,285 patients at three TAVR centers in Israel between 2008 and 2014, showing that as the years have gone by, the procedure has become safer, the need for

pacemaker implantation, the complications of infection have reduced, and there is a downward trend, although not statistically significant, for other complications.

To get an idea about TAVR safety now, we queried the ACC TAVR history for the four quarters ending in quarter three 2017. Of 45,395 cases, only 220, which is 0.5 percent, required emergency conversion to open heart surgery. Annulus rupture, only 39 cases, which is usually a fatal complication, but has become rare due to improved understanding of valve sizing, improved CT imaging and better planning

of the procedure. Overall, these numbers show that TAVR is a cath lab procedure and not a small modification of aortic valve replacement.

So, showing that volume really does not imply quality, that TAVR is streamlined, and in the age of electronic records where we can actually measure quality and no longer need to use volume as a surrogate for quality, I propose that the time is now to change the NCD and use quality, not procedural volume, as a

requirement for TAVR. So in no way am I saying we don't want quality, but we want to actually have a true measurement of quality.

If we continue to adhere to the volume criteria, there are a variety of outcomes that may not be good. For example, we know that since the development of appropriate use criteria, AUCs, the volume across the nation of coronary interventions is dropping appropriately, along with the effects of statins.

So ask the question, if procedural volume drops below 400 PCIs per year, should a high quality TAVR program stop doing TAVR? I think that would be the wrong decision. If we

leave the TAVR criteria in place, TAVR programs will also have an unhealthy motivation to meet minimum volume and might be motivated to consider performing unnecessary procedures. Consider also if a program is doing 350 cases a year and brings in ten operators each to do five cases, and thus reaches their 400 PCI goal in the NCD, will that improve TAVR quality? Again, the answer cannot possibly be yes.

As TAVR has shown excellent results and now has been approved not only for high risk but also for intermediate risk patients, surgical aortic valve volume is dropping. TAVR is, as I said, a cath lab procedure, not a minor modification of surgical aortic valve replacement, so surgical volume should not be a factor in qualification of a TAVR program. Should a program performing quality TAVR stop doing TAVR if their surgical volume appropriately drops? Again, I would say no. Again, consider the potential motivation for a program to unnecessarily perform surgical aortic valve replacement in order to maintain their TAVR program.

TAVR revision with removal of the

volume criteria will allow new programs to open and provide TAVR for their patients. Patients and families will not have to travel for the procedure and not encumber expenses for that travel. Care quality actually, I believe, will improve because the patient will be having their procedure in their hospital with their

primary care doctor, their normal group of specialists who have cared for them, they know them, and their cardiologists.

Lastly, since we would be basing procedural approval on quality, not volume, I submit that outcomes will actually improve. In other words, allowing low volume but high quality programs to exist will improve because there are programs, and again, I'm not trying to insult anybody, but there are probably high volume programs perhaps that are not high quality, and if we actually base our decision on quality, not volume, I believe quality will improve across the board.

So, what would a rational TAVR NCD look like this year or next year? Quality, not volume, should determine program initiation and maintenance. Operator training, experience and

skill should be the most important determinant of program quality and outcome, whether it be for the interventional cardiologist or heart surgeon skilled in structural heart catheter therapy and an alternative non-transfemoral access that the cardiovascular surgeons

provide.

When considering operator training and skill set, MitraClip, transvascular mitral valve intervention, Watchman, as well as ASD and PFO cases, should be included along with TAVR. These cases use the same structural heart skill set, combining CT and transesophageal echo imaging with fluoroscopy to deliver devices in three-dimensional space.

Case numbers conferring proficiency for the operator can be argued, but a hundred cases, hundred structural cases seems reasonable to me, although, again, I don't think there's any data to support that. The TAVR operator must be skilled in structural heart, PCI and peripheral intervention in order to perform this procedure.

So today the committee is going to be voting on a number of questions, and as you can

tell from the data I've provided, I submit that quality, not surgical volume should be important in the program, whether that be for surgical aortic valve replacement, PCI, and I

believe that the volume criteria for those procedures should be removed from the NCD. Similarly for maintenance, we should be looking at quality, not volume. I believe that for a TAVR surgeon to perform the procedure, as I said, this is not a minor modification of a surgical skill set, so the surgeon if he's actually going to be doing TAVR, should be skilled in catheter-based intervention, but also the surgeon who is participating should be skilled as stated in the NCD, in surgical aortic valve replacement as well as alternative access routes, whether it be direct aortic puncture or direct aortic puncture from a minimal sternotomy or subclavian access.

Again, TAVR quality, I believe, is most dependent on the primary operator's experience. For the interventional cardiologists, they should be able to do structural heart, coronary PCI, peripheral intervention, and have sufficient case volume

of the type of cases that I've mentioned, not simply TAVR or balloon aortic valvuloplasty.

Volume criteria do create barriers for

patients. They limit the number of hospitals that are able to do TAVR. As I said, in Los Angeles it can take one-and-a-half to two hours to drive 15 miles depending on the time of day, at four in the morning, not, but during waking hours, yes. Gender, ethnicity, race and socioeconomic status will potentially be limited from access to TAVR because of the requirement for paying for a hotel, driving, coming back and forth to visit family, or for the patient themselves to get to a TAVR program. Community hospitals tend to be smaller and I'm at a community hospital which is, let's say medium sized, very high quality, lower volume, and my community is basically excluded from TAVR.

It's my hope that after considering the data today that the committee will vote to remove the volume criteria. Later today, based on my assumption from the ACC position paper that was released last week, which is proposed changes to the NCD guidelines, that paper does

discuss how important quality is, which I'm

very happy to hear, but they do not recommend complete removal of the number of cases, volume requirements, and with that, I have to respectfully disagree. For example, you will probably hear that they recommend doing 50 TAVRs per year instead of 20 TAVRs per year. Reading the fine print in that document, that statement is based on, quote-unquote, preliminary data from the Duke registry. In that same paragraph they go on to say that more data is needed because this isn't really a final finding, but yet still recommend 50 TAVRs per year. They recommend 300 PCIs per year, I don't believe any of the data supports any of that. We need to move into the modern era and actually measure quality and have quality be the determinant. Thank you for your attention.

(Applause.)

DR. BACH: Thank you very much, Dr. Pelikan, and thank you on the small point of being on time. We are ahead of schedule, which I appreciate, I suspect everyone appreciates.

Next up are Dr. Carl Tommaso, who's a

cardiologist at North Shore Medical Group, and Dr. Joseph Bavaria, who's the past president of the Society of Thoracic Surgeons; Brooke Roberts-William M. Measey Professor of Surgery; Vice-Chief, Division of Cardiovascular Surgery; Surgical Director, Heart and Vascular Center; director, Thoracic Aortic Surgery Center, Penn Heart and Vascular Center at the Perelman Center for Advanced Medicine. These are recommended speakers from the AATS, the American College of Cardiology, the Society of Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons. Thank you very much.

DR. BAVARIA: Ladies and gentlemen, and panel, good morning. My name is Joseph Bavaria, I'm a cardiac surgeon at the University of Pennsylvania and former president of the Society of Thoracic Surgeons. I serve as co-chair with Dr. Tommaso of the writing committee of the 2018 expert consensus document. This document, which is a joint statement of four professional societies, was published last week, as you heard, on July 18th. You will hear many references to

this document in the subsequent presentations today.

Those references will refer to an early draft of the consensus document. We received valuable input from stakeholders and revised our recommendations based on the public comments during the fall. There are substantial differences between the two documents. Unfortunately, many of today's presentations include assumptions and conclusions based on the early draft consensus document rather than the final version. I would like to summarize the key final recommendations of the professional societies.

Number one, access to care is complex and multifactorial in the U.S. healthcare system. The TAVR consensus document recommendations support both high quality outcomes and access to care. The document does not, I repeat, does not recommend closing of any of the current 584 TAVR programs in the United States. A major threat to growth of low volume TAVR sites would be opening even more TAVR sites, especially in the same geographic regions.

The document emphasizes the importance of the multidisciplinary heart team, this is very important. Quality metrics, rather than volume, should be the ultimate assessment of TAVR site performance, as you've just heard. There is significant statistical complexity regarding the ability to accurately evaluate outcomes in low volume TAVR centers. The most current analysis of the TVT registry data demonstrates a clinically meaningful analysis of the association between higher mortality and other major comorbidities with site annual volume below the recommended threshold of 50 procedures per year.

This is our, both Carl's and my disclosure slide. You will note that my disclosure is mostly related to all the manufacturers and their FDA clinical trials.

The 2018 consensus document is the result of a collaborative approach. There was equal representation on the writing committee with 16 total members. The 2012 NCD has been magnificent. The number of TAVR sites has expanded in the United States to 584, and TAVR

outcomes have been improving yearly. This is a

very important concept.

So, one of the questions is why volume, why a minimal volume floor? There is a well known and robust body of literature showing a volume-outcome relationship in almost every complex medical procedure. This is true for TAVR as well. The volume-outcome relationship has really become almost common sense. It is why every patient in every office for every procedure in the United States asks, how many of these have you done, Doc?

So the professional societies decided to update the document. The TAVR registry -- I'm sorry, the TVT registry has given us a better understanding of TAVR quality, which was unknown at that time in 2012. The primary focus of the new document is quality measurement and risk-adjusted outcomes. As this slide emphasizes, direct comprehensive assessment of quality is required. Volume is not a substitute for quality. This is a positive evolution.

The document reports some core infrastructure requirements and recommendations. They include a minimum floor,

volume floor is required to reliably measure quality, the overarching importance of the multidisciplinary team, the importance of training, and institutional support for resources and facilities.

The writing committee recognizes that one of the key quality issues is the substantial variability in clinical outcomes. It will be very important to determine the contributing factors to variability in TAVR quality through the CMS coverage with evidence development, CED. This is one of the most pressing issues in the near term.

So, Dr. Canos asked for data and evidence, so the next few slides are going to be data and evidence. Members of the panel, CMS initially asked about the validity of the volume-outcome relationship and why it is important. We will try to answer this question. Oops. Can I go back? There you go.

The circles represent TAVR programs in

the United States through December 31st, 2016. The X axis is the observed over expected, O to E (O:E) ratio of death in 30 days. Generally any O to E (O:E) ratio over two is certainly problematic. One

of the things you should know about this slide is the average O to E (O:E) ratio was .72, not 1.0.

DR. BACH: I'm going to interrupt for just one second, not to get you off your topic. Just so everyone realizes I'm not editorializing, this graph has the axes flipped relative to the prior speaker. It has no effect on the interpretation, but just so everyone knows, volume was counted along the horizontal or X axis by the prior speaker and mortality was shown on the Y axis, this is the other way around. That's all. Sorry for interrupting, and you'll get those 15 seconds back.

DR. BAVARIA: That's a good point, thank you. Okay, where was I? On the Y axis is site annual volume, as you just heard.

There are a few takeaway points. There is undoubtedly a volume-outcome

relationship, it is dramatic. This initial, initial 2016 analysis of the volume-outcome relationship was the canary in the coal mine that informed the writing committee to examine quality of TAVR in the United States further.

96 percent, another point, 96 percent

of sites with an O to E (O:E) ratio of greater than two were programs with less than 100 TAVRs per year, and most were less than 50 TAVRs per year.

This slide shows the data, the same data, with all programs under 100 TAVRs per year removed. It shows that the volume-outcome relationship flattens at over a hundred cases per year.

This is a recent phase of care mortality analysis presented at the 2018 ATS meeting by the Michigan Quality Collaborative Group studied the root cause of death and whether the death was avoidable following TAVR. The analysis revealed the highest percentage of TAVR mortality, at 41 percent, occurred during the procedural phase of the operation or the procedure, and 51 percent of those deaths were

classified as avoidable. A volume-outcome relationship was then evaluated for TAVR. The graphic display you see here shows that TAVR exhibited a volume-outcome relationship as an exponential decay function with flattening of the curve between 50 and 100 cases. This volume-outcome relationship supports the

consensus document recommendation that new program sites have an experienced proceduralist on the heart team to minimize avoidable deaths, in other words, to obviate the learning curve.

These are a series of important slides. This is the most recent data not from a while back, this is hot off the press from the TVT registry, it includes patients treated over a one-year period ending in 2017. The data was analyzed by the DCRI, an independent analytic center. The outcome shown here is 30-day mortality, there are three plots. The left is raw mortality frequency and the next two on the right are mortality expressed as an observed to expected ratio, the O to E (O:E) ratios. On the horizontal axis is site annual volume

expressed as bins. This allows us to see the results for sites below and above a 50 annual threshold. The open circles represent the mean values of 30-day mortality rates.

So first, the absolute 30-day mortality is strongly associated with annual volume. The O to E (O:E) results strongly suggest that low volume sites have worse results. The red dots show individual site results. The colored

bars of inter-quartile range show that there is variability in site outcomes that is greatest in the low volume sites and minimal at the high volume sites.

This slide highlights in yellow the result of the sites below the 50 annual threshold. There are three points to be made. The average value showing a higher mortality at low volume sites is clinically meaningful, death is death without statistical uncertainty. Uncertainty of the quality of care is problematic. We want a healthcare system structure and policies that provide greater, not less certainty as patients, families and clinicians make treatment decisions.

The overall trend in the last five years of commercial TAVR in the United States has shown a steady and meaningful improvement in outcomes. These concerning signals for worse low volume outcomes are buried in the overall improving results because the sites doing over 50 cases a year account for 84 percent of all cases performed in the United States.

Finally, these results represent sites

that have opened under the requirements of the original NCD, including the volume thresholds we currently now have in place. Reducing these thresholds would be expected to create a large increase in number of low volume sites, potentially decreasing volumes at existing sites and potentially shifting the overall outcomes in the United States towards low volume sites and away from much better results of the higher volume programs. Reducing volume standards would sacrifice quality for expansion of access, without any scientific evidence that 584, as we speak today, centers is inadequate.

On this slide the blue shading highlights 30-day mortality rates that exceed four percent. There are sites above this threshold in all volume bins except the two highest volume bins. We are focused on providing data so all sites can improve their outcomes and not, repeat, not on closing programs that fail to meet volume thresholds. Our immediate goal over the next three to six months is to provide CMS and others with more in-depth data addressing additional questions CMS may want answered as part of the coverage

with evidence development. We would suggest that any updated CMS policy, be it a new NCD, be based on solid evidence provided by this data.

This slide from the TVT registry answers the question of whether low volume programs are treating higher risk patients and if that is the reason their outcomes are worse. The answer is no. They are actually treating lower risk patients with worse outcomes.

The next series of slides show how we interpret the relationship between volume and

outcomes and the special conundrum of low volume. Programs in the green box are high volume with good quality. This is real. These results are statistically valid. High volume programs in the red rectangle, unfortunately this is real as well, it represents statistically valid poor quality. These programs need remediation. If programs are low volume, there are wide error bars, and statistically we cannot draw valid conclusions on quality. Simply put, quality cannot be reliable determined for low volume centers, either good or bad. This is the conundrum of

the yellow-orange rectangles.

This slide is basically the same concept, so I'll skip over it for time purposes.

This slide outlines, documents quality control recommendations for low volume centers in the sense that we want to not close anything but keep them under good quality.

The past few slides demonstrate that a volume-outcome relationship is real,

programmatic TAVR volume requirements are essential, quality cannot be measured at very low programs, that have very low volume.

TAVR is a complex procedure. There is a 6.5 percent need for alternate non-femoral access. This is the most recent data from the TVT registry. TAVR still has major morbidity and mortality. There is a high risk of pacemaker necessity, and there is a combined intraprocedural catastrophic risk for cardiac arrest, conversion to open surgery, need for emergent cardiac bypass, left main coronary occlusion, or aborted TAVR procedures. When you add them all up, any one of the catastrophic events occur in approximately two

to 2.5 percent of the cases. This data answers the question concerning the need for experienced cardiac surgeons and interventional cardiologists to perform these procedures safely.

Slides 23, 24 and 25 will be addressed by Dr. Shahian in a few minutes.

I would like to also highlight other important sections of our consensus document

that I recommend, multidisciplinary team review as one of the absolute keys to quality; the use of appropriate use criteria; and importantly, shared decision-making with patients and families.

The TVT registry is presently engaged in developing robust quality metrics. We already have in-hospital and 30-day risk-adjusted quality metrics that all sites in the United States now receive in benchmark formats. Sites also receive major complications on their dashboards. We are currently developing a patient-centered quality of life metric which is a one-year alive and well concept, some of you might know KCCQ. Most importantly, most importantly, the TVT is

developing a risk-adjusted composite measure which will be the basis for national public reporting of TAVR outcomes in the United States. This slide represents three examples of the methods the TVT registry will use for site and public reporting of quality metrics.

One of the most important goals for

the NCD and TVT is to answer new questions and future concerns through continued evidence development. Examples are shown here, there are many.

SAVR requirements will be discussed by Dr. Tommaso and Dr. Sundt at the later meetings. Importantly, though, SAVR volumes have been reduced and definitions have been broadened.

At this point I would like to introduce my co-chair of the four-society writing committee, Dr. Carl Tommaso from Chicago.

DR. BACH: Thank you very much, Dr. Bavaria.

DR. TOMMASO: Good morning. Thank you very much, Joe. I am the co-chair of the 2018 writing committee document. I was the chair of

the 2012 writing committee document. I am the associate director of the cardiac catheterization laboratories at the North Shore University Health System in northern Chicago, the former president of SCAI, associate professor of medicine at Rush Medical School.

I'm an interventional cardiologist but I am one of four writing committee members who do not perform TAVR.

This morning I will address criteria for initiating and maintaining TAVR as outlined in our current document, and address some issues concerning access to TAVR care.

This slide outlines the suggested experience for initiating a new TAVR program. In the 2012 document the outlined prerequisites for a TAVR operator included procedures such as experience with balloon aortic valvoplasty and procedures involving large bore arterial access. In the current document we have done away with these prerequisites. We feel that the actual experience with TAVR is necessary. The manuscript states that operators should have had an experience of at least 50 TAVRs as primary operator. In addition, participated in

an additional 100 transfemoral TAVRs in a structured training program such as an interventional cardiology fellowship, surgical residency, or preceptee in an established TAVR

program.

With the increased number of fellows and cardiac surgical residents being trained in TAVR, as well as the number of physicians participating in preceptorships, we think this number is appropriate according to the learning curve outlined in several papers that Dr. Bavaria cited. We feel a TAVR operator should be experienced in TAVR, and the opportunity is available for such training. Board eligibility or certification in the appropriate specialty is necessary, device-specific training is appropriate, and the TAVR site must have an expertise in multi-imaging modalities, and the imager must be a member of the multidisciplinary team.

This is the requirement for the TAVR surgeon in a new program. We feel that the requirements for the TAVR surgeon in a new TAVR program include a lifetime experience of at least a hundred TAVRs, or 25 a year or 50 over

the prior two years. The surgeon should have done at least 20 SAVRs in the year prior to initiation of the new program. The surgeon

should be board eligible and certified.

As mentioned earlier, these requirements have been liberalized. In the 2012 document it was actually aortic valve implantation. We have liberalized those in this document to include any aortic procedure involving the aortic valve.

This is the institutional requirements for a new TAVR program. The PCI volume has been reduced to 300 PCIs per year. The institution must be an active participant in a registry. In regard to the quality, the PCI hospital needs to be above the 25th percentile for the most recent four quarters.

To address Dr. Pelikan's concerns, the inclusion of PCI as a requirement has been controversial, since PCI and TAVR are different procedures for different indications. In the 2012 document, the inclusion of PCI was used as a surrogate for an adequately sized cardiovascular program including all the necessary adjunctive programs. PCI is

important as we have found, because up to 40

percent of patients undergoing TAVR had significant coronary disease, and the presence of an established PCI program will help to prescribe appropriate approaches to therapy. In addition, .2 percent of patients undergoing TAVR will have coronary catastrophe during TAVR and will require an experienced PCI team for bailout.

Additionally, over 20 percent of patients undergoing TAVR will undergo an associated PCI subsequent to the TAVR. Experience in arterial, vascular arterial intervention repair is appropriate to assist with periprocedural and postprocedural bleeding complications, and an electrophysiology program needs to be available 24/7 because of the incidence of sudden dysrhythmias and need for pacing in the periprocedural period.

The SAVR requirements for a new hospital, this includes a minimal hospital volume of 40 SAVR procedures per year or 80 over the prior two years. This includes, again, all aortic valve procedures, not just SAVR, as was the recommendation in the 2012

paper. A quality assessment program must be in place. It's suggested that, active participation in a recognized database. The quality metric recommends a two- or three-star rating for isolated AVR and AVR plus bypass in the last year. Two or more hospital-based cardiac surgeons who spend greater than 50 percent of their time at that institution are necessary. This was inserted in order to prevent a situation where a surgeon is involved in the TAVR program and then move on.

The reason for these volume requirements is threefold. One, to ensure an experienced surgical team in case of procedural catastrophe; two, to allow patients, to provide alternative therapy to TAVR; and most importantly, to make sure the institution has an adequate volume of patients.

The next slide is the overview of maintaining established programs. The center should perform greater than 50 TAVR cases per year or a hundred cases over the prior two years. This only pertains to centers that have been operational for two years. This allows a ramp-up of new centers. More than 84 percent

of current programs in existence have, meet this volume criteria; in other words, 84 percent of the 584 programs -- I'm sorry -- of the 450 programs that have been open for two years meet 50 cases per year. Documentation of multidisciplinary approach and access to all forms of therapy for aortic valve disease, TAVR, SAVR and palliative care is necessary, and using a shared decision-making process. Active institutional participation in a registry. Heart team quarterly meetings. Documentation from corporation of TAVR/SAVR appropriate use criteria in patient selection process and obviously, CME for all heart team members.

The institution should perform greater than 300 PCIs per year. Active participation in a recognized registry, appropriate PCI outcomes and, again, a vascular team and an EP team are necessary. The institution should perform greater than 30, again, broadly defined SAVRs per prior year, or 60 over the two, to ensure maintenance of surgical skills. Quality assessment, quality improvement program, active participation in a database to monitor

outcomes, and a quality metric of two- or three-star rating for isolated AVR and AVR plus bypass in both reporting periods.

I'd like to skip to access to care. I want to define access to care in three general areas. One is geographic access to care, two is access to care in minorities requiring TAVR, and three is access from primary care.

This is a slide depicting all the U.S. TAVR centers as of May 1st, 2018. At this time there were 579 sites. This is approximately one site per 556,000 U.S. population. If we compare this to site density in other countries, Germany has one site per 840,000 population; France, one site per 1.4 million population; and the U.K., one site per 1.96 million. In these Western Europe countries with a combined population of 214 million, there are 178 centers or one site per 1.2 million people.

This is even more disparate if we look at population greater than 65 years of age. Europe has 15 percent of its population greater than 65, which translates to one site per

25 83,000 people older than 65. Germany where 21

1 percent of the population is over 65, this
2 translates to one site per 177,000 people over
3 65. In France, 20 percent of the population is
4 older than 65, with one site per 279,000
5 people. In the U.K., this is one site per
6 374,000 patients over 65 years of age.
7 Now getting back to the map here, the
8 blue dots are centers that have been open
9 greater than two years, and the red stars are
10 centers that have been opened in the last two
11 years. Several points to be made here. One,
12 Wyoming is the only state without a center.
13 Two, 84 percent of the centers that have been
14 open for two years have an annual volume of
15 greater or equal to 50 procedures per year. If
16 you were to superimpose a map of population
17 density over this map, it would demonstrate
18 that TAVR centers correspond very well with
19 population density in the U.S., with the number
20 of centers in the heavily populated eastern
21 corridor, Florida, major midwestern cities, and
22 west coast. Of note, the red stars which

denote the sites which have been opened in the last two years, have been opened in many smaller urban areas, including the southeastern

portion of the United States and the far west, but almost half of the centers opened in the last two years have been opened on top of areas with existing centers.

Do these requirements create unintended barriers to TAVR based on geographic location? With 584 current U.S. centers, they provide broad geographical access with rare exceptions, again, markedly better than high performing industrialized European countries already. Urban TAVR access is hindered by health care delivery issues such as narrow networks of payers, providers, along with the upstream lack of identification and appropriate referral for aortic stenosis management.

Next slide. This is a projected TAVR growth. With increased indications such as low risk surgical patients, treatment of bicuspid aortic valve disease and aortic insufficiency, the number of TAVR procedures is expected to reach a hundred thousand by the year 2020. At

a hundred thousand TAVR procedures a year and no further growth of the 584 sites, that would yield an average of 172 TAVRs per site per year, 3.3 TAVRs per center per week.

It's unknown where the margin of profitability lies, the point of economy of scale, or what market forces will apply, but performing less than one TAVR per week, 50 per year, imposes significant stress on the resources of an institution and may deteriorate the operator's skill set. Unlike PCI where STEMI has increased the number of centers to provide emergent care, there is little need for emergent TAVR.

This is some demographics from the TVT registry. The median age of patients undergoing TAVR is 82 years of age, so before we were talking about patients 65. The median age is 82, and we don't have any data either in census, U.S. census or in the Medicare projections as to this older population, and it's a vary narrow range in those patients.

More than half of patients undergoing

TAVR are men, which is somewhat surprising and unexplained since in this age group there's thought to be a predominance of women. Do these requirements create unintended barriers to TAVR based on gender? Any potentially identified gender access issue reflects U.S.

patterns of care rather than barriers created by inadequate number of U.S. centers. Further study of understanding gender disparities is ongoing in the TVT registry.

15 percent of Americans are African-Americans and 17 percent are Hispanic. The numbers of TAVRs from the TVT database suggest that only four percent of TAVRs are performed in African-Americans and 4.3 percent in Hispanics.

DR. BACH: Dr. Tommaso, please try to wrap up.

DR. TOMMASO: I will. There are several other things to consider, including that in the SCAI census there are only 6.3 percent of Americans aged 65 or older. We realize that the Medicare projection is an increase of nine percent by 2020. We also note

that in the STS database, only 5.7 percent of SAVR were African-Americans.

The other issue I want to discuss in terms of hindrance to Americans of TAVR is a lack of education of primary care in understanding the pathophysiology, prognosis and treatment options in patients with aortic

valve disease. This has been anecdotal and there's no data available, but all clinical cardiologists have patients who present with end-stage hearts as a result of aortic stenosis, and those patients have been followed by a primary care and never been referred for care. It has been said too many Americans are dying from aortic stenosis. I think it better that Americans who die from aortic stenosis have not gotten appropriate care. Education would go a long way in minimizing this problem.

So in conclusion, quality variability, not access nor volume alone is the key challenge. This document provides framework for moving from volume requirements to quality metrics, but adequate volume is necessary to

assess quality. Low volume centers should have ongoing case reviews as metrics are unstable. All studies should engage in ongoing measurement and QI. Registry is essential to assess long-term outcomes and variability involving patient cohort. Evolving quality would suggest external review programs to understand variability.

Thank you very much for the

opportunity to present here.

DR. BACH: Thank you very much.

(Applause.)

Next we'll have Dr. Martin Leon, who is the AdvaMed recommended speaker. Dr. Leon is a professor of medicine and director of the Center for Interventional Vascular Therapy at Columbia New York Presbyterian Hospital. He's the founder and chairman emeritus of the Cardiovascular Research Foundation of New York City. Thank you, Dr. Leon.

DR. LEON: Thank you. Well, you've been treated to a great deal of data, I'll do my best not to be repetitive and to provide a slightly different perspective.

AdvaMed did support my travel, accommodations to attend the MedCAC panel, and these are other relationships that you should be aware of that represent potential conflicts. Importantly, I've been an interventional cardiologist for 35 years. I've been involved in the early device development of TAVR for more than 20 years. I've been a principal investigator of the randomized PARTNER trials for more than a decade. I've personally

performed thousands of TAVR procedures as a primary and secondary operator, and I work in a center that last year did over 450 TAVR procedures in a hospital system that did over 700 TAVR procedures.

My role in this presentation is truly to represent the TAVR community and its stakeholders, particularly the patients. Let me start with several caveats. The public health imperative is to deliver improved access to all AVR therapies with optimal clinical outcomes for all patients with severe symptomatic aortic stenosis. The data

regarding the need for imposing increased minimal procedural volumes to initiate or maintain a TAVR center are imprecise and poorly validated. Recommendations rely disproportionately on expert opinions and do not incorporate quality metrics. Future significant growth in TAVR case volume due to expanding clinical indications must be accounted for in all decisions which may adversely affect patient access.

The nine questions posed by MedCAC and the additional topics for discussion will be

answered responsively as a supplement to this main presentation and have been made available to the panel. The purpose of my presentation is to provide needed clinical perspectives, to frame the critical issues regarding procedural volume thresholds as a central metric for TAVR site selection, and to suggest alternative quality-based approaches which will optimize both patient access to and clinical outcomes after TAVR procedures.

This is an overview of my presentation. There are many slides and in the

interest of time I will scroll through some of them and focus on the ones that I think are most relevant. The entire presentation is obviously available for your perusal.

Let's begin with background. This is the 50th year anniversary of a seminal manuscript in Circulation describing the natural history of aortic stenosis and an iconic figure, probably one of the most recognized figure in all cardiology, demonstrating that once patients have severe aortic stenosis and develop symptoms, there's a precipitous fall-off from the standpoint of

survival.

We had an opportunity in the first PARTNER trial to recapitulate prospectively those retrospective necropsy observations that were made 50 years ago. These data were published and the five-year follow-up were also published in prestigious journals, and this is a single figure which clearly indicates that in this population of 358 randomized patients, those that received non-TAVR treatment had a 50

percent one-year all-cause mortality, and TAVR had an absolute reduction of 20 percent in all-cause mortality in the first year, meaning the number needed to treat to save a life in the first year was five.

Now these are data from a clinical trial. As we make public health statements we need epidemiologic data, we need real world U.S. data. We've engaged the Optum electronic health record and claims database to try to get more information that will help us to make some of these decisions. The size of the population, 160 million records. These are older and younger patients, commercial and Medicare patients. The scope includes multiple

institutions. The depth is significant, including performance status, symptoms, traceability and specificity. It's a rich database.

I'm going to start with this heat map which gives you an estimate of the U.S. incidence of severe symptomatic aortic stenosis in 2016. It's between 250,000 and 350,000 patients, including both diagnosed and

undiagnosed aortic stenosis. Now I've superimposed here the SAVR centers and the TAVR centers that are currently practicing in the United States. Importantly on this heat map, you see the AVR treatment penetration relative to aortic stenosis incidence in 2016. Overall it's less than 35 percent, averaging 24 percent, despite over a thousand surgical centers and over 450 TAVR centers. In fact, no state had over a 40 percent treatment rate in patients with severe symptomatic aortic stenosis.

There are several factors that impact AVR treatment likelihood and in this multivariate logistics model, certainly elderly patients are less frequently treated, blacks

are less frequently treated, women are less frequently treated, and depending on who the diagnosing cardiologist is and his interest in referring patients for AVR, has a significant impact on whether or not patients receive any AVR therapy.

So to summarize, untreated severe

symptomatic aortic stenosis has a grave prognosis. There's a wide gap between the incidence of this disease and AVR treatment due to both underdiagnosis as was mentioned, but also undertreatment after diagnosis. Undertreatment bias is affected by multiple factors. Current access to AVR, either surgery or TAVR, is still suboptimal and will only worsen as case volumes increase in the future, recognizing that with this NCD, we are projecting well into the future.

I want to spend a moment talking about TAVR evolution and growth, this is an important slide, it shows you the estimated U.S. TAVR growth between 2018 and 2025. This year we expect to see close to 70,000 TAVR procedures done; by 2025, that number will increase to over 160,000. As a percent of total AVR this

year it will be, about 48 percent of all AVR will be TAVR. That number will also increase to more than 75 percent by 2025. So we expect that surgery for aortic stenosis will decrease at a time when we see a rapid and almost dramatic growth in TAVR based on expanding

clinical indications.

So what drives this growth? Certainly the acceptance of a multidisciplinary heart concept which we all believe in; the commitment to evidence-based medicine clinical research, something that I feel strongly about is the evidence that CMS is asking for; rapid technology advancement; simplification of the procedure, all of which has resulted in a striking reduction in complications and improved clinical outcomes, which I'll demonstrate to you in some subsequent slides.

This is an interesting slide because it shows you the 24 previously done or ongoing randomized trials in TAVR throughout the world. It's an extraordinary outpouring of clinical evidence that has justified this procedure over the past decade. And in fact, since 2007 in the United States, more than 15,000 patients

have been enrolled in these studies, including ten randomized trials with multiple generations of four different TAVR systems. There's no lack of data which has informed the guidelines.

Most recently we focused on intermediate risk patients, and I want to share with you some recent data in a late-breaking trial presented at the PCR last month where they looked at intermediate risk patients with the most current balloon-expandable TAVR system, the so-called Sapien 3, and compared data from the FDA qualification study and the TVT registry. So the FDA trial involved 51 high volume largely academic centers as part of a thousand-patient study. If we scroll over to the TVT registry, we now have 453 centers, low, medium, high volume centers involving almost 9,000 patients.

The methodology was a propensity matched analysis one to one to three of the transfemoral population, very important, with 24 baseline covariates using a logistic regression model with S3 used as the control. These are the propensity matched, again in TF patients, 30-day mortality and stroke outcomes.

We could not find a difference in all-cause mortality at 30 days if you were part of the FDA's 50-site study that were high volume

versus the TVT registry, including all centers, and the same was true for stroke.

And if you look at other outcomes, exactly the same. As you generalize to well-trained sites that have had experience with TAVR whether high, medium or low volume, the overall outcomes were as good as the highest volume sites in the most recently approved indication.

Certainly there are many other clinical indications which we think will be served by TAVR in the future, and there's no question, I believe, and I think most of you in the room would agree that this has been a breakthrough therapy with rapid evolution of technology, procedural factors, with an expected significant growth that will strain the capacities of many centers threatening to limit TAVR access. And importantly, in the current environment of strict adherence to evidence-based medicine principles, careful site selection, rigorous site training and

continuous monitoring and oversight, the

clinical outcomes have stabilized, they've become mature and are excellent across the spectrum of TAVR sites under the current NCD case volume requirements, as shown in this most recent intermediate risk patient cohort that we analyzed.

But the central question is the TAVR volume-outcome relationship issue. Now it's difficult. These are two joint society expert consensus documents. Many people who are on the writing committee are close friends, they've been drafted, they have significant health policy and patient access implications. We did not have access to the final version as we were asked to put this slide set together, but under the preamble I think it's quite similar to some of the earlier versions that we have previously seen. So these are important documents and I'm certainly not trivializing the necessity to have consensus documents that are supported by multiple societies.

But let me put this in some perspective. This is real world perspective from 2017. There are 1,872 hospitals

performing PCI, of which 1,103 hospitals perform surgical AVR, of which in 2017, 540 were performing TAVR. So of the hospitals that performed PCI, only 29 percent had access to a TAVR program, and of the hospitals performing surgical AVR, less than half had access to TAVR.

Now the TVT registry provides enormously valuable data. This is an important publication that initially spoke to the volume-outcome relationship. It was initially an early experience from 2011 to '15. It was a consecutive case sequence analysis involving devices, frankly, that are no longer being used. The mean age was 83, the STS score average was 6.6, almost 40 percent were over eight. These were high risk patients. 30 percent were transapical. This is not the real world, or the modern era of TAVR. They looked at unadjusted and risk-adjusted outcomes for four different outcomes, mortality, strokes, vascular complications and bleeding.

Let's just focus on mortality because this seems to be the focus for many people. If you look at the mortality in this case sequence

analysis, certainly there were statistical differences suggesting that both unadjusted and adjusted outcomes were affected by volume, but if you look at the absolute difference in mortality, it's one percent, and half of that one percent is in the first 50 cases, which is undoubtedly the learning curve. So truly, about a half a percent of absolute difference in mortality defining the overall volume-outcome relationship in these early experiences.

In the transfemoral subgroup, which is now the state of the art for TAVR, 95 percent of patients being treated that way in most centers, there was no association between site volume and outcomes in risk-adjusted mortality with a P value of .15, and in both unadjusted and adjusted strokes.

Now let's enter the modern era. This is one of the two currently practiced valves, the Sapien 3 valve, and this is from the TVT registry looking at unadjusted 30-day mortality. We could not find, using a case sequence analysis, any significant change in mortality associated with volume using the

Sapien 3 device in the recent experience. If you translate that, and this is a carefully conducted weighted analysis of volume cohorts into low, intermediate or high volume, you can again see there's essentially no difference in 30-day mortality, unadjusted 30-day mortality or unadjusted 30-day stroke rates.

Now let's look at hospitals that are seeing Sapien 3 as their first valve, newly initiated hospitals, and there are 53 in this analysis from the TVT registry, and again, we could not see in low, medium and high volume centers any significant difference in the unadjusted 30-day mortality in these new sites as well.

This is not isolated to the Sapien 3. The self-expanding CoreValve in its current characterization as the Evolut R/PRO, if you look at TAVR volume and you look at mortality, there was no statistically significant difference from the TVT registry. In fact, of the 60 hospitals with TAVR outcomes, excuse me, TAVR volumes of less than 50, achieved zero in-hospital mortality.

25 Similarly, if you look at this

1 analysis slightly differently with volume
2 cohorts, once again you see no significant
3 difference in low, intermediate or high volume
4 cohorts in a carefully weighted analysis. Now
5 these are the same data that were recently
6 presented by my colleagues, and we have not
7 been able to replicate some of the observations
8 that were made in the unpublished data set that
9 was presented, which is something that we
10 should be discussing later today.
11 Now those were data from the TVT
12 registry. This is MedPAR data, which is all
13 data, all valves currently in use in the United
14 States, to address the issue of whether or not
15 either prior or current volumes of surgery or
16 PCI have an impact on TAVR mortality, and in
17 this combined slide you can see that prior
18 surgical volume, current surgical volume, prior
19 PCI volume or current PCI volume have
20 absolutely no impact on TAVR mortality. These
21 are the individual data from those four panels.
22 Most importantly from the MedPAR data

analysis looking at current TAVR volume and its impact on TAVR mortality, as you can see, there is no significant relation to suggest that we

should be urgently changing the volume requirements in the current NCD.

In fact if you look at this again carefully, and look at the mean TAVR adjusted in-hospital mortality, once again, you do not see a relationship as you go down to lower volume centers. And if you look at the upper bound of the 95 percent confidence interval for the lowest volume centers, the absolute in-hospital mortality is only 2.2 percent.

What is interesting is that if you look at surgical volume and its effect on surgical mortality, there is a relationship, it's not quite statistically significant, but the more surgery you do, the better outcomes you get, not so with TAVR.

Looking at changes in mortality trends over time are important. This is the same MedPAR data analysis looking at in-hospital mortality. Let's start with surgery. If we go back to 2012, the surgical mortality was 3.9

22 percent. If you scroll forward now five years
23 to 2017, it's 4 percent. It does not deviate
24 very much and has not deviated very much. If
25 we look at TAVR in 2012, it was 4.7 percent.

1 Now in 2017 it is 1.5 percent, dramatically
2 less than surgical mortality, despite the fact
3 that the patients are almost ten years older
4 and the Charlson Comorbidity Index was 30
5 percent lower in the surgery patients.
6 Now as to literature on AVR
7 volume-outcome, and Dr. Pelikan already alluded
8 to some of it, and we exhaustively tried to do
9 a search to see what data is there. We've
10 identified 30 manuscripts we think are worthy
11 of discussion and I've summarized them on this
12 slide.
13 First looking at surgical volume as a
14 reflection of TAVR outcomes, only two studies,
15 and no relationship between surgical volume and
16 TAVR outcomes. There are two other studies
17 that indicate that increasing TAVR volume was
18 associated with improved surgical outcomes.
19 What about PCI volume and TAVR outcomes? There

were no manuscripts, there was only one abstract, showing no association between PCI volume and TAVR outcomes. How about TAVR volume predicting TAVR outcomes? There were 26 studies, seven reported no relationship, 19 reported that as TAVR volumes increased,

adverse TAVR outcomes decreased. The 19 reports showing the relationship were limited by small sample size, poor control of confounders, and early, before 2016, time bias in all cases, and none really assesses specific recommended volume thresholds that would alleviate the situation.

You know about the existing TAVR programs, NCD, and at least the information we had about the draft multi-society consensus documents. Currently, institutional surgical volume, 20 per year or 40 over two years, with a recommendation to increase by 50 percent but liberalize the definition of SAVR per year, or 60, so increase the surgical requirements at a time when surgery is going down. And the institutional TAVR volume, from 20 per year to now 50 per year, a two-and-a-half fold increase

as the base, as the minimum volume threshold to be a TAVR center.

It gets worse when you talk about new TAVR programs where the expectation is, and these are essentially lower volume sites, you have to have at least 40 SAVRs or 80 over two years. And when you look at the requirements

for an interventional operator, and that could be either a surgeon or an interventional structuralist, 100 transfemoral TAVRs with 50 as the primary operator, placing significant burdens on starting up new sites.

So let's do some scenario testing. If you apply the 50 TAVR, 30 surgical annual volume requirements, looking at 2017 data from the 540 centers that are open, you would find that almost 40 percent would not fulfill those requirements and you'd have to decrease the TAVR centers in the U.S. It's not clear that we're going to be closing centers, but when you publish these kinds of thresholds, the impact has nothing to do with what the society says, but certainly CMS may be obligated to enforce,

and institutionally and administratively, it imposes significant burdens.

When you look at that same heat map that I showed you on penetration, every one of these circles would be eliminated if you applied that 50-30 threshold, and among those, the white circles are centers that had achieved zero mortality in 2016, so 70 percent of the below-volume threshold sites had no mortality

in 2016. If you try to talk about how we're going to potentially increase numbers of TAVR sites and you look at the existing surgical only sites, less than 25 percent would be eligible for TAVR based upon the increased volume requirements.

So TAVR outcomes have not been affected by either surgery or PCI volumes, the MedPAR data is conclusive. The TVT registry had indicated an association between TAVR volumes and TAVR outcomes in the early analyses, which is difficult to dissociate with learning curve issues related to a new therapy. The recent TVT registry analyses involving new devices after 2015 have shown no volume

threshold outcome relationship with Sapien 3 or Evolut R/PRO, the currently practiced devices. And scenario testing clearly indicates that arbitrarily increasing the TAVR and SAVR volume requirements will adversely affect patient access.

So finally, some additional topics and program recommendations. I read carefully the consensus document. It's an extremely well written and thoughtful document, I appreciate

the addition of the preamble which clarifies many things, but it doesn't go far enough. Many of the statements in the document I certainly agree with. The last bullet here, the TVT registry has gathered data in over a hundred thousand patients, and the focus is three new directions, and I want to reference each of these directions.

One, emphasis on direct measures of quality of care. Two, emphasis on the care of all patients with aortic valve disease rather than only those receiving TAVR. And three, emphasis on the importance of shared

decision-making processes.

In that document they speak to four phases of TAVR, an early investigative phase, an initial rollout commercial phase, and then a commercial steady state, which is I guess where we are now, and a mature state by 2025. The narrative from the consensus document makes good sense with clear goals to rely on quality metrics rather than crude site volume thresholds to determine TAVR and surgery performance, and site readiness as a new or existing TAVR center. The main difference in

opinion is the need for acceleration in timing to the quality metric platform, without a burdensome and arbitrary increased volume transition period of seven years, which will limit patient access. So these last two phases, the steady state and mature state should be combined, as TAVR has already demonstrated excellent outcomes at the current NCD volume thresholds.

Direct measures of quality of care alluded to in the consensus document, they should begin immediately with direct quality of

metrics using a database which is already here, the TVT database. You could look at raw in-hospital mortality outcomes compared to national benchmarks, risk-adjusted outcomes, specifically in-hospital and 30-day mortality, as a start. You can evolve over time to other validated outcome measures, including composite endpoints, including quality of life. The methodology has already been developed for surgery outcomes with the STS database accounting for low-volume center statistical considerations. They've been doing this for a decade. In fact, there's significant published

literature on how to deal with the lower volume sites from the standpoint of statistical adjustments.

This is a complex slide, it speaks to the issue that outcome thresholds and not volume thresholds will lead to better patient care. I want you to focus on just the left panel. If we look at the data that we currently have from 2016 from MedPAR and we look at centers, now imposing a 50 TAVR 30 SAVR

threshold, in pink, which you can see there, 43 percent of the current practicing centers would no longer be practicing, 16 percent of the patients who receive TAVR would not receive TAVR.

But what would be the impact on the overall mortality? We're going to go through all of this trouble to try to adjust the volume thresholds. Well, the mortality would go down from 2.0 percent to 1.98 percent by making all of these adjustments and increasing the volume threshold.

The second point, emphasis on all AS patients and therapies, so all forms of treatment should be available and offered to AS

patients, including TAVR, surgery, medical care, palliative care, as appropriate for the clinical circumstances and directed by a multidisciplinary heart team. Everybody in this room should feel that way. The dilemma of SAVR-only centers in the U.S., which is the 600-pound gorilla in this room which nobody wants to talk about, which is currently one half of all AS AVR treatment centers, creates

caregiver and referral biases resulting in disparities in optimal AS treatment. Increased volume requirements will further limit patient access to TAVR as a treatment alternative at a time when the aging population and expanded clinical indications will demand more, not less, access to TAVR. Decreased access to TAVR will result in prolonged AVR treatment wait times and geography-based constraints which will negatively impact AS outcomes.

This is data, again, from the MedPAR database, demonstrating that in the surgery-only centers, the annual mortality, that the mortality was 6.7 percent, and in centers where TAVR and surgery were available, the surgical mortality was 4.4 percent. By

having TAVR at a surgical hospital, it reduces the surgical mortality substantially.

This is a slide showing the impact of waiting, increasing wait times, which is common in many countries including Canada. This data from Chris Malaisrie at Northwestern indicates that in the third quartile up to 5.1 weeks, if

you don't do a procedure, four percent of the patients will die; if you wait to three months, that number climbs to ten percent. And if you look at the Canadian data, they're almost identical, an additional 15 percent of the patients will be admitted to the hospital for heart failure. So if you limit the access and increase wait times for whatever reason, these are the outcomes you can expect from a public health standpoint.

DR. BACH: Dr. Leon, please wrap up.

DR. LEON: Okay. A systematic review of the association between patient travel and travel distance in healthcare services has been done, indicating distance decay is important, and this association was present in many studies across a wide range of technologies.

I think we all care about the patient

in this room. I want to speak to the last point, which is shared decision-making. The profound influence of a shared decision-making process and declared communication aids is now being embedded into the patient management discussions, informed consents, FDA approval,

clinical trials, and CMS coverage determinations.

Some seminal work has been done by Megan Coylewright, who you'll hear from, where the appropriate questions are asked of patients as to what's important. It struck me that aortic stenosis patients care as much about staying alive or reducing symptoms, but cared a lot about maintaining independence and the ability to do a specific activity, so the concept of shared decision-making becomes distorted in an environment when patient access to all therapies is further limited, especially a therapy like TAVR. Currently, the high prevalence of SAVR-only centers for AS is problematic for shared decision-making and in the future if this is to be coveted, then the goal must be to reduce SAVR-only centers for the treatment of AS patients.

So the consensus document thoughtfully addresses the need for quality metrics, patient access to all AS therapies and shared decision-making processes. However, arbitrary

implementation of increased volume requirements and the delay in introducing quality metrics are counter to the above-mentioned principles. The limitations in access to TAVR will create a distance decay, delayed wait times, and will serve to worsen clinical outcomes, and shared decision-making will be eroded by available therapy disparities.

So I want to conclude by offering a compromise from the standpoint of AVR volume recommendations. In the spirit of maintaining and hopefully improving both patient access to all therapies and achieving optimal clinical outcomes for all AS patients, clearly quality metrics should supersede arbitrary volume thresholds as a general principle. We feel that surgery volumes in fact can be eliminated as a criteria for new and existing TAVR centers, and they should be replaced by a quality metric such as having and maintaining a two star rating defined by the STS. PCI

volumes should be decreased, although we need to have an infrastructure from the standpoint of skills to be able to perform PCI. TAVR

volume should be maintained at the current NCD levels of 20 cases per year or 40 over two years to maintain necessary infrastructure and skill. The reasons to justify maintaining these volumes are that we've already seen excellent clinical outcomes --

DR. BACH: Dr. Leon, you're out of time, I'm sorry. Can you just hit on high points?

DR. LEON: Okay. Last bullet. A TAVR quality metric should be integrated in the proposed new NCD to rapidly replace the need for volume requirements and to more closely monitor the clinical outcomes of all TAVR centers, especially the low volume centers, with corrective measures for poor performance installed as needed. Thank you.

DR. BACH: Thank you very much.

(Applause.)

Again, apologies for interrupting people but we are trying, we have to stay on time.

Next up is Dr. Aaron Horne, who's a

structural interventionalist, and a board member of the Association of Black Cardiologists. Good morning.

DR. HORNE: Good morning. Thank you for the invitation. Again, I'm here as a representative, a member of the Association of Black Cardiologists and as a co-chair of the Structural Heart Task Force for the Association of Black Cardiologists, which was actually implemented three years ago when some of the data that you saw previously from the TVT registry showed that over a five-year period of time, there was still only a 3.8 percent penetrant of this particular technology within the African-American community. So we've spent a significant amount of time researching this, and we think it's incredibly important that you are giving us a platform to discuss this today.

I have no conflicts to report.

So, we look at the question that, one of the questions I was asked to address is, again, whether or not there are unintended barriers to access created by volume requirements? The simple answer to this is

yes, and I think that it's important to be a little bit provocative with this because oftentimes, and again, the mission of the Association of Black Cardiologists is to help equity. We have an opportunity, I believe today, to prevent being able to go down this path again of talking about unintended consequences. By looking at the data critically, I think we have an opportunity to not go down that same path.

So, do hospital volume requirements create unintended barriers to TAVR? Again, there's limited evidence supporting specific volume requirements. As we've seen today, volume requirements create barriers to access for undertreated populations that I'll demonstrate in my talk today, especially minorities, and the focus should be on broadening appropriate access.

So today I'll go through some of the literature in discussing and understanding access to valvular heart disease treatment and existing disparities. We'll talk about the impact of volume requirements, and again, I think most importantly, we'll discuss solutions

to providing TAVR to underserved populations.

So, disparities exist in a range of different areas, race, women, elderly, community versus academic centers, and geography. So, we have one study that's reported lower severe aortic stenosis in African-Americans with significant limitations. You know, I think that one of the things that we see when you critically evaluate the data is that there's clearly underdiagnosis and undertreatment of aortic stenosis within the African-American community. I have some data that I'll demonstrate later, and if you look at the way in which this information is amassed, it's critically important. We know that there has been limitations to long-term care relationships within African-American communities specifically, and we know that also if you look at patients that are in long-term healthcare facilities, you see that actually there is an increased diagnosis if those patients actually have an opportunity to be in a sustained environment. So again, we'll go through each of these articles, but we know that existing disparities in TAVR are well

documented.

Here is a study that was published by Dr. Ben Rodriguez and he looked at, again, a retrospective cohort design in four community-based hospitals, at patients greater than 40 years of age with aortic valve disease from January of 2011 to June of 2016. And after adjusting for clinical and echocardiographic variables, black patients were less likely to be referred for cardiothoracic surgery for treatment of aortic valve disease than white patients. An adjusted odds ratio for CTS referral was .48 for blacks when compared to whites.

This, again, was a publication by Dr. Waksman and despite an overall increase in referrals for TAVR, blacks are still less likely to be referred for treatment. And this is, I think again, very interesting information. Again, if we go back into the FDA approval in 2011 and even if we look at, again, the fact that now that we've gone from inoperable and high risk patients being able to be treated via the guidelines to now, even with

25 the intermediate risk patient populations being

1 able to be treated and even, I think we have an
2 opportunity to improve on this, but even with
3 more familiarity with this disease process,
4 African-Americans are still treated less
5 likely.
6 So if we look at, again, racial
7 disparities in TAVR implantation result from
8 multiple complex factors, and this is a topic
9 that I think really hopefully as a panel we
10 have an opportunity to discuss, because
11 oftentimes when we talk about health equity, I
12 think it's important to not hopefully be
13 paralyzed by the fact that it is a complex
14 issue, but I would argue to try to be creative
15 and try to find solutions so that considering
16 the high mortality associated with this
17 particular disease state, this is something
18 that I think does need immediate attention.
19 So, aortic stenosis impacts all races.
20 So based on limited data, prevalence of aortic
21 stenosis does not vary by ethnicity. However,
22 African-Americans are at increased risk for

earlier onset of aortic stenosis, hence becoming symptomatic more quickly, and we saw the Brownwell and Ross curve and how these

patients can very quickly fall off that curve and again, it results in death. We know there are about 78,000 African-Americans at risk of severe aortic stenosis in the United States.

So, aortic stenosis impacts all races with little variance, and again, this is a very interesting slide, because what happens is if you look at this particular document, we know that actually African-Americans in the hospital settings have been less documented to have aortic stenosis based on physical exam or based on their interaction with the particular healthcare providers.

However, if you look at objective findings such as echocardiographic findings in African-Americans, Hispanics and white men and women greater than 60 in a long-term health facility, again, these are patients that are in a captive environment, and you follow and you do echocardiograms in these patients, they actually have just as high of a prevalence,

even if they might not have had an opportunity to interact with a long-term health provider over time and to be able to have that documented in their medical record. However,

when you have them in a long-term health facility, they actually have just as high prevalence of aortic stenosis.

However, we know again that African-Americans are at an increased risk for earlier onset of aortic stenosis and become more symptomatic quickly and obviously, most importantly, clearly all the presenters today have made the focus of this the patient. The critical nature of this disease state means that these patients obviously have increased morbidity and mortality, and there's obviously increased costs associated when they are becoming more symptomatic more quickly and having increased hospitalizations and emergency room visits for heart failure exacerbations and the like.

So again, this is another trial that Dr. Shaked, et al., looked at a cross-section

of a healthcare utilization project of aortic stenosis inpatient discharges of patients greater than 50 years from 2002 to 2012. Blacks were thought to have a lower prevalence of aortic stenosis than whites based on patient records. But again, this is incredibly

important; based on clear objective data, based on echocardiography, the prevalence was parity. So the discrepancy, again, may be underdiagnosis of aortic stenosis in African-Americans.

African-Americans historically have been undertreated for valvular heart disease and again, I think this is important because obviously this is not just in the aortic valve space but also in the mitral valve space. If you look at this particular trial, we saw that about 1,400 adult patients who underwent first-time isolated mitral valvuloplasty or mitral valve replacement at two institutions between 1993 and 2003, you can see that African-Americans were less aggressively treated.

We also know that -- and this is a

very important slide. If you look at the lower right, aortic valve replacement in African-Americans and low income groups to the single urban tertiary care referral center in a retrospective case control study, 67 TAVR patients with severe aortic stenosis, to control with TAVR, non-blacks were

significantly more likely to receive TAVR than blacks, and income disparity was also significant; so for every $1,000 increase in income, a .9 percent increase in the odds of receiving TAVR.

I'll show you some data a little bit later and if you look at, again, the Medicare population, there's a staggering difference in the median income of African-Americans compared to their Caucasian counterparts, and there's also a more striking disparity as it pertains to savings. And we talked about, again, a patient's ability to be able to access TAVR sites outside of one's particular community, cost is obviously associated with that as well, and so I would argue that this has further

exacerbated this particular issue and it is something that, again, I'm happy that we have an opportunity to discuss today.

So this is, again, was my foray into TAVR. I happened to be in that first wave of structural heart fellows to come out of training, and it was striking to us when we got this particular data that showed that only four percent of African-Americans, 3.8 percent to be

specific, were actually penetrating the transcatheter aortic valve technology, and this is why we spent a significant amount of time trying to bring light to this particular issue.

So, low TAVR growth among African-Americans. Again, TAVR penetration and growth in the African-American population remains low, and part of this topic has been frustrating because it's challenging at times to have to disprove a narrative that we don't see founded in terms of whether or not there is truly an underpenetration of aortic stenosis amongst African-Americans, and I'll show you more data that I hope is more compelling that while I hope we have already demonstrated that we see

that there's an underdiagnosis and undertreatment of aortic stenosis in the African-American population, it's also interesting to note that there's a higher refusal rate of this particular technology within the African-American population. So when we talk about the disparities that exist, I think it's important that we talk about the full array of this particular topic as it pertains to disparities.

So, Medicare beneficiaries will become more diverse as population demographics change, and that obvious information was revealed earlier as well. So, I think that what's really important, and again, this is true in the surgical literature as you'll see here, also in the transcatheter aortic valve replacement literature, that even though African-Americans have been underdiagnosed and undertreated, once they actually get to the therapies, the outcomes are just as good. So this is a very important point that again, in this era of hopefully shared decision-making

and health equity, and ensuring that patients are aware of the array of technologies that are available to them, that if they actually get offered the therapy and accept it, they are doing just as well.

So again, the first slide that I just showed was the surgical outcomes, but even if you look at transcatheter aortic valve replacement, and this is also from Dr. Waksman, that if they actually get referred, their outcomes are just as good.

So, reducing access to TAVR has a

disproportionate negative impact on women as well with severe aortic stenosis. If you look at this particular slide, women benefit more from TAVR than SAVR. And again, as my earlier slide said, the disparities exist not just as it pertains to African-Americans but as it pertains to women, as it pertains to regional variations, where people live in rural environments, et cetera, so this is something I hope that the panel will review as well.

So patients, and Dr. Leon actually showed a similar slide about this, patients

over 65 years of age avoid traveling for care. When presented with a one percent increased risk of death, 75 percent of patients would still prefer their local hospital. So that's pretty powerful, obviously especially as it pertains to shared decision-making, patients obviously deserve that autonomy to choose, again, you know, what's important to them. And the question is, considering the high mortality associated with this particular disease state, does it makes more sense to, as we've shown with the 1.5 percent projected mortality risk associated with this procedure, does it make

sense to not offer that patient an opportunity to receive this particular therapy when clearly they state that they're not willing to travel for their care?

So patients, again, this reiterates this, 23 percent of their decision to seek surgical care was decided by travel time. It's not an insignificant thing. You know, patients, a lot of times it's the hospital in which their children were born, this is the

community that they know, this is a place that they feel safe and comfortable in. And again, in this era of shared decision-making, those are all incredibly important factors that I think we have to take into consideration.

So, this was also shown earlier, the different variations in time between diagnosis and treatment is greater for TAVR patients. In 2016, the days between aortic stenosis diagnosis and treatment for SAVR versus TAVR, and you can see that there's a 134-day difference between diagnosis and treatment for a disease state, again, that had a one-year adjusted mortality of 50 percent if not treated.

The number of visits between diagnosis and treatment, again, is greater for TAVR patients. You know, 11 additional visits are typically seen for TAVR patients as opposed to patients that are offered surgical aortic valve replacement.

So if we look at, again, this higher volume requirement, it can negatively impact select rural communities. With a 50 TAVR and

30 SAVR annual volume requirement scenario, there are ten sole community centers that would be under volume thresholds, so there's a potential for ten communities to be left without access to appropriate therapy. It is very profound, and again, our membership base in the Association of Black Cardiologists is in Jackson, Mississippi, Pensacola, Florida; I mean, these are real communities, these are real patients, and I hope that this is something that we continue to discuss.

And if we look at it again, aortic stenosis patients do not do well waiting. If we look at it again in the interest of time, this is a slide we went over previously, but you can see that this is a particular disease

state with a very high mortality associated with it, and hints again under the current iteration, we see that patients that undergo TAVR evaluation wait 134 days more and have more visits, this is something that we hopefully can figure out how to streamline as well, and if we look at again at the 1.5

percent in-hospital mortality in 2017.

So, impact of volume requirements. Volume requirements would heighten socioeconomic and racial disparities. This is, again, a different study, and I hope that what's reassuring, because obviously the point here is to only address evidence that's here in the literature, and you can see that in the lexicon of literature on this particular topic, there actually is a significant amount of information demonstrating the issue that we're trying to address here. So again, for every $10,000 increase in income, the odds of receiving TAVR is increased by ten percent, and non-blacks were significantly more likely to receive TAVR than blacks, with an odds ratio of 2.812.

And so this is the slide that I

alluded to earlier. If you look at minority Medicare beneficiaries and the less economic stability to overcome additional barriers to access healthcare services, if you look at, again, the median per capita income of Medicare beneficiaries by race and ethnicity in 2016,

you're talking about 30,000 for whites and 17,350 for blacks, and 13,650 for Hispanics. And again the median savings, which is incredibly important, you have a difference that's, you know, eightfold. And so this disparity is something that we can't ignore, because we know that obviously economics are going to influence patients who are consumers in the healthcare space decision-making process, and the way in which we are currently constructed, this is something that these patients are still having to deal with.

So, few hospital programs will meet the proposed advanced center of care volume thresholds and again, this is an acknowledgement that this slide does not reflect the consensus document that was discussed earlier today, this is an older iteration that was a consensus document

regarding centers of excellence, so again, I want to acknowledge and clarify that. However, if you looked at the requirements that were previously suggested, only 10 percent of

centers would meet all three of these volume requirements, and therefore you would have a disproportionate amount of patients that wouldn't have access to what is clearly a lifesaving therapy.

So, volume thresholds could significantly reduce the number of hospitals providing valve services. So again, if you look at the reduction in the number of hospitals providing valve services from 1,135 in 2016 to 119 after the imposition of thresholds, this would be the environment in which patients would have essentially deserts of places where they could receive care if you factor in their preference or lack of preference to travel in, the economics surrounding their ability to be able to get access to said care.

So most importantly, what are the solutions? So, this slide is incredibly important, and I hope it's something that we

can reflect on a little bit. What I think we need to look at, again, patient reasons for not undergoing aortic valve replacement, you can

see here that you have a disproportionate number for patients in the African-American community that actually declines this lifesaving therapy. At the least, I would argue that is a rationale for some self-reflection, and I think it's multifactorial. Travel is clearly a piece of it, education is a piece of it. I think that, at least what I would hope, is an acknowledgment that this is something that we need to delve into a little bit more.

So we looked at, again, from the Journal of Racial and Ethnic Health Disparities, that after echo, blacks were more likely to decline AVR, be lost to follow-up, and to not be referred to cardiology.

So again, this is again from The American Journal of Cardiology and this is something that I mentioned earlier. But again, after adjusting for clinical and echocardiographic variables, black patients were less likely to be referred to

cardiothoracic surgery for treatment of aortic

valve disease compared to their white counterparts.

So, a potential solution. I would argue that existing geographical barriers would lead us to better geographical alignment. If we look at counties where 20 percent or more population is African-American and focused on centers in those particular areas, then one would argue that you'd have a better opportunity to, again, get care to the patient as opposed to putting the onus on the patient to go to where the treatment is available, considering other variables such as cost and comfort and preference that are currently limiting patients' ability to seek particular care.

This obviously, again, is a very very important article, and this was mentioned earlier, that it's critical to this discussion. However, I would argue that some of this data was based on earlier iterations of the valve when we had larger sheath sizes and you didn't have development as it pertains to ability to decrease perivalvular leak and things along

1 those lines with the new technologies.
2 So, solutions. I would argue, again,
3 that there needs to be a frank and honest
4 discussion, and acceptance of the need to
5 improve in this particular space. Three
6 potential opportunities are to conduct patient
7 outreach surveys, patients receiving TAVR and
8 those who refuse treatment. We should, I would
9 recommend developing a TAVR advisory board
10 partnering with the Association of Black
11 Cardiologists to increase patient awareness,
12 and develop a national campaign to address
13 disparities.
14 So, this is my experience. I am in
15 Dallas, Texas, and I came to a center which is
16 not dissimilar from a lot of other centers in
17 Dallas. However, if you look at the median
18 U.S. income, it's 57,000. If you look at
19 Dallas it's 47,000. In Oak Cliff where I
20 practice, it's 41,991. So during the period of
21 time that I've been there, we have actually
22 performed -- this was presented in May so we're
23 actually up to about 60 now, and in that period
24 of time, 28 percent of our patients have been
25 African-American when four percent is the

national average.

So, I would argue that this is not insignificant, and clearly there is the opportunity to do a better job of penetrating this particular demographic as we've shown in our smaller community-based hospital, that that's been what we've accomplished, and you can see, I'm proud of the outcomes that we've had, and this is something that clearly is a single center case study but I think it's indicative of the opportunity to improve, and note that if you look at just the stark difference in the penetration of African-Americans that we were able to treat in comparison to the national average.

So, implications and conclusions. I think we need to reconceptualize hospital metrics. Shared decision-making is not optimal unless all valve centers offer both SAVR and TAVR. Limiting patient access through arbitrary procedure-specific quotas will create unintended barriers and hopefully we have an opportunity to prevent those barriers from being unintended. Transparent quality metrics is how programs should be differentiated.

And we need to build greater understanding and awareness. Develop greater understanding of patient barriers to TAVR. Use that information to inform awareness campaigns directed towards patients and physicians.

And plan for community TAVR centers and novel outreach, aligning TAVR centers in communities where need is greatest and the population is underserved.

Thank you for your time.

(Applause.)

DR. BACH: Thank you very much, Dr. Horne. It is ten -- we are 14 minutes ahead of schedule, so thank you to all the speakers for that, for being crisp and concise. So the break is moved up and it's going to end at 10:31, we'll be back in our seats.

A couple of housekeeping announcements. There are, I've seen a number of my friends from the press in the back. Particularly, there's a separate sign-in sheet for people from the press which is currently blank, so may I ask that you sign in on that press sheet? Don't be ashamed of your

profession.

As regard to the press, we are all private citizens on this panel, but we will not speak about the topic of this MedCAC in the halls. Many of us are friends with people in the audience, we are happy to socialize, but we will neither speak amongst one another nor with the press, nor with anyone here during the breaks or at lunch. Afterwards, we are all free to do and speak with whomever we like. Thank you very much for your attention this morning.

(Recess from 10:17 to 10:31 a.m.)

DR. BACH: Thank you, Dr. Feldman, you have five minutes.

DR. FELDMAN: Thank you very much. I am Ted Feldman, representing the Society for Cardiovascular Angiography and Interventions. I'm a past president of the organization and an interventional cardiology practitioner in a medium-sized community hospital. I have been involved with PCI for over three decades and TAVR since its inception in trials here in the

United States. This is my disclosure statement.

First, I want to say on behalf of the

society that we endorse the multi-society expert consensus systems of care document, and I want to emphasize two points.

As a practicing interventional cardiology and TAVR operator, I am confident that a PCI volume threshold is important to both begin and sustain TAVR programs. Expertise in PCI is critical, not only to the ability to handle the not uncommon catastrophic complications of TAVR procedures, including coronary occlusion, but also the complex concomitant coronary artery disease that requires treatment ahead of these procedures in at least 20 percent of cases and commonly afterward.

And I also want to emphasize that the society is confident that procedural volume requirements for TAVR programs outweigh the harms of limiting access to TAVR to only hospitals that meet these volume requirements. We are confident that we've identified a

volume-outcome relationship with TAVR as has been demonstrated with virtually every other complex procedure in medicine, and we remain unconvinced that there's an access to care

issue that would be resolved by the addition of more TAVR programs.

I want to say further that the individual operator and institutional requirements may be less important than the aggregate of these requirements that we believe define institutions that have the physician resources, the institutional infrastructure, and the capability to deliver highest quality TAVR services.

I want to also take a minute to emphasize that the multi-society effort to promulgate a set of recommendations to optimize quality care for patients represents the real ideal of professionalism, and I want to reference a document that defined professionalism here, and note that this has been a collaborative work among four societies representing the majority of interventional

cardiologists and surgeons in the United States, and that this is the best of a process for self-regulation and standard setting, and that the goals of scrutiny and transparency in the document are really critical.

We do believe that patient and

physician education are the most important elements to improve access to care, and I think several of the prior presentations emphasized that the barriers to access are actually complex and multifactorial, and I want to emphasize one data point I've seen in the discussion of this issue over the last several months. In the state of Wyoming, which has zero TAVR sites, the rate of TAVR per Medicare population is significantly higher than in my home state of Illinois with 19 TAVR sites. It's very hard when you see those data to argue that adding sites in Illinois is going to improve the access to care, rather than working hard to educate patients and physicians regarding this disease. And I would say that a lot of the growth of TAVR that we've seen in the last half decade represents existing

efforts to promulgate education and educate both patients and physicians.

So we do remain focused on quality, and I think a couple of the next speakers are going to talk about how difficult and critical it is to measure quality, but the idea that access and more sites are equivalent, I think

has been a big part of the discussion up until now and there is absolutely nothing to suggest that those two things are equated with one another. Thank you.

DR. BACH: Thank you, Dr. Feldman. Next up is Dr. John Carroll, who is a professor of medicine at the University of Colorado School of Medicine, representing the American College of Cardiology, and thank you for coming.

DR. CARROLL: Thank you. My name's John Carroll, I'm a clinical interventional cardiologist, I perform, or I treat patients with valvular heart disease, and I do perform TAVR. These are my disclosures, I'm salaried, I volunteer my time to ACC.

The STS/ACC registry is a new model of collaboration among many stakeholders -- could I have my slides? So, this is a new model of collaboration among many stakeholders and we agree on much more than the disagreements that have been aired today. The registry has multiple critical functions creating a clinical knowledge machine, developing metrics for high stakes applications, providing the

infrastructure for aid to regulatory reimbursement colleagues.

Did the original NCD succeed in its purpose of rational dispersion of a new treatment? The huge growth in TAVR is related to the treatment access of 584 sites, and the professional consensus document does not close those sites, as has been thought by a draft. And the U.S. has the highest density of TAVR sites anywhere in the world. The excellent clinical results in the U.S. cited by many today have occurred in the context of the original requirements that include volume thresholds. That should go into the decision of the committee voting on these volume

requirements.

These data from DCRI have been explained by Dr. Bavaria. These are contemporary data, combining S-3 and Evolut. If you separate them out, you will lose the power of your statistical ability to determine differences. But clearly buried here in the overall improved outcomes is a signal that low volume sites have a great variability. Yes, some have zero mortality, but do you want to go

to a site that's done ten cases with zero mortality?

These outcomes are apparent with a 50-case threshold, and reducing the proposed requirements would be expected to create a large increase in the number of low volume sites. So, Dr. Leon, do you want to marry low volume SAVR sites with low volume TAVR sites, and low volume TAVR sites with higher surgical mortality? No.

As individual outcomes have improved, it increases the need to use composite outcomes to assess site performance and its relationship

to volume. These recently acquired concerning data argue that it's premature to discard consideration of volume thresholds.

We acknowledge that there are issues with access to TAVR due to patients not being told about TAVR and we need to correct that, not by opening more sites but by education. We acknowledge a concern with broad healthcare disparities based on rural locations, race, et cetera, and we would love to partner with Dr. Horne in addressing most of those issues that have nothing to do with opening more TAVR

sites, but basic healthcare education and access issues.

The TVT registry does gather data on reported healthcare outcomes pre and post TAVR, and we developed predictive models of patients at one year of being both alive and with an improved quality of life. This is groundbreaking work that must be continued. The NCD must continue with its coverage with evidence decision if we want to continue to learn, and solve many of these questions that have been raised today in a scientific way and

come up with the right solutions.

TAVR is not a simple procedure. 22 percent of patients undergoing TAVR have significant in-hospital procedures. It's not like simple hernia and should be distributed to all hospitals. The need for a PCI threshold is not related to a volume-outcome relationship, it's related to the experience and expertise to treat patients with severe AS and coronary disease. The need of a surgical AVR threshold relates to having high quality staff as an option for patients to select, and having surgical experience and expertise for the

multiple TAVR-related issues, and six percent of TAVR procedures still require surgical access.

And I'd like to point out that Dr. Leon actually agreed in his compromise with the need for some volume thresholds.

In conclusion, the transition to using sophisticated quality metrics to assess site performance has begun. Your voting to support certain volume thresholds during this

transition will protect patients and allow large families, a large family of high quality programs to continue to grow and fully mature. Metrics for performance assessment do not magically appear, they require much work to develop and validate from independent experts in health outcomes research. An accreditation process must be also developed, and I implore the MedCAC committee not to discard any consideration of volumes, you're not to vote on absolute numbers, but whether there should be any volume thresholds for programs to open and continue.

The unintended consequence of reducing standards, volume thresholds is

straightforward. It is to compromise the quality of care for all Americans, rural, African-Americans, et cetera. Thank you.

DR. BACH: Thank you, Dr. Carroll.

(Applause.)

DR. BACH: Next up is Dr. Shahian, I hope I'm pronouncing your name correctly, who's a professor of surgery at the Harvard Medical School, chair of the Society of Thoracic

Surgeons Council on Quality, Research and Patient Safety. Dr. Shahian.

DR. SHAHIAN: Thank you, good morning. Well, you've heard, or you will hear from other presenters, that volume thresholds are simply an inferior proxy to measures of quality and that they should be eliminated. Quite to the contrary, we believe that volume thresholds are an absolute prerequisite for accurately measuring direct quality. No organization in health care has demonstrated a greater commitment to quality measures than STS, as evidenced by our largest in class number of NQF-endorsed measures, most of which are risk-adjusted outcomes. 65 percent of our adult cardiac surgery participants publicly

report these on our website, note both risk adjusted and morbidity and mortality for aortic valve replacement, as well as several process measures for CABG.

This slide from our manuscript shows that we are developing a similarly robust portfolio of direct outcome measures for TAVR,

and will also institute a public reporting system.

So given this commitment to direct quality measurement, especially outcomes measures, why volume thresholds, why are we supporting this? Well, one reason is the volume-outcome association shown by Dr. Carroll and others today, but there's another critical reason. If we want to accurately and reliably measure quality, we have to address three fundamental measurement issues, random sampling variation, measure reliability, and the statistical power to detect outliers.

This slide depicts the 95 percent confidence intervals of a proportion or a rate at various sample sizes corresponding to program volumes. If you take a sample, let's say a year's worth of cases, that has only 50,

or even a hundred procedures, and you get a result of three percent for mortality, the real underlying mortality rate of that program could be anywhere from one percent or less to eight, ten, or even 12 percent.

Now, you remember those very low

volume programs in previous slides that some presenters described as being high quality low volume programs? Well, the fact of the matter is, and they know this, that we know absolutely nothing about a program that does 30 or 40 cases and has zero mortality. They could easily have ten mortalities in their next 50 cases and have an overall mortality of ten percent.

This slide shows a related concept, prediction intervals, which are the basis of funnel plots, which we and others use to assess quality. If we know the average rate in a population, say about two percent as in this slide, prediction intervals show you the range of sample values. Again, let's say a year's results from individual providers, that would still be consistent with that program having a rate that's not statistically different from

the population average of whatever confidence intervals you choose. Again, you can see that at volumes of 50 or a hundred cases, sample values of ten percent mortality could still be

perfectly consistent with the true underlying mortality rate in the long term of around two percent. So, two different statistical techniques with the same message. Small samples, low volumes, substantial random sampling variations.

Another fundamental characteristic of a good performance measure is reliability, signal and noise ratio, reproducibility, which for all STS composite measures, we require to be at least .5. In this example which is taken from colorectal surgery where the event rate here was 20 percent, below volumes of a hundred, that is to the left of a hundred cases, reliability is consistently well below .5, and if you take lower, even lower event rates, the kind that we're talking about here with TAVR, that reliability would even be much lower, so we have no reliability really to speak of at the kind of volumes that would occur if we didn't have some kind of volume

threshold.

And finally, the power to detect true outliers is highly dependent on sample size.

As shown in this slide for a procedure with about a three percent mortality rate, to detect a doubling of mortality with an alpha of about five, .05, you'd need hundreds of cases to have 80 percent power, which many regard as desirable. The smaller the sample size, the more likely you are to have a Type II statistical error, failure to identify a true difference in performance.

In summary, outcome measurement is highly problematic with low volumes. If we're truly interested in assuring high quality TAVR, then programs have to have sufficient case volume to allow meaningful quality measurement. Frankly if I had my way, it wouldn't be 50 cases, it would be a hundred cases, because I think both volume-outcome data and the statistical considerations are much more convincing at a level of a hundred, but we'll settle for 50.

DR. BACH: Dr. Shahian, please wrap up.

DR. SHAHIAN: Sure. And just in case

some of you are wondering, well, how do we deal with this in the case of STS performance measurement, for our composite measures, they have much more ability because they encompass many different kinds of outcomes, much greater ability with fewer cases to detect differences in outcome, and we do require a reliability of .5 for every measure. Thank you very much.

DR. BACH: Thank you very much.

(Applause.)

Next up is Dr. Thoralf Sundt, who is the chief of cardiac surgery at the Massachusetts General Hospital. And please, may I ask you to please try to stay on time? There's a clock here to the right so you can monitor yourself. Thank you.

DR. SUNDT: All I need is my disclosure slide. My name is Thoralf Sundt, I am chief of cardiac surgery at the Mass General Hospital and professor of surgery at the Harvard Medical School. More importantly, I'm a clinical heart surgeon, I've practiced cardiac surgery for more than 25 years, and I frequently care for patients with aortic

stenosis. I appreciate the opportunity to address the panel.

We're here because transcatheter aortic valve replacement has been transformative. We celebrate this advance, we embrace the technology, and welcome the innovations that make it more technically reproducible and accelerate the learning curve. As the technology came on line, CMS wisely recognized that access to high quality care demanded rational dispersion of this powerful technology. The NCD has had a very very positive effect by reinforcing the importance of the multidisciplinary team.

The issue at hand here is broader than the ease with which a device can be implanted in an aortic annulus, the issue here is the treatment of aortic stenosis in human beings. The Institute of Medicine established patient-centered care as one of the six dimensions of healthcare quality. This requires informed discussions of all options. Only when all options, including surgical aortic valve replacement are available with high quality outcomes, can truly

patient-centered care be provided, care in which the treatment is tailored to the patient rather than tailoring the patient to the available treatment.

A functional heart team is critical to providing this care, especially to the most vulnerable patients, those patients least empowered as their own advocates to navigate the complexity of the medical system. We want to very directly address the specific questions you have posed.

Doctors Feldman and Carroll have focused on TAVR, including importantly the variability in outcomes among low volume centers, and Dr. Shahian has discussed the inescapable challenges in proving quality when numbers are small. As a representative of a surgical organization, I will address your questions specifically surrounding the surgical requirements.

You asked us about the requirements for initiating a SAVR program, specifically how confident are we in the surgical volume thresholds we've set. The answer is very confident. We all strive to be evidence based.

Still, there are few randomized trials in the treatment of valvular heart disease. Accordingly, we rely on collective experience and judgment. Surgical aortic valve replacement has been performed for almost 60 years with a decline in operative mortality rate currently to two percent according to the STS database, not four percent. The cumulative experience of the surgeons on the writing committee exceeds 200 years, 200 years of clinical experience in the centers to which patients with failed operations are referred, Stanford, Penn, UCLA, Pitt, Michigan, Emory, Harvard. It's the view of this group, as I suspect it is for many of you, and I guarantee is the view of the patients I see every day in my office prior to undergoing heart surgery, that teamwork, experience and practice matters.

How often am I asked by a patient, how many of these have you done, and how frequently do you do this operation, and do you work with the same team regularly? These are appropriate questions, as evidenced by Dr. Leon's demonstration of the relationship with outcomes

and surgical volumes. Thank you, Marty. The

number set in this document is just shy of a week, one a week for a new program, not an impossibly high bar by a long shot, less than one a week.

You also asked us the closely related question, how confident are we in the threshold of procedural volumes for the principal cardiovascular surgeon? The answer is very confident. The learning curve for many surgical procedures has been studied and published; it's remarkable how often the number 100 recurs. This is required to safely and reliably achieve the high quality outcomes our patents deserve. Remember, these are also the surgeons that will be called on to rescue patients from the uncommon but potentially catastrophic complications of TAVR. This is particularly important in institutions starting up their TAVR programs where the complications may occur more frequently, and especially as the move to lower and lower risk patients occurs. The annual volume threshold is less

than twice a month, again, not burdensome.

How confident are we in our threshold SAVR procedure volumes to maintain a program?

Very confident. The threshold recommended at a bare minimum is less than one a week. If care is to remain patient centered, the surgeon and team must be able to offer the same access to high quality care to the patient more appropriate to undergo surgical aortic valve replacement.

In conclusion, the AATS believes that it's critical that CMS continue to support the value of this multidisciplinary approach. It's about ensuring access to high quality patient-centered care. We've heard the analogy to pediatric cancer care, but this care is provided in only specialized centers, it has nothing to do with the ability of the pharmacy to mix the drug, and it has nothing to do with the ability of the IV team to conduct the infusion, it's about the experience and judgment of the whole team. We all know that care is best provided by teams, teams with experience and teams that work together

frequently. The team needs to keep sharp and like any technical exercise, whether playing the violin or performing heart surgery, experience matters and so does ongoing

practice. Isn't that where you want your care? Thank you.

DR. BACH: Thank you very much.

(Applause.)

Next up, Susan Strong and Donnette Smith are presenting together. They're heart valve survivors. Susan Strong is president of the Heart Valve Voice U.S., Donnette Smith is president of Mended Hearts, and they collectively have ten minutes.

MS. STRONG: Good morning. As you said, my name is Susan Strong, and I am a TAVR patient. I am also a founding board member and the president of Heart Valve Voice. Heart Valve Voice is a nonprofit organization that's committed to improving the diagnosis, treatment and management of heart valve disease for patients. We are exclusively focused on representing the voice and priorities of heart

valve patients.

I am a long-term survivor of Hodgkin's lymphoma with radiation-induced heart valve disease. My valve was replaced via TAVR in 2014.

For the past four years I've had the

opportunity to connect with hundreds of patients, and I'm grateful that you today are including our voices in a meaningful way in this very important discussion. I hope that you'll remember this from today, that patients want to be a part in shared decision-making. We deserve to know about all of our treatment options and to have appropriate access to all of them.

It's my pleasure to share the podium with Donnette Smith, president of Mended Hearts. I'm now going to cede the remainder of my time to Donnette, who will give the formal presentation on behalf of our task force.

DR. BACH: Ms. Strong, just a procedural issue. You need to give disclosures verbally since you don't have slides, if you can.

MS. STRONG: Okay. My disclosures are on our slide. Will that work?

DR. BACH: They're on the next slide? Okay, great. Thank you. Sorry about that.

MS. SMITH: Thank you, Susan. On behalf of the Heart Valve Disease Policy Task Force, thank you for the opportunity to present

our views on access to all appropriate treatments for all heart valve disease patients. These are our disclosures.

I was born with a bicuspid aortic valve and have had three open heart surgeries. Every week I'm honored to visit with patients and their families to help them as they face their treatment and their recovery. As an organization, Mended Hearts supports more than 200,000 patients throughout their journey each year, so we know the patient story.

Mended Hearts is honored to partner with organizations such as the Alliance for Aging Research and Heart Valve Voice. Sue Passion, the president and CEO of the alliance, and Marilyn Serafini, the executive director of

Heart Valve Voice, are here with us today. The mission of the task force is to advocate for policy solutions to improve access, research, and awareness of heart valve disease detection and treatment.

There's no question that valve disease is deadly. Let's all acknowledge the elephant in the room, patients die from lack of access. So what stands in the way of better health

outcomes? First of all, awareness of the disease is low. Three out of four Americans report knowing little to nothing about heart valve disease. Additionally, six in ten heart valve disease patients surveyed responded that they did not have or recognize their symptoms, they were diagnosed only because they went to the doctor for something else.

You all already know from previous speakers that as valve patients wait for treatment, we die, so our focus today should be on getting patients more timely access to these lifesaving treatments. As has been previously shared, the undertreatment of aortic stenosis is very well documented.

Today, not every patient has a fair shot. When discussing treatment options, we know that even if patients qualify for TAVR, this option is not always presented. Based on multiple analyses of TAVR that were cited earlier today, significant disparities exist based on race, ethnicity, income, and actually where people live. While these disparities are not unique to valve disease, the questions behind them remain unanswered, and we need to

continue to search for the why.

When the original NCD was decided, volume was used to ensure quality in the absence of other evidence. Thanks to the TVT registry and numerous studies, we now have a significant body of evidence that proves TAVR is safe and effective. TAVR is an important treatment option that can reduce the burden on the patient. Not only is it less invasive, but it also improves the patient experience, it shortens hospital stays and recovery times, and it produces better outcomes.

Despite good intentions, the current

NCD creates unintended barriers. Choosing to use volume instead of quality as a measure may inappropriately restrict access. Typically only the largest hospitals in the country offer these new therapies. The bottom line is, patients do not hear about all their options unless they are lucky enough to walk through the right door of the right hospital. This creates inequalities. Experiences vary greatly depending on which hospital a patient visits, and which provider they consult. And frequently, the patients who are harmed are the

most vulnerable in our community.

Quality is what matters to patients, not quantity. In the case of TAVR, there are ample studies to help patients like me make informed decisions based on our personal priorities. This panel should consider the more recent studies that have shown excellent outcomes in both high and low volume hospitals. Patients should not be put in the middle of meeting annual volume requirements to maintain programs.

Additionally, outcomes that are

meaningful to patients are what really matters. Depending on where a patient may be in life, certain outcomes may be more important than others. Outcomes that were important to me were how long I had to stay in the hospital, being able to recover at home, and what kind of a burden I would be on my husband and my family. For some patients, these outcomes may be even more important than survival.

The Heart Valve Disease Policy Task Force believes that all patients should have access to all appropriate treatments. To achieve this goal, we have the following

recommendations. First, we need to move away from volume requirements and adopt specific quality -- sorry, one more slide. First, we need to move away from volume requirements and adopt specific quality measures that matter to patients. We also need to provide patients access to unbiased easily understood information on hospital and provider performance through a tool like Hospital Compare. Last, we need to apply the same rules

to both SAVR and TAVR. Every patient deserves the opportunity for real shared decision-making so we can choose the right treatment at the right time and at the right place.

Speaking as someone who has literally placed my heart in a surgeon's hands multiple times, it makes me sad when I meet patients or caregivers who would have made a different decision had they known their options. You have an important opportunity in front of you today to continue moving forward to ensure better access and hope for more patients and their families. On behalf of the patients, thank you for this opportunity.

(Applause.)

DR. BACH: Thank you very much. Ms. Strong, it's me over here. I'm sorry. You have to disclose your own conflicts of interest, not those that were in the slide deck, you weren't listed on that slide. So if you don't know what to disclose, we can go over it.

MS. STRONG: Okay. I have once received a speaking fee for a patient day from

Edwards Lifesciences.

DR. BACH: Thank you. Next up is Dr. Steven Goldberg, the director of structural heart disease, Tyler Heart Institute, Community Hospital of the Monterey Peninsula.

DR. GOLDBERG: Thank you very much. I'd like to thank the committee and I'd like to thank CMS for this wonderful opportunity to have this debate today, and I think to provide an opportunity to air some opinions that otherwise have not had a forum for this discussion. I titled mine, that this is an access of care issue rather than a volume requirement issue. I don't believe I have any conflicts of interest to disclose on this matter.

Volume requirements, of course, is used as a surrogate for quality of care, but access to care is the dynamic tension that is impacted by these requirements. This is a busy slide, I'm going to skip through many many things here, but I think that we have to focus in on data versus opinion. We've already heard

excellent discussion on the lack of data on PCI volume and TAVR experience, but I would like to go down to the fourth line here and say, is there any representation from the smaller hospitals that are impacted by these volume requirements? If not, who is protecting the interests of patients treated at those institutions? And here after that is just another reference saying that there is controversy as to whether volume requirements, volume measures are accurate surrogates of quality, at least with relationship to CABG.

Assume for a moment there is a statistically significant but clinically small difference in outcome when the procedure is limited to larger hospitals compared to smaller volume hospitals. Is it not important to ensure that the drop in access to care doesn't

numerically overwhelm the small difference in outcome?

Why do patients go to smaller hospitals? Geography; and Dr. Pelikan mentioned, even in an urban center, geography can be a major issue. Cultural, which has been

well addressed by Dr. Horne. And efficiency; patients prefer to go to smaller hospitals, this has been documented, with higher satisfaction rates of patients treated at smaller hospitals than larger hospitals.

It is interesting to see that the, a distribution of hospitals in this country, that the majority of hospitals that are large enough to provide TAVR but are -- in other words, at least a hundred beds, most of them are less than the large hospitals. So the five-percenters, I think, is where most of the key opinion leaders and the opinions are coming from, but there are four to five times as many hospitals that could be providing TAVR that are in the less than 500-bed range.

And if we look at who is doing most of the work, in fact it is the operators at these smaller hospitals. From the California OSHPD

or Office of Statewide Health Planning and Development, we see that there are 16 hospitals with over 500 beds, but the other hospitals perform most of the valve surgeries on

patients, so there are three to four times more valve surgeries done in the smaller hospitals. And I would ask, is there appropriate representation for these hospitals in making the decisions for CMS or for these guidelines?

Consider the TAVR patients, we've heard this already. They're frequently elderly and/or debilitated. Travel carries challenges, including medical risks, fatigue and costs. Their support system, their family members are also affected by traveling, the time off from work, or perhaps they can't even find time to take off from work in addition to costs. The need to travel is often used as a reason not to pursue TAVR by symptomatic elderly patients. I can just share my personal experience having just moved to Monterey, California, that that is an argument made by many patients, and Dr. Horne has already talked about the minority patients.

So arguments that -- I think I'm going

to skip that and this, and just go to the TVT registry data, that the conclusions from the TVT registry analysis that has been mentioned,

that the data is high quality and is of great interest but is inconclusive. It is reasonable to believe that the data may not be currently relevant in light of the confounder of learning curve as part of that analysis, as well as advances in TAVR.

Relying upon these preliminary data to justify public policy decisions seems to be arguable at the least. Shouldn't it be a clear message that drives public policy decisions, not, quote, way beyond the understanding and skills of the vast majority of cardiologists like us, end quote, the comment from Alan Cribier who wrote the editorial regarding the TVT registry data? The downside of accepting and acting on these preliminary and confounded data will be a restriction to access of care.

DR. BACH: Please wrap up.

DR. GOLDBERG: This is it right here. So in conclusion, maintaining or establishing volume requirements limits access of care to patients with established benefits to TAVR.

Most key opinion leaders come from larger

hospital systems, so have a potential inherent bias and conflict of interest over this issue. Establishing a voice for smaller less vocal hospitals, as Dr. Pelikan has done today, is important in establishing major policy decisions, especially since those hospitals care for a significant percentage of U.S. patients, over three times the volume of larger hospitals. Thank you very much for your attention.

(Applause.)

DR. BACH: Thank you, Dr. Goldberg. Next up is Larry Wood, who's a corporate vice president at Edwards Lifesciences.

MR. WOOD: I'd like to thank the panel for being here today and I'd like to thank CMS for the opportunity to speak. My name is Larry Wood, I run the transcatheter valve program for Edwards globally. This is my disclosure slide, but Edwards pays all of my salary and my entire existence and wellbeing is dependent on my job there, so you should probably take those things into consideration when you take my commentary, but I have also been involved with TAVR since

the very inception of it and in many ways I feel this is my life's work and purpose for being here.

There's the consensus documents that have come out from the societies, and unfortunately the documents were not finalized prior to us submitting our slides so we were all working off drafts. I think the societies have moved a long way in their preamble to try to address many of the concerns expressed by many of the stakeholders. However, there still are volume requirements in the documents that we believe could adversely affect patient care.

I think the evidence around, that we've heard today around the volume-outcome relationships, you know, from our perspective does not exist, or is not supported by the evidence, but restricting the access to care we know will harm patients. Even increasing patients' wait to care will adversely impact patients, as was shown in a number of presentations today.

Intuitively, volume-outcome makes sense, intuitively I think everybody thinks it makes sense and we all believe it does, but the

question before us today is what evidence do we have to support it, and when we look at contemporary TAVR, we just don't see the volume-outcome relationship with our latest technology, and I think that's true of both companies, I think that's true of Edwards and I think it's true of Medtronic as well.

When we started TAVR and we first commercialized, our first full commercial year was in 2012, and when we started there were a lot of questions about whether this procedure could be rolled out safely, whether it could be rationally dispersed, and whether we could duplicate the high quality outcomes from the clinical trials in the generalized setting. We started with about a hundred centers and we had a mortality rate just under five percent. We've continually added centers every year and we have watched the results continue to improve, and in 2017 there were 540 active TAVR programs and the mortality rate fell to 1.5 percent. So I think this shows that we have been able to expand, and through high quality training and high quality proctoring, and the entire community coming together to teach each

other from their own mistakes so that new centers didn't have to repeat them, we've been able to advance this therapy in an incredibly responsible way. I think most people point to this as the best example for rolling out a new disruptive technology, not something that we need to attack or change.

This is a slide, this is Medicare claims data so this is the Medicare population, this was shown earlier so I won't spend a lot of time on it. I think what this slide illustrates, though, is when you have two therapies that can be used for the same patient population, it's critically important that you look at those procedures holistically, not individually in isolation. It's important that patients want to know how well their aortic stenosis is being treated, not how well the center might do one procedure versus another procedure, and I think that that's critically important.

Many of the experts have agreed that TAVR will likely become the preferred option for patients, I've heard people say it will be

25 70-30, or 80-20 would be the split, and I think

1 that those are reasonable estimates as we go
2 forward. As TAVR continues to shift volume
3 from surgery to TAVR, it will become
4 increasingly difficult for centers to meet the
5 surgical volume requirements.
6 What do we want in the healthcare
7 system? We want centers to do the procedures
8 that they can do well and we want them to refer
9 the procedures out that are beyond their
10 capabilities. But when you put volume
11 thresholds in place, you create incentives to
12 do just the opposite of that. If a center is
13 struggling to meet their volume requirements,
14 they have to hold on to every single patient,
15 they can't refer them to another center for
16 what may be a more appropriate procedure for
17 that patient, and this gets very real if you're
18 a patient.
19 This is a patient, this is a real
20 patient that we have, but I'm using it as an
21 example here. Let's say that there's a
22 hospital, and in November this patient

presents, he's 82 years old, he has a number of comorbidities, he would be considered intermediate or high risk. The center's done

52 TAVRs, they've met their TAVR threshold by the new requirement, but they've done 25 surgeries. This center is now faced with a dilemma, do they do the procedure that they think may be best for this patient, or do they do the procedure that they need to do to meet their quota. And the irony of this is in this theoretical world, if they didn't meet their surgical quota they would lose their TAVR program but they would continue to do surgery, and that just doesn't make good logical sense for patients.

I think when we look at the system we have to think about this from a very patient-focused perspective, and what do patients want? Patients want to get high quality care. We have the ability to measure quality today. Things like the STS risk score is very sophisticated, we can use O to E (O:E) ratios, there's things that we can do today that we can measure how all valve patients do at any

center, and I think that that can be done. I think patients want to make sure they get the right procedure, and that means the right procedure for them as an individual.

And I think they want to have that done as close to home as they can possibly do it and get high quality care, because it does create a burden on their family. The average TAVR patient goes through ten to 15 hospital visits before their procedure, and many of these patients, the average age in the United States is 80 years old, so there's a significant burden on these patients to travel distances. So with that I will conclude my comments, thank you.

(Applause.)

DR. BACH: Thank you very much. Next up is Dr. Pieter Kappetein, who is the chief medical officer at Medtronic who is in charge of Structural Heart and Cardiac Surgery. Oh, no, I'm sorry. He's been replaced by Eric Vang, Dr. Eric Vang, also from Medtronic.

DR. VANG: Yeah, unfortunately, Pieter

was not able to be here due to unforeseen circumstances. Again, my name is Eric Vang. I'm the senior director for clinical research at Medtronic Structural Heart. I've been in clinical research for about 20 years and been on the forefront of a lot of the evidence

development in therapies, and so with that, I do believe that the discussions we've had today do require a strong balance between quality outcomes and patient access, and be data driven. Medtronic does not believe that there is sufficient evidence to modify the volume requirements in the TAVR NCD at this time.

Obviously not my disclosures, but I am an employee of Medtronic and a shareholder as well.

Medtronic has invested significantly in evidence, and the procedural training for the safe and responsible growth of this therapy, as illustrated on this slide. Our analysis of the data has shown excellent outcomes under the existing NCD and that there is no relationship between volume and outcome. We share the concerns expressed today regarding

any potential decrease in the number of centers which could impact the patient access.

The following slide illustrates the TVT results which are being shared today for the first time. The TVT registry shows that mortality, stroke and major vascular complications, and pacemaker implantation in

the real world setting in patient populations will continue to improve and have improved, and are shown here to be numerically lower than our clinical trial results. This holds true across all risk strata, you see that with extreme risk, high risk and the intermediate risk cohort. These are 30-day complication results and as you see here at one year, they still hold true.

Given today's focus, we analyzed the data from the TVT registry on the outcomes based on site volume, and then compared this data. While this is a complicated slide with a lot of information, the key takeaway from this slide is we do not see a difference in outcomes across site volumes. This prompted us to

conduct further analysis to understand this discrepancy. So at this point in time I'd like to move away from the slide and like to direct the panel to a handout that we provided you earlier today. This is also available outside of the room just as you move outside the doors.

This is a handout that includes analysis that we provided to CMS earlier this week, and they allowed us to share this with

the panel today. In looking at the volume-based outcome relationship, we attempted to replicate the analysis presented by the societies as it was inconsistent with our own analysis. Working with direct research, we utilized the MedPAR data. This data is publicly available on the claims data set which reflected TAVR procedures preformed on Medicare patients. Please refer and look at the top of page one, the first slide.

We believe that the society analysis uses an unweighted average methodology to evaluate site volume and outcomes. In this methodology, the unweighted results reflect the average of individual hospital mortality rates

without accounting for procedure volumes. This can yield variable results, especially when analyzing small sample sizes. In contrast, the use of weighted averages reflect the actual mortality rate seen in the patients treated across all centers. Additional data regarding these methodologies are included in the first slide.

The slide at the bottom of page one highlights the flaw of using unweighted

averages versus the conventional weighted averages. When considering this, the actual mortality rate seen in patients treated at low volume centers is three percent, not 4.4 percent, which is comparable to the higher volume centers.

In looking at page two at the top of the chart, using the conventional weighted average methodology, this illustrates statistically significant reductions of mortality over time. The mortality difference between the high volume and low volume centers also converges in the most recent years. You

can see this in 2017, that there is no difference in outcomes.

So as you consider the questions posed to the panel, please consider the methodology used in analysis regarding volume and outcome. We believe the use of conventional weighted averages provides a more representative and accurate depiction and assessment. Thus, I believe that achieving quality outcomes must be balanced with appropriate patient access. Other speakers have underscored the importance of patient access already, so in the interest

of time, I'm going to move through the next few slides.

Thus in conclusion, we believe that CMS policy making should maintain quality while protecting patient access to TAVR therapy. Medtronic does not believe there is sufficient evidence to modify the current operator and facility outcomes to the TAVR NCD at this time. Thank you for the opportunity to present.

(Applause.)

DR. BACH: Thank you very much. Next up is Megan Coylewright, Dr. Megan Coylewright,

who is the associate director of Structural Heart Disease Program, Heart and Vascular Center, at Dartmouth-Hitchcock.

DR. COYLEWRIGHT: Thank you for the opportunity to address these important questions about how we provide care for our patients with aortic stenosis. So, today I'm representing myself as a cardiologist, my patients. My institution provided support for me to come down, Dartmouth-Hitchcock Medical Center, the most rural academic medical center in the country. And I'd like to speak from my experience, as many of us have, the experience

of sitting in clinic with patients who have very different goals and preferences than I do, and listening to them. My disclosures are that I speak on shared decision-making to clinicians, hospital centers, industry, and now government, and I learn and listen about shared decision-making from my patients.

We're here today to ask, what is the evidence? We love looking at the evidence as cardiologists, we pore over it. We start with

clinical research, and thanks to many of the leaders in the audience, we have a lot of evidence about the safety and effectiveness of this therapy. That goes to our guidelines, which we've seen, expert consensus documents, and that leads us here, to figure out how we're going to create policy to ensure adequate outcomes for our patients.

But we're just starting to focus on the fact that maybe at the very top of this curve, are we asking the right questions, what's most important to patients? And we heard today, you all picked four variables, those aren't necessarily on my list, so we need to think about what matters to patients. Does

the small difference in mortality, in-hospital mortality between the varying centers, is that what's most important?

We've answered Medicare's questions from the original NCD, how does the real world population differ from those in the clinical trials? Very similar patients with improving outcomes as the technology evolves and as we share best practices with each other. I think

that's the beauty of this therapy, we've been great about sharing what works and what doesn't, and that's helped improve outcomes for patients.

Now I know the men and women of the panel, and Medicare, are committed to serving Medicare beneficiaries, that's what you're in the job for, but I think it's actually the mission statement of the Office of Minority Health within Medicare that says it best for what we should focus on, and that is to ensure that the voices and needs of the populations we represent are present as we develop, implement and evaluate policies and procedures. That the voices and needs are present.

And I would argue we haven't asked

those questions yet, so we have a lot of different outcomes that we've decided as scientists and physicians are important, but now we can move to processes where we make sure we listen to the patient voice. And when I say to a patient, when I sit down in clinic, they don't ask me how many I've done or what our

outcomes are, they ask me to take care of them there in the community. It's a different experience, but it's mine to speak of, and specifically I don't want to exchange best patients, I want to exchange best practices.

And I'll just share a story with you, not the patient's real name, but a real story. Mrs. Richardson, who had a valve problem, and she needed to have a transcatheter valve placed but it was in a different valve position, and in our community hospital we weren't offering this yet within the research trials, so I spent hours preparing the Power Point, getting the slides and the films down to Boston, conference calling with my partners. And she called me a week after the appointment was made and said I will not travel, I won't go there unless you go with me. And I don't say this to boast, I say

it that it matters to patients to get care in their community. She died six months later of heart failure.

And I think about many patients like that who've refused to travel and how important it is, and it's specifically important to

vulnerable populations. We've heard about a couple of them. Number one, women benefit more from TAVR than SAVR, and yet get it less. We've learned from our national research endeavor called Win Her, where they're looking at how do we get women involved in cardiovascular trials, they tell us, listen, I'm a caregiver, grandchildren, my husband, I can't travel, I have all those other responsibilities that are just as important, and in fact for some it's more important than the differences in mortality. It's our job to give them the information so that they can tell us what is best for them, and we have that information.

Similarly for African-American patients. There's no doubt that that category of patient refusal has a lot to do with having racial concordance and congruence with their

providers, and making sure that we're communicating in ways that match with their experience.

And finally, patients with low

resources in rural areas. There is a lot of data already out there that shows that it's difficult for them to access care, not for us, for me to drive down, not for me, but for understanding that the values and preferences are different for our patients. We've got data out of North Carolina showing that rural populations aren't accessing AVR, and we've got the heat maps to show the very low penetrance of TAVR, that we're not treating the patients that need it.

A study from Dartmouth a long time ago asked patients, let's just say the mortality risk increased from three percent to six percent, it doubled. Would you go to a different center? 45 percent said no, I still want to stay here. You could argue, maybe they don't understand the numbers, but let's trust our patients. There are other things that are important to them besides that chance of a different mortality.

DR. BACH: Please wrap up.

DR. COYLEWRIGHT: We just concluded another study recently, and patients told us if

we're going to consider new therapies, we're going to discuss it with a trusted physician. So those conversations are needed and best held in a shared decision-making process where we present the data to patients, we're the experts in that, and they're the experts in their values and preferences, and then together a true shared decision can be made, and I think that's how we will improve our outcomes together. Thank you.

(Applause.)

DR. BACH: Thank you very much, Dr. Coylewright. We now have a period for open public comment, there was a signup sheet for nonscheduled speakers out front, we have approximately seven of them, and I would like to ask them to come to the microphone. You each have one minute. I'd like you to start with your name, your affiliation and your disclosures, after which time I'll start the clock on you, in case you have, I don't know, two or three minutes of disclosures.

And I apologize, I'm doing my best

reading. Michael Deeb, from the University of Michigan.

DR. DEEB: Good morning. My name is Michael Deeb, and I represent the University of Michigan. U of M would like to acknowledge that the disparity of access to care is real and exists in isolated geographical areas such as Wyoming and in low income socioeconomic underserved areas such as rural Alabama and Georgia, not in large urban areas, and certainly not in Southern California as we heard earlier, where the ratio of patient lives to TAVR sites is among the best in the country. The majority of low volume sites are not in the underserved areas but in the overserved areas of high access and significant competition.

U of M would also like to bring to the attention of the MedCAC panel another major reason for the patients being underserved, and that is financial. If you look at the two DRGs for reimbursement for TAVR in the underserved areas, it is on average $35,000. If you look at the manufacturer charge to the institutions for the TAVR, it is between $30- and $35,000

per case. This leaves the institutions approximately $5,000 per case to cover all the remaining costs of the entire procedure --

DR. BACH: Your time is up.

DR. DEEB: -- including facility and resources. Thank you.

DR. BACH: Thank you. Next up is David Cox, and could I ask Robert Cubeddu to come up after Mr. Cox.

DR. COX: On behalf of over 3,000 U.S. interventionalists who are --

DR. BACH: Please state your name and affiliation, and disclosures. Thank you.

DR. COX: David Cox, SCAI, no disclosures.

DR. BACH: Thank you.

DR. COX: On behalf of over 3,000 U.S. interventionalists who are SCAI members, thank you for allowing me as president of SCAI to share our views. Quality of programs doing TAVR remains the most important goal, and we believe that all programs, but especially low volume programs are charged with the need to know their data and to do internal reviews to improve it, and failing that, to turn to

external reviews to help improve poor performance. All that's pointed out in our paper and presentation, and that outcome data should be transparent to patients.

Secondly, we cannot overemphasize the importance of a heart care team. Our presentations and paper emphasize that we now have to focus on imagers who help us with echo and CT, as well as 24/7 pacemaker backup. If you can't do that at your hospital, then you shouldn't do TAVR.

Finally, we believe SCAI should be involved in a massive educational effort to educate both patients and primary care practitioners about aortic stenosis in the hope to improve access and improve mortality. Thank you for your time.

DR. BACH: Thank you very much. Robert Cubeddu. I'm sorry if I'm mangling that. Okay. Tom Nguyen?

DR. NGUYEN: My name is Tom Nguyen, I'm a cardiothoracic surgeon in Houston, Texas. As part of my disclosures, I'm a consultant for Edwards Lifesciences, Abbott and LivaNova.

We've seen a transition in treating

TAVR patients from high risk patients to intermediate risk patients, and most likely low risk patients. We can argue that it's safe to do TAVR in these lower risk patients in lower volume centers because, well, they're lower risk, but I want to build an argument against this, or for the contrary.

As Dr. Joe Bavaria previously presented, there is some data to suggest low volume programs performing TAVRs on lower risk patients are having, or might have worse outcomes. I would like to argue that these lower risk patients, there's an increased need to have perfect outcomes in these patients. Outcomes for low risk patients need to be perfect, and that's why it's imperative to have qualified surgeons and cardiologists involved and available, and maintain strict criteria for TAVR programs. If we do a TAVR on an 85-year-old with CAD, PAH, renal disease, COPD, and a complication occurs, most surgeons would be less likely to intervene. But if we do a TAVR on a 60-year-old bicuspid, otherwise healthy, and complications occur, we will

25 intervene and our surgical procedures can be

1 life-saving. These patients will be more and
2 more of our patients as we see a trend towards
3 lower risk patients.
4 DR. BACH: Your time is up. Thank you
5 very much. Dr. Nguyen, after this, could you
6 see Ms. Ellis, please? Thank you. Richard
7 Wright.
8 DR. WRIGHT: Good morning, Richard
9 Wright, Providence Saint John's Health Center,
10 Santa Monica, California. I have no conflicts,
11 I paid my own way. I also am the cardiology
12 advisor to the RUC and I co-chair the Medicare
13 Contractor Advisory Committee for California.
14 Several points. Number one, I don't
15 even know why there's an NCD for TAVR. Having
16 been involved in LCD development for a long
17 time, NCDs are supposed to be for coverage.
18 Everybody agrees here it's a terrific
19 procedure. I would suggest that CMS consider
20 retiring the NCD, I just don't see why it has
21 to exist.
22 Number two, as Dr. Goldberg said, the

80 percent of the hospitals that don't do TAVR were not represented on the ACC expert consensus document. I don't understand why

that's the case.

Number three, why the focus on PCI? We did 400 Watchman's in our facility, they don't count. We live in a place where we have less than two percent smokers, our STEMI volume is down 70 percent, and somehow we get penalized for being conservative for doing PCIs, we don't do elective PCIs very much at all. I don't think that should prohibit us from doing TAVR. Thank you.

DR. BACH: Thank you. I'm sure we will all have RUC questions for you later. Ron Waseman, or Waksman, sorry.

DR. WAKSMAN: I'm Ron Waksman, I am director of cardiology at the MedStar Washington Hospital Center. My disclosure is that we received grants from both companies, Edwards and Medtronic.

I have four points, very short. First of all, in 2019 we're going to have a moving target of TAVR. The TAVR of ten years ago,

seven years ago, five years ago, and nowadays are going to be different, we are going to see less and less surgery because by that time we're probably going to have also lower risk

approved. In our own experience with our lower risk TAVR which we presented at the CRT meeting, 125 patients, ten centers, low volume did as good as the high volume center.

Third, I don't understand why we need two signatures of surgeon. If we have one surgeon that does the procedure, isn't that enough?

And the last point is the TVT registry. It is taxing, our institution pays about half a million dollars a year to get this information. While this information is important, I think it should be revisited, what we should ask, how should we get the best information, and who should sponsor it. Institutions cannot carry that for a long period of time, especially when they come to 400, 500 cases a year. Thank you very much.

DR. BACH: Thank you very much. Next

up is Matt Austin.

DR. AUSTIN: Good morning. My name is Matt Austin, I'm a faculty member at the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine, and I have no disclosures.

I'm actually here today speaking on behalf of the Leapfrog Group, a nonprofit based out of Washington D.C. that represents large purchasers of healthcare that buys healthcare benefits on behalf of their employees. Decades of research have demonstrated a very strong link between hospital volume and better outcomes for patients for many high risk surgeries. These better outcomes include reduced mortality rates, reduced complication rates, shorter lengths of stay and lower costs. And while we recognize that we need to ensure, while we recognize the tension with ensuring access for patients to TAVR, we firmly believe that the establishment and use of a minimum volume standard is important to patients. Thank you.

DR. BACH: Thank you very much. Next

up is Susan Peschin, and I'm sorry if I mispronounced your name.

MS. PESCHIN: Actually, you did great. I'm Sue Peschin, and I serve as president and CEO of the Alliance for Aging Research, a nonprofit in Washington D.C., and we have received funding from Edwards Lifesciences.

I wanted to first mention, there has been a lot of mention of older adults and the impact among older adults of heart valve disease in general and aortic stenosis in particular, and I just wanted to emphasize to all of you that the importance of independence to older adults and maintaining their independence shouldn't be undervalued in this context of setting, you know, some guidelines for the NCD. 12 million Americans, according to Pugh, 65 years of age and older, live alone, and seven out of ten of those are women, so the issue of independence is as practical for a lot of these folks as it is psychosocial in nature, so that should be taken into consideration as you look at these issues.

We would like to see more transparency with the TVT registry data. We want to see some of these measures on hospital compared, and not just within the associations, these measures deserve to be, you know, accessible to the public and there has to be a better way to access this data.

DR. BACH: You're out of time.

MS. PESCHIN: Oh, okay. Thank you so much.

DR. BACH: Thank you very much. One more time, Robert Cubeddu.

DR. CUBEDDU: Good morning. Real quick, I just thank the panel and the audience and the colleagues for their presentations. I am Robert Cubeddu, chairman of cardiology at Cleveland Clinic, Florida, also section head of structural heart disease at this institution, formally trained in structural heart disease at Mass General in 2008, and I have been able to work with this wonderful technology and take care of many many patients. As a single operator, we've done over 300 TAVRs, and have proctored many in the community.

We have a real challenge today with the existing guidelines. We are a TAVR -- sorry -- we are a transplant center, we take care of the sickest of patients. We are a quaternary care center and on a day-to-day basis we see no less than two to three TAVR consults. I have to struggle across hundreds of miles of my month to month taking patients to other sites because we can't do TAVR at our facility, and part of it is because of the PCI

volume requirement. As a quaternary care center, we don't take care of the day-to-day PCIs that we see all the time in local community hospitals.

So we endorse and strongly support the updated revision of the society lowering the PCI volume as a metric of quality for TAVR, and would like to just kind of voice that and encourage that. So I congratulate the committee for taking time to revisit and looking at these volume and metrics.

I think just to finalize --

DR. BACH: Please wrap up.

DR. CUBEDDU: Yeah. One question that I think we've missed all along is, we emphasize the differences between one volume and low volumes, and the potential impact on one or two percent differences in mortality, but we have lost sight of potentially the mortality among many other patients that have waited three to four weeks to get an appointment that are living, you know, 60 or a hundred miles --

DR. BACH: Your time is up.

DR. CUBEDDU: -- away from centers without TAVR access.

DR. BACH: Thank you. Just disclosures, please?

DR. CUBEDDU: I have no disclosures.

DR. BACH: Great, thank you very much. Thank you everyone for your attention and for the speakers. We're going to break for lunch. We remain ahead of schedule, thank you for that. We will reconvene at 12:40 in here.

Most important, the speakers from this morning will be part of the conversation. Please, speakers from this morning, if you'd like to participate, and I hope you will,

please be back here on time at 12:40. Thank you. And I'm sorry, speakers have reserved seats here in the front row. All right, thank you. Enjoy your lunch.

(Lunch recess.)

DR. BACH: Thank you very much. We have Liz Perpetua, so name, affiliation, disclosures, and one minute. Thank you.

MS. PERPETUA: Good day. I'm Liz Perpetua, I'm a nurse practitioner and consultant from Seattle, Washington, I have been caring for TAVR patients and coordinating their journey in TAVR for the last ten years in

community hospitals and academic medical centers alike. My disclosures include consulting fees from Edwards and Abbott for valve disease patient education, and consulting directly with hospitals for a structural heart program launch and optimization.

I'd like to speak today to the role of the clinician coordinator in the TAVR program. We often spend the most time with the patient and serve as a boots on the ground translator

and enforcer of the NCD. We establish and adhere to clinical pathways that ensure NCD compliance, safety and quality.

So what do minimum volume requirements really mean to patients? Do they really allow for the right care for the right patient in the right place at the right time? Data today have shown us that gains in outcomes are minimal with increased volume requirements and that living better, not longer, is what patients want. They want choice with shared decision-making and care locally. For some, safe care may mean partnership with small and large programs in the spirit of patient-centered systems of care.

It's the patient that absorbs the consequences of failure to meet volume requirements to the NCD. Patients may refuse therapy because of costs and hardship, or they can't incur these things for treatment or travel to another place. Due to delays in care, lack of access to beds, we see clinical decline and death. This is happening now and stands only to get worse with further

restriction and the increasing minimal volume requirements. There are also significant implications for patients and programs if the NCD creates two standards of care, one for TAVR and none for SAVR, for a single disease state.

Direct measures of quality are what matter, and the parity, not serendipity in access to quality programs. It's my hope and the hope of nurses that the NCD will measure and provide what matters, direct measures of qualities and access to patients for a therapy that is already underutilized and sorely needed. Let the NCD enable, not prohibit, patient-centered care in which the goal is the right care in the right place at the right time, based on direct measures of quality and

shared decision-making with the patient at the center. Thank you very much.

DR. BACH: Thank you very much. So, I hope everyone had a good lunch, thank you for returning on time.

The next phase of the MedCAC meeting is a, if you will, an open discussion. We will

probably have discussions between one another, of course in the open, and we thank all the speakers from this morning for joining us, because there will also be questions for you. I'd propose that you view this as a dialogue, a discussion, and as long as you don't ask us any questions, it will work fine.

So, I guess I'll ask if any of the MedCAC members have any questions for any of the speakers, and we will go from there. Dan?

DR. OLLENDORF: So, I actually have a couple questions that are very data focused, and since I don't have access to some of the primary papers, I want to ask these questions. And some of the information, as many of you noted, was presented by multiples of you, so whoever feels that they can answer the question best would be fine.

So, I'm interested in how the authors of the Israeli study describe the trend that the presenters spoke of for some of the very important and patient-centric outcomes. I'm looking at the slide now and I see high P values, so normally a P value close to .05

would be described as a trend and they're not, and I'm also seeing point estimates that bounce around in the later years, I guess whoever presented and used that study as an example, if you could describe how the authors characterized the trend, so to speak.

DR. PELIKAN: I believe that's the paper that I quoted.

DR. BACH: I ask you to reintroduce, just say your name.

DR. PELIKAN: Peter Pelikan. Still no, I haven't been bribed yet, still no conflicts.

DR. BACH: You don't have to restate your conflicts, unless, if you got one over lunch, see me. I was available.

DR. PELIKAN: So, if you remember what I said, and I don't have my notes in front of me, but that there was a decrease, a definite

decrease for infection and for pacemaker implantation, and a trend, and the trend I'm looking at, most of the curves trending downwards, but I said it was not statistically

significant. I think other presenters have shown other data that would support it, but that particular slide doesn't.

DR. OLLENDORF: Okay. I really just wanted to clarify whether you were describing it as a trend or whether it was something that the author said, so I appreciate the clarification. Can I ask one more?

DR. BACH: Of course. Actually, we'll just as a process, put up your tent card if you want to ask a question. You don't have to do that, Dan, you can put it down now.

DR. OLLENDORF: So, another question and I think, again, this information was presented in multiple presentations, but the MedPAR data that looked at mortality reductions over time with TAVR, I'm wondering if one or more of the speakers wants to discuss how that potentially could be confounded with temporal trends and length of stay, which also seems to be the case over time. And in addition, unless

I'm mistaken, MedPAR collects data not only on in-hospital mortality but also 30-day mortality, and again, I didn't see 30-day

mortality highlighted as much as it probably should be in this kind of circumstance, so, whoever would like to talk about that?

DR. LEON: Thank you. Marty Leon. Yes, we did present the in-hospital data which was the only data set that we had available to demonstrate those trends. I think your question is an interesting one, suggesting that if there's reduced length of stay, the in-hospital mortality would be less simply associated with reduced length of stay. I don't believe that that is the case. I think that those are true differences in mortality that have been confirmed in innumerable other data sets, including the TVT database, and including a variety of randomized and other clinical trials that have been developed over time.

I think one of the important differences is that over time that the risk strata of the patients change. In the beginning we treated the sickest patients who

were higher risk, and progressively over time

that scaled down to higher than intermediate risk patients, and I think that probably is more of a confounder in explaining the reduction in TAVR mortality than anything else.

DR. OLLENDORF: I probably should have been more clear, I was kind of linking the two ideas, because I'm not trying to claim that a length of stay is an explanatory factor in mortality reduction, more that it's a case finding issue, and so that's why I would think that the 30-day mortality would be a more precise measure.

DR. BAVARIA: Yeah, I think that, just a couple comments. I mean, that slide of the SAVR-TAVR MedPAR five- or six-year data was shown at least three or four times, I thought. So from a couple, just a couple points that are different from what Marty just said.

Number one, the MedPAR data for the SAVR part is about all, it's a claims adjustment thing, it's not precise about AVR only, so this was a, in the MedPAR data, any person who gets an aortic valve of any type, whether it's a double valve, whether it's an

AVR CABG, whether it's whatever, is in that database. Because the STS isolated AVR database for patients over age 65 was 2.06 percent for 2017.

The second thing is really more important and exactly what you're talking about, which is why the TVT registry is going completely away from in-hospital metrics to 30-day metrics, and you were exactly right, it had to do with length of stay. The length of stay is going down, so the delta between in-hospital mortality and 30-day mortality is actually going up. And what's happened is that for any of the procedures that we see in cardiovascular surgery or medicine, the delta between the hospital mortality rate and 30-day mortality rate is actually the highest in TAVR, it's pretty unnerving actually. So the in-hospital mortality rate is basically worthless and the 30-day mortality rate is really really important, and so I agree with your point.

DR. BACH: Thank you.

DR. VANG: Eric Vang. So, if I could just address the question on 30-day mortality?

So using MedPAR, and this was again on the handout that I actually had and I think you all got that, if you look at both the slides for both graphs, both the graphic volume looking at the adjusted and unadjusted weighted averages, we actually focused on 30-day mortality, so that actually does include that for, this was in the volume for TAVR.

DR. BACH: Please. I can't actually see from the end, I wasn't watching the sequence. Go ahead, please.

DR. DESVIGNE-NICKENS: Thank you. Patrice Nickens. You know, we've had such focus on volume for obvious reasons and I was wondering --

DR. BACH: I'm sorry, can you speak into the microphone?

DR. DESVIGNE-NICKENS: I'm sorry. Can you hear me now?

DR. BACH: You have to be quite close.

DR. DESVIGNE-NICKENS: Yes. So, I wanted to ask about in training for procedures in TAVR, is it a number that you look for, what are the qualifications that you look for as you are training someone to use this procedure, and

then what do you follow, you know, and how many do people do in training programs to say that they're then confident to do it unassisted?

DR. TOMMASO: Carl Tommaso. Very good question. The criteria we put in the manuscript was that people had to participate in 100 transfemoral TAVRs and be first operator in 50 transfemoral TAVRs. That point, the difference between the 2012 and the 2018 document is we did away with prerequisites. If you're going to do TAVR, you have to be trained to do TAVR, and I don't know that any of us know the numbers that specifically you're asking, but there are probably 20 to 30 trainees finishing every year, both interventional cardiologists and cardiac surgeons, plus a number of people who have been junior operators and undergoing a preceptorship who meet these numbers. There's an adequate number of people, if that's the question you're getting at.

DR. DESVIGNE-NICKENS: Yeah, so, I guess my point more was towards this, you know, focused on a number, if you will. There's

25 simulations, there's all kinds of way for

1 people to develop the skills, if you will, to
2 manipulate catheters, et cetera, and so, you
3 know, to focus on volume seems a little
4 misplaced.
5 DR. TOMMASO: But a lot of it is the
6 evaluation of the patient, preop management,
7 the selection of the valve, not just going into
8 the laboratory and blowing up a balloon with a
9 valve on it in the aortic annulus. It's also
10 the postop management, it's knowing when you
11 have to call EP, it's knowing when you have a
12 bleeding problem. It's more than you can do
13 with just simulation. We have simulation at
14 our institution for PCI, for a number of
15 procedures. It doesn't replace the actual
16 patient care.
17 DR. BACH: Thank you.
18 DR. SUNDT: Thor Sundt. If I could, I
19 think I'm following where you're going with
20 this. If the question relates to the use of
21 volume criteria as a surrogate for competence,
22 for example, I'm on the American Board of

Thoracic Surgery, and my board, like everyone else's board, I would imagine, certainly proceduralist boards, to get board

certification we all still incorporate case volumes, case numbers. Is that a perfect way to assess competence, no, but yes, it is still a common part of the way we as professional organizations address that issue, imperfect as it may be.

DR. LEON: I just wanted to speak to kind of the real world issues of training centers and physicians for doing TAVR, which I think is a little bit about what you're trying to get to, because at Columbia we do training courses every other week and we've trained 55 percent of the centers in the United States to become qualified for TAVR. It's generally a one-and-a-half-day course. The centers are identified based upon the ability to demonstrate that they have a functional heart team, that they have competent individuals who can do surgery, who can do cardiac imaging, who can do interventional cardiology with endovascular experience and PCI experience as

well. Once a site is identified, they go through a fairly intense training program, there's an online portion, there's an in-person portion. We have to validate that they're able

to correctly do the preprocedure planning that was just discussed. Then there's a proctoring period of as many cases as is necessary to be able to demonstrate that the site has operators and a functional team that can orchestrate doing the procedure correctly.

So it is a very intense and rigorous process, more intense than any other interventional procedure that's ever been devised in interventional cardiology, and I think probably as intense as a training program that you would see with surgical procedures. There's also refresher courses as new techniques become available, so there's an ongoing process to train these centers, which I think, you know, has helped to result in some of the outcomes that we've observed.

I would never argue that there shouldn't be some case volume threshold. The

question is to me that if it ain't broke, don't fix it. Right now the NCD has certain volume thresholds. Whether that needs to be adjusted slightly in one direction, I would not take issue with. You clearly have to have a functional environment with experienced people

who can demonstrate excellent results, and there has to be transparency and there has to be oversight to make sure that the lower volume centers are not straying from the standpoint of what would be appropriate medical outcomes, with a shift from volume to outcome metrics, so the sites know how well they're doing, and can improve and aspire to get to within what we think is the most credible threshold of excellence.

DR. DESVIGNE-NICKENS: Thank you.

DR. PELIKAN: Just to follow up on that, clearly I believe that there is a volume-quality relationship when you're training and learning. I don't know what the number is, but there probably really is that relationship and I hope that the committee will separate that, because when you train, you need

to learn how to do this and be competent in all aspects of it, as Dr. Tommaso said, but that has really no relationship between how many PCIs a whole hospital does, or how many surgeries a whole hospital does.

DR. BACH: Thank you. Mark? Oh, I'm sorry.

DR. FELDMAN: Ted Feldman from SCAI. Another really critical part of the volume discussion both in training and in practice is the management of emergencies. And in a very paradoxical way as TAVR has become safer for a trainee, the frequency of emergencies to learn how to manage real time and to have experience with has become less, and that does drive the need for volume, and I would argue that after training it's no different in real practice, that you have to have the aggregate of experience with PCI, TAVR and surgery to be facile as a team to manage emergencies, and those are real frequency events, so that takes a lot of experience.

DR. BACH: Okay. Mark, please.

DR. CARLSON: Thanks, Peter. I think my question is for Doctors Leon and perhaps Bavaria. If I understood correctly, different eyes have looked at the same data set and come to very different conclusions about relationships between volume and outcomes, and there was mention of the term weighted analysis versus unweighted. Could you speak a little more to what that is, and why one approach is

better or more appropriate than the other?

DR. LEON: We have looked at the data as exhaustively as we can. The TVT registry really comprises data from two specific valve types, those data are available to the companies that functionally own those data, and we've looked at those data sets and have attempted to replicate as carefully as we can the analyses that were done by the consensus document, and have been unable to replicate the observation that there is the kind of volume-outcome relationship that would suggest importantly that we increase TAVR volume requirements.

The only way that we can get close to

replicating it is if we looked at volume groups and instead of doing a weighted analysis, that an unweighted analysis was done. So quite simply, an unweighted analysis would be taking every center, looking at their annual mortality, and simply averaging those annual mortalities, as opposed to a weighted analysis where you look at, for that particular grouping, that group of let's say zero to 50 cases, you looked at all of the deaths and all

of the cases, and then created a number which represents the totality of that grouping. So the only way that we could replicate or get close to replicating the data that was shown was if an analysis that was unweighted was performed, which from a methodologic standpoint we felt was the less robust way to do those kinds of analyses.

DR. BACH: So let me, just a technical point, it seems to me that using a random effect is the right way to do this analysis, so is that what was done? Which is different from a weighted analysis. Okay. I'm sorry.

DR. SHAHIAN: We don't have our representatives from DCRI here today, but I can assure you it was not based on aggregate data as was just described, that's pure supposition. We would never do an analysis like that when looking at volume and outcome at individual centers, so I can tell you that's not what was done.

DR. BACH: Thank you.

DR. BAVARIA: Obviously Dr. Shahian is the statistical expert for the ACC and STS databases, but from the standpoint of the DCRI

analysis that we put up, and John Carroll is here and I'm sure he'll say something as well, both of us are the co-chairs of the TVT registry so we're intimately familiar with this. One of the big differences everybody should know is that that data is the data from all transcatheter valves, not just Medtronic or Edwards or any of the others, it's the entire data set, and it was presented in a couple different formats regarding raw data, O to E (O:E) ratios based on TVT and O to E (O:E) ratios based on STS, so it's presented in a number of different

ways. I cannot comment on the weighted versus unweighted issue.

DR. CARROLL: I think your question is good and I don't think you're really able to see the specific methodology based on five-minute presentations, and that's critical.

Secondly, if you do split the total data set into two halves, you reduce the power of detecting differences.

Number three, as I tried to illustrate, yes, due to the initial NCD and the volume requirements, et cetera, outcomes have improved, some advances in technology, some

learning curves, some lower risk patients, but the outcomes have improved, and so statistically to look at site performance, you really have to move from just using one metric like mortality to using a composite. We've looked at some of the data shown where it didn't show a mortality difference between different volumes, but there was a consistent trend with low volume sites, and so you have to look at composite outcomes, and that's what

we're doing in the TVT registry. That's really more up to date, more robust, and will give us more meaningful insight into performance differences, with the goal of not shutting down sites, but allowing sites to have feedback and to improve. That's so critically important, and God forbid if the NCD should not be renewed because we don't have any accreditation process to take over, to allow monitoring of -- if we move to purely quality metrics, who's going to do anything?

This is just site reported, it's up to the sites to do their internal QA/QI. So we've got to get going in terms of developing accreditation processes using robust metrics

that are composite metrics and have a valid risk adjustment, and that's one of the reasons why we have gathered so many data elements in the TVT registry. To do valid scientifically strong risk adjustments, you can't do that, you know, is your grandmother alive or dead in 30 days, you've got to understand what goes into these differences in mortality and other major outcomes.

DR. BACH: Great, thank you. Eric.

DR. VANG: So, I wanted to address the weighted versus unweighted. As we look at trying to understand --

DR. BACH: Eric, I'm sorry to interrupt. So, we're all familiar with you, but can you, may I ask each of you to state your name and your affiliation? As I mentioned, you don't have to disclose your conflicts again.

DR. VANG: Eric Vang, with Medtronic.

DR. BACH: Thank you.

DR. VANG: So, I want to address the weighted versus unweighted, and as we get into the discussion around methodology, I think that's really the key to understanding the

evidence. So we've discussed the need for evidence-driven decisions. This is where we're trying to understand as an industry how best to replicate, understand the data that's in front of us. Replicating the data that we had from TVTR yesterday was our own data; hence, that's why we actually looked at the MedPAR data,

which is comprehensive of all. I don't think we fully understand, and I think with the discussion at hand, five minutes doesn't give justice to what is being presented.

But again, one of the concerns, or at least the ask, is try to understand the methodolgy to really drive at the answer. We do know that the complications around these analyses is complex, it's confounded by risks, it's confounded by volumes, just a number of different things including technology, and so I think there's a need for a better understanding of the methodology to really drive at the answer.

DR. BACH: Thank you. Sure. Just try to stay focused on the question. Name and affiliation.

DR. LEON: Marty Leon, Columbia,

AdvaMed representative. Just two points. Composite endpoints are difficult. When you look at the TVT registry and look at certain of the composite endpoints like stroke, the quality of life, the ascertainment of those endpoints is difficult and has not been fully

validated, so it becomes problematic as you begin to move forward, these are things that we have to overcome certainly, which I think is important. But it would be difficult right now to suggest that we have enough data and composite endpoints to indicate that we can determine quality.

DR. BACH: Thank you. Okay. Dr. Pelikan.

DR. PELIKAN: Peter Pelikan, Santa Monica. I just want to take one issue with one thing that Dr. Carroll said and that is, he attributes the improved quality to the fact that there is an NCD. There's no way to prove that statement since we have not been doing TAVR without an NCD, it has just been in existence, so that logically cannot be concluded.

If we look at other procedures where

there is not an NCD, let's take coronary stenting for example, there's been steady improvement over the years without an NCD, without volume criteria. Thank you.

DR. BACH: Thank you. Zoltan?

DR. TURI: Yeah. Actually, if you don't mind, although I have no TAVR conflicts, I wanted to mention that I gave a talk for grand rounds on PFO closure that Abbott reimbursed me for, I'd rather have that out there. The other is that CMS, I noticed this morning, gave me a degree of Master's in Public Health, which is nice, but it would be a surprise to my parents who paid for my education.

So, I want to follow up on something Dr. Carroll said. Dr. Bavaria showed us the observed versus expected ratio for 30-day mortality. I'm fond of full disclosure slides so you see every data point, and he pointed out that 96 percent of those with a O to E (O:E) ratio over two were in the low volume group of less than a hundred cases.

Dr. Pelikan showed us a curve reversed to some degree and said that, you know,

significant numbers of hospitals doing less than 50 cases had no mortality, and he said well, this was a marker of high quality in

those institutions.

So, my question relates really to how much risk adjustment we have, how good the risk adjustment is, whether the speakers believe the risk adjustment to the extent we have it, and how much can we say about that zero mortality as a marker of, in fact as a marker of quality, if it is?

DR. SHAHIAN: As I mentioned in my remarks -- Dave Shahian, STS.

As I mentioned in my remarks earlier, we know nothing about a program that does 30, 40, 45 cases and has zero mortality. Chances are they're going to have a substantial number of deaths in the second 50 of their first hundred just by random chance. We can make no inferences about their quality, and that's the crux of the second argument favoring volume thresholds. We simply cannot determine the quality of a program that's doing 40 cases.

DR. TURI: But do we know anything about the risk level, in other words, the STS

score of those low volume centers?

DR. SHAHIAN: Well, Dr. Carroll's presentation showed that the issue is not that these sites are doing harder cases; in fact, they're doing cases that are less complex.

DR. BACH: Thank you. Actually, can I follow up on that, not necessarily with you, Dr. Shahian, but I was struck by that as well. So when you get into the high -- I'm allowed to ask questions, by the way. When you get into the high volume categories, I mean, we had slides that there were zero facilities that had perfect scores, in fact they seemed to have some mortality rate. And so I think it was Dr. Pelikan, but a number of people focused on these low volume hospitals with zeroes.

And my question for you is, is it your interpretation of the data that these low volume with zero rates are better than these high volume hospitals, none of which had zero rates?

DR. PELIKAN: Peter Pelikan, Santa Monica. So, when Dr., if I'm pronouncing it correctly, Shahian says a hospital that does 40 cases and has zero mortality, the next year is

going to maybe have 30 deaths, there's no way to really know that either, and that statement is based on a presumption that volume is a predictor of quality, and really there is no data supporting that.

There are ways around that, you can look at over multiple years how a program does, there are many different ways to analyze that. So I think simply saying that we throw our hands up and we can't evaluate quality in a world where we now have medical records that are electronic, speaking to the risk adjustment, where hopefully the people putting the data in the medical records on their problem list or their preoperative testing, it's all there, so we can assess that.

DR. BACH: And maybe it's an unfair question, but I did ask, do you conclude from those data that those zero event hospitals are better than any of the high volume hospitals? Because as I pointed out in those graphs as I read them, you don't have any high volume hospitals with zero events, and you're relying a great deal on those zero events as a signal of quality.

DR. PELIKAN: Well, actually I relied on the lower left quadrant there showing low event rate, not zero, there clearly were some at zero, but there are also a number of hospitals or, if you're looking at coronary stent implantation, a number of operators at low volume who have zero or low or acceptable mortality rates. So I wasn't trying to draw a conclusion that they were better, clearly I don't think you could conclude that.

Second of all, I was not in any way saying that, you know, these are fabulous hospitals that have zero mortality, because any time you do a procedure, there's going to be complications, so I wasn't implying that at all.

DR. BACH: Why can't you conclude it? You pointed to those and said they have zero events.

DR. PELIKAN: Well, I would be happy with that, but I'm not saying they're better or worse. I'm not sure what the error bars are there, and I'm not enough of a statistician to make that comparison. But on the other hand, I wouldn't throw my hands up and say okay, you

had zero or low mortality, but we don't know what that means, so we're going to exclude you.

DR. BACH: Okay, thank you. Is it on that, do you have a follow-up question?

DR. DEHMER: So -- and again, Dr. Pelikan, you, and Dr. Bach emphasized, you focused on the facilities in the lower left-hand corner, the low volume zero mortality facilities, but in both Moscucci's study and in the 2013 competency document for PCI, what you didn't point out was the studies in the upper corner, that's the upper left-hand corner, which were the low volume facilities that had high mortality, and that actually came out in the most current version of the combined society document, that that's really a focus that we have to key in on, and how do you respond to that?

DR. PELIKAN: Peter Pelikan. Well, I completely agree with you and my entire thesis, not just me, other speakers here feel we should look at quality. If it's a low volume low quality institution, then they should not be doing TAVR, if a high volume low quality

25 institution exists, they should not be doing

1 TAVR. So I'm in no way ignoring them, I'm --
2 in no way should my words be construed to mean
3 that I think all low volume centers should be
4 doing TAVR. I'm simply saying that we need to
5 make this decision based on the quality of the
6 program, not on the volume.
7 DR. DEHMER: As a follow-up, I agree
8 that quality trumps quantity every day of the
9 week, I don't think anybody would argue about
10 that, but how can you measure quality with no
11 volume? Now, no center's going to do zero
12 volume, but as Dr. Shahian I think pretty
13 eloquently showed in his statistical
14 presentation, when you have low value centers,
15 the confidence interval on trying to determine
16 mortality or any of the other metrics that you
17 might look at is so wide that it would take you
18 several years in order to figure out whether
19 there is really truly a difference, and what
20 happens to all these patients during those
21 several years?
22 DR. PELIKAN: Well, if you remember

what he said, basically he implied that, you know, centers doing three or 400 cases a year should be the only centers by his logic. And

then he said, well, I guess we could compromise at 50, so I don't know what the right cutoff number is, but I do believe that hospitals with robust quality assurance programs monitor what's going on, and if you are producing good outcomes with high quality, I don't believe you should be prevented from doing the procedure.

DR. BACH: Thank you. I'm going to ask everyone to try and contain their questions to shorter, and also to try and contain your temptation to characterize what other people have said, they're standing in the room and can speak for themselves.

DR. TOMMASO: Carl Tommaso, chair of the writing committee. In response to your question, if you look at that slide, of the low volume centers, there were a number of them that had zero mortality, but the highest mortality overall was also in those low volume centers, and that's why the median became similar to the rest, but you had a lot of low

volume centers with the highest O to E (O:E)s or mortality or however you want to measure it. And that's the reason, as Dr. Shahian showed the funnel plots, that at low volume, you

really don't have statistical accuracy as to quality, and that's why we think a volume criteria is appropriate.

DR. BACH: Thank you. We'll take these two, keep going, and then I'm going to take the next question.

DR. SHAHIAN: Dave Shahian. I just wanted to clarify something that Dr. Pelikan said. First of all, my comments related to the zero mortality programs, that has nothing to do with volume-outcome association, that's simply a random sampling issue, and we just know from the phenomenon of regression to the mean that if you're zero mortality, even if your actual long-term mortality is average, you're going to have a blip on the other side because you're going to fluctuate around the mean. It's the same reason somebody, a major league hitter that hits .350 this year and gets a gazillion

dollar contract, next year hits .175. It's the same phenomenon.

DR. BACH: Don't remind us.

DR. SHAHIAN: Exactly. And secondly, I never quoted anything about three or 400 cases, obviously. I said I could make a good

argument for a hundred cases as opposed to 50 cases just based on both the volume outcome and the statistical issues, but I certainly said nothing about three or 400. Thanks.

DR. BACH: Thank you. Dr. Goldberg.

DR. GOLDBERG: Steve Goldberg, two comments.

DR. BACH: Affiliation, please?

DR. GOLDBERG: The Tyler Heart Institute, Monterey, California.

Bringing it back, it is challenging to have these statistical discussions about volume and mortality and so forth, but we cannot lose sight of the fact that if that is going to have an impact on access of care, that the numbers are really not going to be reflective of how we're taking care of patients, so we cannot divorce those two things if the volume

requirements are going to reduce access to care, then that has to be factored in.

The second point is I wanted to comment, it's been made a couple times today, that in the TVT registry, that the larger volume hospitals had sicker patients based upon the STS risk calculation, but in fact the

smaller volume hospitals had older patients. And there are many features that go into the STS risk that lack, excuse me, that don't go into the STS risk calculator because those patients tend not to be operated on, and those features such as porcelain aorta or severe lung disease increase with age. So it is maybe a word of caution, that that specific analysis may be fraught with some misleading interpretations.

DR. BACH: Thank you. Naftali?

MR. FRANKEL: I just have a few questions. May I ask them?

DR. BACH: Uh-huh.

MR. FRANKEL: I just have a couple clarification questions. Dr. Pelikan, given

the reduction but still reducing mortality, stroke, other complication rates from TAVR such as pacemaker implantation, aortic regurgitation, Dr. Carroll mentioned before 22 percent serious in-hospital complications, I have just a comment. I noted in your letter for formal request, that you described TAVR that it's now become a safe procedure, and it was mentioned a couple times in the letter, and

I just found that to be somewhat surprising. Obviously it's dramatically improved, but to call it a safe procedure is one of the things that I'm concerned when I'm involved with patient advocacy, that patients should be aware of the risks involved, even if they're decreased risks.

The question, if you know that TAVR is not affected by procedural volume of non-TAVR procedures, so if so, I was wondering, in your conclusion you noted that you have recommended volume requirements for structural heart procedures, and I was wondering why you would recommend that, given the other assertion of TAVR not being affected by procedural volumes

of non-TAVR procedures.

Dr. Bavaria, I was wondering that --

DR. BACH: No. Sure, we'll do one at a time.

DR. PELIKAN: Peter Pelikan, Santa Monica. I'm sorry, could you just give me a succinct question there, I'm sorry.

MR. FRANKEL: You noted in your letter TAVR -- well, it's not a question, that was just a comment. The question was that you had

noted that the experience of non-TAVR specific procedures does not improve the outcomes. I believe you noted that non-TAVR procedures are not actually helpful in equating to improved outcomes, but in your recommendations sent in the letter, you noted that the recommendation for requirements for structural heart procedures, and I was wondering why that would be if that doesn't actually help TAVR outcomes improve.

DR. PELIKAN: Okay. So I believe what you're -- okay, the answer is the following. I think in order to do TAVR, you clearly have to

be as the interventional cardiologist able to do coronary intervention, you have to be able to do peripheral intervention and structural heart intervention, so I believe clearly you have to be competent and good at those things to do the procedure. The procedure, and I can tell you from personal experience compared to five or six years ago and now, it has gone from general anesthesia, you know, 15 people in the room, a lot of anxiety, things occasionally didn't go well, to conscious sedation, percutaneous access, fairly streamlined VAS

procedure.

I'm not disagreeing with the quote of 22 percent in-hospital complications but that really has not been the experience that I've had. But clearly, you have to be able to deal with a coronary emergency, you have to be able to deal with a peripheral emergency. My only point is, if a hospital does 300 or 400, or 200 coronary interventions a year, it doesn't necessarily make that operator better at doing those procedures. So I'm divorcing --

DR. BACH: Thank you. I'm sorry, I

want to -- you answered the question. Thank you. Dr. Tommaso, quickly.

DR. TOMMASO: Carl Tommaso, committee chair. In the 2012 document there were no training programs, there were very few people experienced in TAVR. We put in prerequisites, having done balloon angioplasty, having done other structural issues. This document said if you want to do TAVR, you've got to be trained to do TAVR.

DR. BACH: Thank you. Aloysius.

DR. CUYJET: I have two questions. The first question I'll ask as a cardiologist.

During lunchtime I was trying to imagine, I'm a cardiac surgeon, I do 200 aortic valve replacements, but they were all elective. So my question is --

DR. BACH: Closer to the microphone.

DR. CUYJET: I'm going to ask two questions, first as a cardiologist. During lunch I was trying to imagine, I'm a cardiac surgeon, I do 200 aortic valve replacements but they're all elective, which is an entirely

different scenario if you have a complication from TAVR and a patient crashes in the cath lab. Now the technology for TAVR has really accelerated, so my question has to do with training. Is there any data on simulation centers to either help train people initially or to update or reassess skills at centers that are doing TAVR? Because we hear a lot about volume, but simulation centers could be a useful tool.

DR. BAVARIA: Well, I think Marty answered a little bit of that earlier regarding the training question. There are training simulators, they're actually quite good and they're being used ubiquitously throughout the

country as Dr., as Marty said, and he's, probably about 50 percent of them are done at Columbia, and both the Medtronic device as well as the Edwards device, in fact all of the devices have simulators. It's been shown in the kind of education training world that simulation is pretty good at the beginning of one's experience but after a while, as Dr. Tommaso said, simulation doesn't, you know,

make that much difference compared to real life scenarios. So that's actually a well-understood procedural issue in simulation education circles.

DR. BACH: Thank you. Do you have another follow-up comment?

SPEAKER: Yes, I do, representing the surgical side of it. So for example, when I think about the complications that occur during transcatheter aortic valve replacement, rupture of the aortic root, all right? Our cardiac surgical training is to learn how to deal with that problem basically by doing root enlargements during elective aortic valve replacement, or repairing aortic roots that are affected by endocarditis where the root is

destroyed. So that's where people get the familiarity to deal with these, and every one of these complications will be completely unique, they need to be able to do root replacements, they need to be able to do root repairs, root enlargements, patch repairs and things of that nature. Does that answer your

question?

DR. CUYJET: Partly. But is there any data to assess the efficacy of simulation?

SPEAKER: None of which I'm aware.

DR. CUYJET: Okay. The second question I want to ask just related to my population public health issue. I still can't digest the 3.8 percent rate of TAVR in African-American populations in the U.S. And I'm dating myself but I'll go back to the old CABG data where they used Medicare populations, one white, one black, so insurance was not an access issue, and utilization and recommendations for intervention of bypass surgery were lower in the African-American cohort. So the issue is complex to say the least, it's multifactorial to say the least, but it has persisted, whether you're talking

about CABG back in the late '70s, early '80s, or TAVR in 2018.

The answer to the issue is not to increase the number of facilities doing TAVR, there's a more fundamental root question in how the healthcare system works, and that's more a

comment than a question, but I had to get it off my chest.

DR. BACH: Great. I apologize. Naftali, you actually had two questions, the second for Dr. Bavaria, so please, I apologize for cutting you off.

MR. FRANKEL: Yes. That question was if mortality indeed is increased at low volume centers and if there is really no concern about access, then why, if -- you concluded by being very clear that you're not recommending for those sites to be closed down. So if you translate the low volume centers into an increased risk for those patients, why is that your recommendation?

DR. BAVARIA: I think there's two answers to that question. First of all --

DR. BACH: Sorry, name and affiliation.

DR. BAVARIA: Oh, I'm sorry, Joe Bavaria, co-chair of the writing committee.

DR. BACH: Thank you.

DR. BAVARIA: So, we know, we think we

know for a fact based on the most recent data out of the TVT database that there is a volume-outcome relationship and it's quite significant under 50 and very significant under 25, and you can see that data. And so the question is, well, why not close them, you know, why not kind of close them down. Our, as the four societies, our job is not to close down sites, our job in regarding this kind of a document which is a consensus care document, is to provide for remediation and provide the data so that sites can get better, as Dr. Carroll said.

So you are right, the answer to the question is if you're a consistent low volume site with poor outcomes, even though it's hard to measure the poor outcomes, but if you do have poor outcomes, then there needs to be a process for remediation, a process for identification and remediation, and the societies are prepared to do that. Shutting

down a program is not in the purview of the four societies, and since we wrote the document, that's not really in our, something

that we would do, that would be a CMS issue.

For example, when we have to do transplants and we're below a certain threshold of either quality or volume for transplants, you know, we get a letter from CMS saying, you know, they're not going to pay for transplants for a year or two until something happens, that's kind of a thing in the United States. So they can do that, but the four societies provide remediation, identification and remediation, but we don't shut down programs.

MR. FRANKEL: But the consensus position is that there is a concern for those patients that are ending up at those sites, that they're at a higher rate of risk than having gone, if they actually end up in a higher volume site?

DR. BAVARIA: Well, you know, as I showed, someone even said it, and that data set that we showed, one site was a high volume site with very bad outcomes, and so you do have a few of those.

MR. FRANKEL: I'm looking nationally

on average.

DR. BAVARIA: Yeah. I don't really know where your question is going, but I would say that I would reiterate that the societies are not in the position of shutting down programs, but maybe John can say something. We are in the business of identification of poor quality, measuring poor quality and good quality, and then remediation efforts for the sites as best as is possible so they can get better.

DR. BACH: Briefly.

DR. CARROLL: John Carroll, ACC. That's a great question. The TVT registry delivers to all sites on a quarterly basis their results with national benchmarks, and that gives the site an opportunity to say how are we doing, let's sit down and talk about how we're doing well, how we're not doing well, where we can make improvements. And we hope, because there is a learning curve and there is experience gained over time, that those sites will improve.

But as Dr. Bavaria said, we don't have

an accreditation process yet, any way of really creating external factors to bear, and CMS hasn't done anything like that yet, but that should come as the next natural evolution in this treatment.

DR. BACH: Thank you. Smadar.

DR. KORT: So, I just want to shift briefly from outcomes to access to care, which is a matter that was discussed here today, and the thought of low volume centers, just speaking as an advocate, those typically don't really have the infrastructure to allow for large volume of patients to get care in those centers, and I wonder if there's any data to show, to support or to negate, low volume centers actually cherry picking the patients that they could accommodate and care for, and therefore, still producing or contributing to a problem with access to care by sicker patients, minorities, et cetera.

DR. BACH: The question is if there's evidence that that happens, correct?

DR. KORT: Supported by data.

DR. HORNE: Aaron Horne, Association of Black Cardiologists. So, I think we all

agree here that patient selection is imperative regardless of the center, right, so we definitely can see that. However, you know, we obviously have a responsibility to treat whoever comes across our doorstep, and I think that what we have found based on the geography data, and patient preferences to actually seek care in an environment in which they're most comfortable and most familiar obviously impacts, you know, the way in which they get treated.

And so while I agree, and we all agree that patient selection is imperative, I think that also, I want to be clear that I think that some of these nontraditional centers, and maybe this is a misnomer, we actually do have the infrastructure to manage these things, we all have a heart valve team, and I think that some of the iterations that make it unique being in the community, for instance, they have a surgeon who's done 50 surgical valves at that one center over a 12-month period of time. In the community, for instance where I practice, the surgeon actually does surgeries in four different hospitals, but has the same

anesthesiologist but it's a different environment. And I think that that's actually what Dr. Goldberg was mentioning before, and actually we all came from large academic centers and obviously we were trained well, and now we're in the community and trying to make sure that we can bring that skill set we learned in those environments to the patients where they are.

DR. BACH: Thank you. I'm not going to -- I want to get to other questions, I'm sorry. I know there's going to be added comments to that.

It's being recorded, so it can't be just hand gestures. Sandy.

DR. LEWIS: So, it came to mind as we were talking about training centers and early challenges. Has anyone looked at the comparison of outcomes for training centers versus non-training centers, versus small programs?

DR. BACH: I think we'll take that as either no, or no one here is aware of it. No? Sorry. I didn't mean to jump the gun.

from Dartmouth. I'll just provide a little clarification about the state of training for structural heart disease in the country to answer that question. We don't have accreditation for training for structural heart disease fellows, so Dr. Horne and I were some of the early fellows that were trained. These were unaccredited programs, there were not specific volume requirements that are applied. We look to the professional societies as well as Medicare requirements when we train other fellows that come to our programs, we have to get funding from other spots to do that.

So it's different than interventional cardiology training programs where this is an accredited program with national curricula and goals that have to be met and that are accessed. So for TAVR operators that are coming out of fellowship and when we're training fellows, it's an unaccredited program without specific guidelines, separate from what Dr. Leon talked about where he's bringing in

attendings that have finished their interventional cardiology programs.

DR. LEWIS: But those fellows

generally have had an interventional year?

DR. LEON: Yes. It's usually a second year of training, so the structural fellowships that are currently available are not accredited, yes, so they are somewhat individualized, and the curriculum is really based on the institutional ideas of what the curriculum should be, and there are relatively few of them. So you can count the number of defined structural programs probably on the fingers of both hands, so there are not enough structural programs to treat, or to train new fellows that would provide an answer to some of the access issues that we've been talking about. It's difficult to get this training out of fellowship.

DR. BACH: Thanks, and now I'm going to cut you off, sorry. Michael.

DR. CINQUEGRANI: This is a question for my colleagues representing societies in that while the TVT registry is well developed

and is doing a great job in defining outcomes and procedures and there's going to be more to come from that, I'm absolutely certain, but have the societies given any thought to

developing structured processes of external review of poor performing programs to facilitate QA/QI processes in those programs? Somebody mentioned the term remediation.

DR. BAVARIA: Joe Bavaria, co-chair of the writing committee, and obviously also STS for this particular answer.

On the TAVR side of things, there is no structured available remediation effort to date. This is one of the things that's in the new document that needs to be created, and is one of the hopes of the new document, and an NCD that possibly might ensue.

Now on the surgical side, on the STS side, there is some rudimentary remediation efforts by the society, by the Society of Thoracic Surgeons regarding remediation for one-star programs in the United States of America, but it's not, they have to ask the STS

for that, it doesn't go the other way around. So it's kind of neophytic, but it does exist and it's actually being discussed right now as we speak at the board level of the STS, and that should be a little more robust.

DR. BACH: Dan, please. No, I'm just

going to allow one answer per question, sorry. Dan.

DR. OLLENDORF: Thanks. So, I've been kind of puzzling over the notion that's been brought up in a couple of different presentations around whether reducing or eliminating volume requirements would be either necessary or sufficient to address disparities. So Dr. Horne, I'm wondering if I can ask a question about the data you presented specific to your community.

So, this is a community that has prevalent Hispanic and African-American populations, has a population that's a quarter Hispanic, a quarter as African-American, but the data you presented on the rate of TAVR in the African-American population as being much higher than is typically seen nationally is

most impressive, but it seems as though the Hispanic population there is still underserved, so I'm just wondering if you wanted to comment on that.

DR. HORNE: Aaron Horne, Association of Black Cardiologists. So, I think you're right, I think it's a huge area that we need to

look at much more closely. I think that to Dr. Cuyjet's point, it's multifactorial, and again, I don't want to generalize, but you have a component of Hispanic population that, not all of them, but a percentage of them might have a language barrier, there might be an uncomfortableness or a lack of awareness in terms of how to actually access their healthcare environment, and many reasons why.

Just anecdotally again, I got a phone call last night from a family friend who was sick, didn't know what to do, and we were able to facilitate getting that patient to care. So absolutely, I think that it's an area where we definitely need to spend more effort and energy, I think it's become a systemic problem

with regards to language barriers and, you know, in some instances inability or uncomfortability with having to figure out how to navigate the healthcare system.

I think that data is actually supported if you look at it again, in terms of the African-American community, if you look at it again, just, we know that there is a correlation many times with income and

education, right? So we showed the difference in median income amongst African-Americans and Caucasians, and their savings as well, and there is a lack of a wherewithal at times to figure out how to actually get access to information and care.

DR. BACH: Can I ask you a follow-up question, even though I'm out of order? So the disparities that you described, and a couple of other speakers described, are frustrating on many fronts, and you listed some of the causes. I'm just trying to look, and this is disparity particularly between whites and African-Americans, it's been long documented across many conditions, equally frustrating. The

question I have relates to the volume standards for TAVR, and if we can look at TAVR and conclude that the volume standards have made the disparities incrementally worse than they are sort of ambiently across all parts of health care? I'm not trying to discount the importance of them, it's a causal question, are we sort of worse off with TAVR because of these volume requirements than we are for traditional cardiovascular care or open heart surgery, or

any -- I work focused on cancer, and we have vast disparities there where we don't have volume requirements. So, do you see a bigger effect, is there a difference?

DR. HORNE: Unfortunately, I do. Because again, we have demonstrated that patients are only going to access care where they are comfortable, right? And we, you know, have the trend lines that show that some smaller programs have had adverse outcomes and, you know, it's somewhat personal. I'm pretty proud of the outcomes that we've had, so some smaller programs actually, I think many of us

have great outcomes. And again, if you're going to offer the patient nothing as opposed to being in a more familiar, albeit less robust than maybe a critically acclaimed national environment because of the way or where your physicians practice, I think that the patients, again, through shared decision-making, should be able to have access to that information.

Every physician has the right to be transparent with their outcomes. I tell everybody we're a small center, we've done X number of cases, these are our outcomes, and I

think that they deserve the opportunity to make that decision.

DR. BACH: Thank you. I'm not going to -- I'm trying to get to the other questions, even though I just inserted a question. Mark, and then Aloysius.

DR. CARLSON: I'm going to ask what is certainly a naive question and it may even be outlandish. There has been the assertion, which is understandable, that it's difficult if not impossible to measure quality accurately in low volume centers. And when we talk about

volume we're talking about not just volume, but volume over time, specifically annual volume. And my question has to do with, what is magical about a year, why not two years? And should we be focusing on time at all, or should we be focusing on the absolute number of cases that is required to assess quality and then assess it at that point going forward repetitively? Sort of like your oil changes in your car, every 5,000 or 10,000 miles. It's just not clear to me why one year should be the answer.

DR. BACH: Because that's how long it takes the earth to go around the sun.

DR. CARLSON: Sorry, I didn't hear you.

DR. BACH: For a serious answer now.

DR. SHAHIAN: Dave Shahian, from STS. Well, you're absolutely right, and you know, we are looking at, a running three years is probably what we're going to settle on, just to address that particular issue. Your point about just doing, you know, if you think you need 150 cases in order to get a statistically

valid result, why not just wait until you have that many cases. It's an option. I can't think of any situation in which that's been done, and there may be no good reason that it's not been done, but it is --

DR. CARLSON: So there might be some centers where you would measure it at six months?

DR. SHAHIAN: Yeah, that's right.

But just to point out some other ways to mitigate this small sample issue, on the surgical side we've gone to composite measures, and just to give you a very quick example, in the development of the CABG composite, the STS CABG composite, using mortality alone, which is

what we've basically been talking about today, we could identify one percent of providers as being outliers when we first did this. When we went to a composite that had more risk-adjusted mortality plus the risk-adjusted occurrence of any of the five major complications, we could identify a total of 23 percent. We've seen the same phenomenon in aortic valve, aortic valve CABG composites, so that's a very powerful tool

for making it possible to address quality and measure quality at lower volumes than we have historically with a single measure like mortality, and we are moving towards composites in TAVR as well.

DR. BACH: Thank you. Anita.

DR. FERNANDER: So, this has been a really informative and educational discussion for me. As a health disparities researcher, I really want to challenge my colleagues around the table as well as those of you sitting in the audience, and those who are on these decision-making boards and committees, to really rethink how you are equating quality with volume. It's very very antiquated. You are sitting in existing committees and boards

where you are vested in focusing on volume.

There are research methods and strategies that exist that, where gold standard does not have to be focused on quantitative statistics. There are strategies where you can think out of the box and think creatively about meaningful outcome data. Volume is not an

outcome data. What are you going to actually extract from a volume number? What is that going to tell you about how your patient is doing, what their quality of life is, how other social factors are being influenced, and influence your patients?

I really am looking at this very, in many ways, homogenous group of folks here who are not used to thinking outside of the box and who can exist in their worlds operating this way until death do you part. But I would really really challenge you to go back to your committees, work with your colleagues, bring in folk who have different views and different outlooks and perspectives, to be able to treat what is becoming more and more a very diverse and heterogeneous patient population.

(Applause.)

DR. CARROLL: John Carroll, ACC. I totally agree. This MedCAC is focusing on volume, that's CMS's decision, and that's why you're heard so much about volume. Quality and this broader definition of quality is very important, and in the TVT registry that is one

of the main reasons we instituted getting this patient-reported outcomes survey done in all patients before, 30 days, and one year, to look at what is the treatment effect in all of the diversity of patients in terms of not only being alive at one year, but feeling better in their own words, to being more functional. That's why we're also looking at rehospitalization rates and whether people go home after a procedure or go to a nursing home. So we are trying to look at much more patient centric ways of looking at therapy outcomes than just, you know, complication rates, et cetera. It's really about the benefit that's accrued.

So I think we're working on that and it's a challenge, because no other clinical registry has looked at one-year outcomes having the patient's voice as a key component of what

defines success. So we're totally on board with what you're thinking.

DR. BACH: Thank you. Naftali, did you have another question? Your card's up.

MR. FRANKEL: Yeah, I just wanted to ask Dr. Leon.

DR. BACH: Please.

MR. FRANKEL: So Dr. Leon, I looked at a couple of the articles that you published as part of the broader literature on this topic, and obviously everywhere you look you see your name, and there were a couple specific things that stuck out when I was reading through them, where you noted in one article, the Canadian Journal on Cardiology, to quote, it's not surprising that several sites have demonstrated the effects of a learning curve. Experience has shown to affect overall outcomes and specific procedural elements.

Then in a JAC article, you noted, in parallel with technology enhancements, patients have benefited from increased operator experience. A large meta-analysis from 25 multicenter registries and 33 single-center studies found an important reduction in stroke

after TAVR. These findings were associated with increased operator experience. The importance of operator learning curves and

experience, unlike other commonly used interventional technology, and for example you noted stents, TAVR expertise requires intensive device-specific training.

So in your opinion, what is the current learning curve, the amount of procedures for TAVR in less complex as well as more complex procedures that you were indicating in those articles?

DR. LEON: Thank you. You quoted several manuscripts that were in very different time domains as well, and I think your points are very well taken. There's no question when you start a new technology like TAVR in the highest risk patients, which is what the original approval indications were, patients who had significant comorbidities, devices that were particularly high profile as I mentioned earlier in the early days, 30 percent having transapical access because you couldn't use a transfemoral approach, certainly there's going to be much more of a learning curve under those

circumstances.

So I would characterize the early days versus the modern era of TAVR, where many of these procedures are done in a minimalist way, where crowd wisdom and group learning and experiences over time have dramatically reduced the learning curve for new operators. So new operators being trained now have a much much more shallow learning curve than we had five, eight years ago when we began this process. And it's for the very reasons that I mentioned. We do as a group have much more experience, we train them against complications to prevent them, 95 percent of the patients have transfemoral access, we've been able to reduce sequentially many of the specific complications by a combination of procedural changes and technology advancement.

So I think the learning curve issue, albeit a very important one five years ago, is less significant now. I can't give you an actual single number as to what is the learning curve for the new operator who is being trained in TAVR. Certainly I think you'd want somebody who's had good experiences with 25 or 50 cases

as a primary operator under supervision, I think that would probably encompass the important aspects of a learning curve, and as being part of a much larger group with more experience in the other disciplines required to achieve optimal outcomes.

MR. FRANKEL: So if you required that amount, would you feel comfortable?

DR. LEON: I would feel comfortable, yes, that people who have proper proctoring with extensive training and had independent operator experiences with 25 or more cases, certainly, yes, I would be comfortable.

MR. FRANKEL: I just wanted to say that that JACC article was from 2016.

DR. LEON: Yes, but it reflects data that was accumulated from 2012 to 2014.

DR. BACH: And was probably under peer review for two years or something.

MR. FRANKEL: Fair enough.

DR. BACH: That's the end of the panel questions. A couple things. Larry, I cut you off and you haven't said anything, and also, you had a comment you wanted to make. Anyone else, if you have comments that are concise,

that are additive, they don't mischaracterize anyone else's comments, we're open to it. But otherwise, we will be discussing things and then we will tell you it is acceptable during our discussions, that if we are wrong on facts and you have input, we would love to hear it.

MR. WOOD: Just a quick comment. I think that one of the challenges here is we keep looking at TAVR in isolation, without understanding there's a competing therapy for these patients, which is surgical AVR. Closing someone's TAVR program without understanding that their AVR program is much better does not necessarily benefit these patients. The idea that if every patient who's a TAVR patient leaves a hospital that got closed down and they go down the street and get TAVR is a false narrative. Most of these patients are going to end up staying at that hospital and potentially having surgery.

Unless we evaluate the quality of how aortic valve replacement is done, then we're missing the forest for the trees. And so, to deal with the sample size issue, one solution is to capture all of the patients' AVRs that

are done, and measure their O to E (O:E) ratio on how they did all their AVRs, combining surgery and TAVR. It would give you a larger sample size and would provide patients with what they need if they want to know, how well does my disease get treated at this hospital, and do I get proper care. Thank you.

DR. BACH: Thank you.

DR. BAVARIA: I just wanted to -- yes, Joe Bavaria, co-writer. Dr. Kort's question was a good one and I just wanted to, you wanted an example of some data but nobody gave it to you. So, one of the things that we see happening regarding low volume centers, et cetera, and how they relate to higher volume centers and, you know, that bit that you were talking about, when you have these large, like ACA, or say for example the big Cleveland systems, and even in our system at the University of Pennsylvania where we have about ten hospitals that we own, so what's happening there is no good data but the health systems themselves are dealing with this.

So you have ten open heart hospitals

in your system but the CEO says we're only

doing TAVR in three, but the other seven are getting, or have TAVR programs up to the point of the procedure and then send them in in a spoke and wheel fashion. So it is being addressed, it's being addressed in an interesting way, mostly by the burgeoning of the large healthcare systems and taking care of the efficiencies of that healthcare system.

DR. BACH: Thank you. Name and affiliation, please.

DR. CUBEDDU: Robert Cubeddu, Cleveland Clinic Florida. I want to believe that the NCD guidelines and recommendations in 2012 really developed within an era where structural heart disease was recently just introduced, where operators and different hospitals really didn't have any kind of credentialing recommendations or guidelines, and so it really has helped tremendously the commercialization of this therapy. I think it has evolved dramatically, and I think it's very important that we're making this the next step,

to update, you know, the guidelines, and I do think this is a very important day for all of us, including our patients.

With that, I'd like to say that when we revise and when we come up with, or when the panel does, just keep in mind the things that have been discussed today, the ethnicity considerations, the geographical considerations, and the training consideration. If I were to take Dr. Marty Leon to my hospital today, he could not do TAVR. That makes no sense in my mind. If I could take any of the surgeons that are sitting in the front row to my hospital today, they could not do TAVR.

And yes, we heard that the question asked in the office is, well, what's your experience, but my question is, what sense does it make for me to jump on a plane and go up to New York or go up to Boston, or drive 60 miles, when you alone have trained in structural heart disease, have all the structural heart experience across the board from Watchman and PVL, and closure with ASDs, and we do heart transplants in our hospital.

22 So there needs to be a careful
23 examination of the volume and the metrics of
24 quality, but there also, because I do think
25 there is a need for some volume metrics and

1 quality metrics, but there has to be some
2 consideration to exception. So what was said,
3 that if you were formally trained and have all
4 the experience, you could do TAVR, is not true.
5 I'm held back by PCI volume, other colleagues
6 of mine are held back by AVR volume. So if I
7 were to take any of the folks that have
8 intervened today, and we park them in a
9 hospital that does 350 PCIs or 25 AVRs, that in
10 and of itself excludes them from providing care
11 to many of our patients that are asking for
12 valve replacement. Thank you.
13 DR. BACH: All right, thank you. Now
14 I'm going to cut it off, sorry. I apologize.
15 We're going to move on to -- thank you for all
16 of your answers to the questions. We're going
17 to move on to a discussion amongst all of us.
18 This is also open. As I mentioned, we are all
19 seeking input and insight, and so during the

course of this discussion if things that come up that are factual in nature, please, I will figure out a way to integrate you into that conversation.

But I want to ask, I will start this, but the panel all knows that they're supposed

to speak to one another, to ask one another questions. I'll start with the central issue. As this point based on the observation of the data, there's strong feelings that there is not a volume signal with relation to mortality. I think that was a triple negative, but those are in vogue now. I'll say it again. Is there a solid conclusion that there is a volume-outcome relationship with TAVR based on the data that you've seen today? That's the question to you guys, and/or, what are the remaining questions that we need to tease through?

DR. LEWIS: So, I've kind of been teasing this question in my mind, and when I think about going down to a site doing one or two of these, that to me makes me nervous, I don't like that. It seems that emergencies come up, teams work well together when they've

worked on a project together, but what is the right number, is there a right number, and is a number important at all?

We certainly have numbers for credentialing in PCI. You can't do PCI in my hospital unless you do a certain volume.

DR. BACH: To remind everyone in the

room, as well as the panel all knows this, the discussion we are having is about volume essentially conceptually, it's obviously numerical, but not about a specific cutoff, like is it 25 or 50 or a hundred, but it's a direction.

So can I, do your answers seem to come from less of a statistical place than it came from clinical experience and expertise and observation, is that fair?

DR. LEWIS: That's fair.

DR. BACH: Okay. Please.

DR. TURI: And I'd add that when we look at the data, the outliers, the unfavorable outliers are clearly in the low volume patients with rare -- in low volume centers with rare

exceptions.

I think I would bring in something else on pilots, and there's probably no organization that's more wedded to outcomes than aviation, or very few, and they in fact look at, in partial answer to Mark's question, they look at time and the number of various maneuvers that are required to maintain currency, so every six months, at least the

rules used to be that you do six hours of instrument flying in actual conditions or simulator, and six landings, and these are just examples, but the idea is that you maintain competence as a factor of volume. And while I can't prove that that's what's led to a linear decline in flying accidents, it's certainly been a significant part of that.

DR. BACH: Dan, go ahead.

DR. OLLENDORF: So, I will take the statistical view because it's all I can do, and I guess I went into the day knowing as I do, having looked at evidence for a number of procedures in a number of disciplines, and I know Dr. Bavaria and Dr. Carroll in their

comments noted this, there's been a demonstrated volume-outcome relationship for a number of complex procedures across a number of disciplines, cardiology and non-cardiology alike, so I felt like I needed to be convinced that there was not a volume-outcome relationship, and so that -- and I don't feel convinced that there is not a volume-outcome relationship.

Now all that being said, this is not

what we're voting on today, but volume as the only surrogate for quality also makes no sense to me, there have to be other quality indicators that could be part of a true comprehensive program to understand what a qualified center and what a qualified practitioner looks like, but I'm -- there was nothing in what was discussed today to tell me that there is definitively no volume-outcome relationship.

DR. BACH: Please.

DR. FERNANDER: So, not only am I struggling with the volume index, but I'm also

struggling with this, we seem to be very focused on mortality as the primary outcome. It is important obviously, but I think that there are other variables that also need to be taken into account that have not been examined.

DR. BACH: I think, just to clarify, I think some of the outcomes that we saw on those slides included things like stroke rate and other sorts of complications, as well as mortality. I might be -- please correct me if I'm wrong.

DR. FERNANDER: Also as a behavioral

scientist, I'm also interested in social behaviors other than, you know, stroke or related illness.

DR. BACH: I wasn't disagreeing, I was just clarifying what we did look at.

DR. KORT: So, my disclosures are that I'm not an interventionalist, I'm an imager, I'm the director of the echocardiographic laboratory at Stony Brook, so I'm involved with our valve center and imaging. To maintain my Level III in echocardiography, I do need to perform a certain number of and read a certain

number of studies a year to keep my lab accredited as it is. Because I highly believe in laboratory reputation and high quality imaging, I do need to demonstrate that each one of the physicians working in my lab is actually reading and performing a certain number of studies.

I'm also part of the structural program at Stony Brook, I'm actually the only person that is involved with those procedures at Stony Brook, and I came here this morning thinking that this should really not be any different and there should be some volume, and

again, not saying what that volume should be, but there should be some volume requirement to start the program and to maintain the program.

Obviously, and listening to some of the things that were so elegantly said today, I also believe that there should be some provision for deviating from that requirement based on expertise in the place where the program is to be started, as well as geographic limitations. So I would have loved CMS to look

into those criteria as well, and add those in addition to a volume requirement.

DR. DESVIGNE-NICKENS: Patrice Nickens, also no conflicts. You know, I agree with all that has been said but I, it's really quite frustrating. It feels like somehow we're in this framework that doesn't seem to work well for the importance of, this is a game changer, such an important advance in this field. And you know, volume is, as we watch cardiovascular disease death rates decline and we continue to do well, you know, volume is not going to be a practical way of assessing much, we need to do better, because that's exactly what we're trying to decrease, our need to do

these procedures.

And I guess my fear is that we can answer these questions fairly well because there, you know, there's a certain threshold below which it wouldn't make sense, of course you have to have some experience with this procedure in order to have good outcomes. But it does seem that it is essentially driving the value of this procedure, and that's wrong.

And it also doesn't, it doesn't allow the fact that this kind of determination impairs access which, again, you know, not having volumes, not even having access, it doesn't allow, you know, never having a chance for this procedure, which also is another way of biasing outcomes if you're only doing the procedures on the patients, the persons that have access to it. So I hope that there's a way that in answering, in going forward with this, that we have an opportunity to point out just how thin, while perhaps a necessary condition, how insufficient volume is to assess this very important breakthrough technology, which we expect to continue to improve in the future.

DR. BACH: So Patrice, may I ask, so -- and I'm not trying to ask a leading question, so if you hear leadingness in it, please don't. You talked about other metrics. I guess the question it comes back to, we are supposed to be discussing volume itself. Are you saying that these other metrics are

superior but volume is still something that matters, or that these other dimensions are really where all the focus should be and that volume should be, you know, left to the wayside?

DR. DESVIGNE-NICKENS: So, I thought I understood the national coverage decision process, but -- and you know, we've talked about competencies and, you know, learning and then, you know, evaluating teams and their quality. And I'm trying to make sense of what we're trying to do by allowing a procedure in hospitals to be covered, if this decision will affect whether or not programs are able to continue or how they struggle to continue and again, you know, it seems that volume, it certainly as the only indicator may not be correct.

DR. BACH: Thank you. Dan.

DR. OLLENDORF: I just wanted to throw this into the discussion because it may represent a factual statement that somebody could correct if I'm getting it wrong. I think someone said that -- so, the access issues are

multifactorial and there may be, a volume requirement may be a contributor to access issues, we don't have a lot of empiric data on this, but there was a statement made that the rate of TAVR is higher in Wyoming which has no TAVR centers, than it is in Illinois which has 19. So residents of Wyoming are going out of state and having TAVR at a higher rate than residents of Illinois are having TAVR, whether that's in state or out of state. So access issues are critically important, but I don't know that we can explain everything relative only to the volume requirements.

DR. DESVIGNE-NICKENS: So, I don't know, but I would imagine that that difference that you're talking about in Wyoming has to do with income and ability, you know, the ability to go. So, these are actually elderly, for the most part elderly patients, but being able to

plane out over to where, a place to have a procedure like this, would not be an option for, you know, other disparate populations.

DR. OLLENDORF: Yeah, and I don't know

how the income disparities play out between the two states, but that was certainly a striking data point for me.

MS. PESCHIN: Have you ever been to Jackson Hole, Wyoming? It's incredibly wealthy.

DR. OLLENDORF: I haven't, but it's not the only city.

MS. PESCHIN: Yeah, so you have to look at what --

DR. BACH: I'm sorry.

MS. PESCHIN: Can I just say something about just --

DR. BACH: I'm sorry. We have to have a process. I made the statement that factual corrections were more than welcome, but the time --

MS. PESCHIN: I have a factual correction.

MS. ELLIS: Ma'am, you need to introduce yourself.

MS. PESCHIN: I'm Sue Peschin, and I'm with the Alliance for Aging Research. The data that's been presented at this meeting is sort

of, it's blinded, we don't know anything about the specific facilities. You know, they're being presented in sort of like a -- and I don't know if you all have seen behind the scenes, you know, that these are, this is the listing of the facilities that --

DR. BACH: But in fairness, this isn't a factual correction.

MS. PESCHIN: It is, because you guys are making assumptions based on not knowing the specific facilities that we're talking about, and the TVT registry doesn't reveal that information.

DR. BACH: That's a factual statement, but I'm going to cut you off. We have to -- I'm sorry, but this is the time, this is uncomfortable for me, but that's it.

MS. PESCHIN: Can I just make --

DR. BACH: No.

MS. PESCHIN: Dr. Bach, can I just make one more point about this whole thing?

DR. BACH: No.

MS. PESCHIN: Which is, the weird

thing, I think with volume that's going on, is they go through massive training and there are minimum requirements to start a program. They should have high quality from day one when they start a program. The very idea that you need a certain amount of volume is basically saying that it's a learn as you go process, and I really hope that's not the case.

DR. BACH: Thank you. Naftali.

MR. FRANKEL: I think that one of the challenges that was mentioned today, and I think that there's broad consensus across the board that if there were other quality metrics available, if we could actually state what the outcomes data, risk-adjusted data from each hospital is based on outcomes rather than volume, I think everyone agrees that that would be preferred. The problem is that first of all, that's not available, today at least, publicly for sure.

SPEAKER: (Inaudible.)

DR. BACH: Let him finish his sentence, please.

SPEAKER: (Inaudible.)

MR. FRANKEL: Per hospital throughout the country reported to the public.

SPEAKER: (Inaudible.)

MR. FRANKEL: The public, I mean, for patients. So until that information is available, patients are blinded in terms of determining where they should go for treatment. Volumes is one of the comforts that they can have, that they know that the hospital that they're going to has at least that measure in place. So while I think that the other measures would certainly be very valuable and perhaps better than what's available right now, until that happens, I don't see how we can cut that away from the patient in their decision-making process.

The other side of that coin is that, as was stated over and over again today, when you have lower volumes, then you can't provide those other, that other data, so I don't really understand how it's argued that we can move forward with these other metrics in lower volume centers if you're not able to actually quantify that data and risk adjust it in lower volume sites. You know, that's something that,

I'm not sure if it was addressed yet, but I haven't heard really an answer to that.

DR. BACH: Thank you. Aloysius.

DR. CUYJET: I think volume, if I'm getting a valve replacement, I'm going to ask the surgeon what their experience is, but I'm also going to ask -- I'm sorry. If I'm going to have an aortic valve replacement, not really, just for the sake of argument, I'm going to ask my own surgeon, or the interventionalist if I'm having TAVR, what your experience has been. I'm also going to ask him where the procedure is going to be done, because one of the things that hasn't been discussed much is the team involved in the patient care, the RNs, the NPs, PAs, physical therapists, and who is leading the team. All of those things are important to me as a patient if I have to decide where I was going to have things done.

So I think there needs to be -- we've focused narrowly on volume for the surgeons, interventionalists, structural heart person, but we haven't had much discussion about all the other components of the team, and I think

that's extremely important in terms of patient experiences and patient outcomes.

DR. BACH: It has to be facts.

SPEAKER: It will be fast.

DR. BACH: Facts.

SPEAKER: Facts?

DR. BACH: F-A-C-T, not F-A-S-T.

SPEAKER: I can do facts and fast.

DR. BACH: Okay.

SPEAKER: I'm from Alabama, I speak fast. With all due respect, Doctor, you said this was all a play act that you're a patient, you're not a patient. You have no idea what it's like to be told that you're going to have to have an aortic valve replacement. You have all sorts of questions. There are other things other than how many do you do and where did you get your training, that's not it. That is not the question that the patient is going to ask you. It's going to be other things, it's going to be will I have to travel far away, I'm too sick to travel. Can I get it done here just as good as I can get it done there, so that I will be here in my neighborhood where my family can

be close to me. It's important to be with your

family and have them with you when you're going through a procedure like this. I love my surgeons. I've been opened up three, actually five times, but I love my surgeons, in fact I have them up on a pedestal. I also love my cardiologist, he is my hero, and my relationship with my cardiologist and myself, between the patient and the cardiologist to me is, it's almost a holy relationship.

DR. BACH: Thank you very much.

SPEAKER: You're very welcome.

DR. CUYJET: What I said was you need to do your homework and where you have things done in addition to, I had my hip done, and I did my homework before I decided who and where it was going to be done.

The other piece of it is, travel's been mentioned frequently as a factor. We need to take a look at some of the children's hospitals. They make provisions for families to be with their kids, not always, but that doesn't mean we can't do it, or make a

recommendation that it be done.

We did a study in Nassau County, Long Island called Vital Signs, and travel was at

the top of the list. People who didn't have neighbors or family to drive them, took an hour by bus, a half-hour wait in the office to be seen for 15 minutes, and an hour to go back home. So it's not something that should be taken trivially, but it's something that we should think about, alternatives to compensate for folks who are reluctant to go to a better place, if you will, because of the travel issues.

DR. BACH: Can we talk more about this travel issue and this balance of access and qualification, and do either, you know, with regard to the disparities that have been described or without regard to them, where are people, how is this data that we looked at, the maps, et cetera, being interpreted, other questions. We're soon going to have to ask this question of ourselves and vote on it, whether or not we believe -- and we can look at the question precisely, but it relates to the

volume thresholds and the effect and the tradeoff, if there is one, between outcomes and access. So I thought it might help to talk about the data we've seen so far, if there are

any views. Please, Patrice?

DR. DESVIGNE-NICKENS: Yeah, just a comment. So I didn't, I don't think I reviewed specifically regarding TAVR, but there's a large body of information for minority patients that, you know, because of legacy of discrimination, that they feel a loyalty to, if you will, minority-serving institutions, often despite quite high rates of, you know, poor, you know, poor performance, poor quality. And so I think, and I just offer that as an example of a patient factor that if these, this kind of procedure which is lifesaving, is offered only at, you know, these quality, you know, high volume centers, there's a large -- well, part of it is the education among other things, but you know, it's what I -- the direct result of that is a large percentage of patients that would never consider moving outside the

hospitals that treated their families, you know, their relatives, you know, mothers and fathers and grandparents, because they couldn't go anyplace else in the past.

DR. CINQUEGRANI: Yeah. I don't recall that we specifically heard discussions

about limitations directly, or examples of access, or had much, if any, data presented on that today. We did have data presented on times of evaluation, and I know that in our program and I'm sure in all the other programs have the same issue, the number of visits patients have to make to go through an evaluation process to receive TAVR, and certainly that would have a negative impact on access. If you live a distance from a program, the closest one you have available to you, or perhaps in quotes, the best one that you have available to you, the times, the number of times you have to return to that program would have a major impact on your ability to access the program.

DR. BACH: Yeah, I actually think, did I hear the number 11 visits?

DR. CINQUEGRANI: Yeah.

DR. BACH: Is that right? You know, do you have a fact for us?

MR. WOOD: We have a fact. We did this analysis, and the average TAVR patient has 13 to 15 visits before they have their TAVR procedure, and this is why it's not just

traveling that one day of their procedure and their hospital stay, it's traveling for all the workups, and most hospitals do their own workups, they're not going to take other people's work. So this travel issue isn't a one-time thing, it's an ongoing issue.

DR. BACH: Thank you. Fact.

DR. TOMMASO: Tommaso, writing committee. I can tell you that maybe they're having 13 visits but in our institution they're doing six to eight of them a day, so it's not like they're going back and forth 13 times. We compress it and get everything done in the shortest period of time that we can. So yes, they may be having 13 visits, but it's not 13 days.

DR. BACH: Got it, thank you. It's got to be additive.

DR. BAVARIA: Yes. The slide says it's from the time of diagnosis of the aortic stenosis, not from the time of the decision-making process towards SAVR or TAVR.

DR. BACH: Got it, thank you. Mark.

DR. CARLSON: Are you interested in anecdotes in the absence of evidence?

DR. BACH: Just as long as you remember that the plural of anecdote is not data, yes.

DR. CARLSON: So, I'm a native of Kansas, and I have a friend with a 95-year-old farmer, active farmer still, father, in Garden City, Kansas. And he's a physician, the son is a physician in Kansas City. He called me up and told me that his father had critical aortic stenosis and they were talking to him about this new experimental procedure, which is the one we're discussing today. So Garden City, Kansas is about 400 to 450 miles from Kansas City, or it's some distance to Denver where John Carroll would be, and it might be a little

bit closer to Wichita, and you can get the procedure in all of those places. But they chose to go eight-and-a-half hours or whatever it was by car, with a 92-year-old man at that point, to the University of Kansas, and I think there were two or three visits before they made arrangements.

But what I can tell you, if it were not that his son was a physician, if it were not that his son knew me and I told him that

this wasn't as crazy as it might have sounded, he never would have gone and gotten the procedure, just never would have taken the next step. And there are -- there aren't many people in Garden City, Kansas who have those kinds of connections to be able to connect the dots, and eight-and-a-half hours is a long distance for a 92-year-old man who's having angina, lightheadedness and periodic bouts of hypotension. Thanks for enduring that.

DR. BACH: I'm sorry about that. Go ahead.

DR. TURI: But the question is, do you

recommend that there be a TAVR program in Garden City, Kansas?

DR. CARLSON: I'm not recommending that, nor am I dissenting against it, but I think it's key to understand, as many have alluded to, the complexity of the issues that exist geographically. And I've heard that the density, and John, you might be able to address this, the density of centers in the United States is greater than anywhere else in the world. It wasn't clear to me whether that's density by population or density by geographic

area.

DR. CARROLL: Population.

DR. CARLSON: Population. So it's a much more complex situation when you've got a country the size of ours, with populated areas and very rural areas.

DR. GOLDBERG: Steve Goldberg, from Monterey. I just want to say that your anecdote is my life experience in a larger area than Garden City, but that is a very very common type of a scenario and we, you know, one small anecdote was a patient we decided was too

high risk for us, we sent him up to a major academic medical center a couple hours away. They evaluated the patient and I called to find out what they thought, and they said oh, you didn't hear, he drove back home and died.

And so, I don't think that it's appropriate for an anecdote like that to drive things, but that is the real world.

DR. BACH: Thank you very much. Other comments on this access issue? Please, Naftali. I'm sorry, the time for public comment is over. I'm sorry.

MR. FRANKEL: What I was wondering is,

do we know that in areas, let's say a 50-mile radius, and you don't have a site available, and obviously for those that are elderly or there's other restrictions, it is a barrier for them to travel further. Do we know that right now, that if the criteria was changed, that those are the locations where we would have centers opening up, and not in the concentrated saturated areas that we're hearing about over and over? And I guess you can't say a blanket

yes, but in a marked way, is there going to be a dramatic improvement on that front in those areas?

DR. BACH: So that's a question of fact. We saw maps with changes in standards and cutoffs, changing centers that could be opened. So, is this an answer to that question?

DR. TOMMASO: I was just going to -- Tommaso, writing committee. I was going to refer you to the map I had with the red stars which were the new programs that had opened in the last two years. 50 percent of them were in relatively rural small urban areas which improved access to care. The other 50 percent

were on top of existing programs. If we had taken all of those programs and put them in the rural area, we wouldn't have had people having to drive eight hours. But conversely, in those rural areas, like Wyoming, those people are used to driving.

MR. FRANKEL: Okay, but obviously there are restrictions.

DR. TOMMASO: I was just in Wyoming.

In Gillette they go to Billings to do their grocery shopping.

MR. FRANKEL: Okay. Given that there can be, you know, elderly patients that are not able to do that.

DR. BACH: We'll do a fact check on whether people do drive more in Wyoming.

DR. PELIKAN: They do, that's a fact. But here is the fact. 50 miles is not the barrier, it's not the only barrier. So in an urban center where there's 20 million living, getting in and being seen and getting the procedure done is also a barrier. And if we have a small number of hospitals, I can tell you where I'm doing TAVR is backed up sometimes three to five weeks to even get a date to do a

TAVR because they're so busy. If we open up to low risk patients, patients are going to have to wait longer and longer if we do not allow more centers to open.

DR. CARLSON: Yeah, I just want to agree with Peter. I practiced in Cleveland for 20 years, and there were people who would not

cross the bridge over the Cuyahoga River, and there were people who would not go from one side of an interstate to the other, and there's nothing we're going to do to change that.

DR. BACH: Thank you. Let's just get back to the facts. Go ahead.

DR. DEHMER: Well, we can't really predict what would happen if one TAVR center is opened, but you can have lessons from the past, and this was a story that I know I was involved with, with the proliferation of PCI centers. And there's a collection of literature that showed that once there were expanded indications for PCI centers all driven by the need to have more STEMI centers, and then STEMI centers couldn't survive unless they did elective centers, they looked at what happened after that. And most of the new STEMI centers

didn't end up in rural areas where they needed to provide MI care, they all happened clustered around existing centers because it was kind of a me too philosophy that existed. So I think the caution is if you open this up, are the new TAVR centers really going to be produced or

open up where they're most needed, and we've heard over and over again that they're most needed in the Garden City, Kansas area, and in other more rural areas or other places where individuals have socioeconomic challenges.

DR. BACH: Thank you. Dan. Is your mic on?

DR. OLLENDORF: Thanks, Mark. So, we're not going to solve all because we could end up locating centers where it's perceived that communities are underserved, if it's too much of a geographic burden, but that's not going to get rid of all the disparities. We haven't even talked about the gender disparity which is plainly evident here, right, so women who need this procedure at higher rates are getting it at lower rates. So, I'm just not sure which direction we're headed in. We need to acknowledge that disparities exist and there

may be remedies on the payment side, and maybe the societies can do something about this, but I'm just not sure where to go with this.

DR. BACH: Great, thank you. Did you

have another comment?

DR. CUYJET: I had just a comment. You know, we can identify problems, whether it's travel, loyalty to a primary care provider or cardiologist, but we need to think about what are collectively referred to as the social determinants of health. There's different ways to solve problems, and one of them might be more TAVR centers, but that might not be the answer. We need to figure out what people are resisting, what's inhibiting them from accessing appropriate care and to see what the solutions are to the problem. That's not part of this discussion but it is something that we should begin to think about.

DR. BACH: Patrice, do you have another question or is your card, that's a legacy? Okay.

I'm not the only one who should be asking the questions. Do you have questions of one another? With an eye to the next phase,

I'm going to take you into a set of questions that are on the sheet next, so in this general discussion, do you have questions for one

another? Okay. So, all right.

So the next phase of this is -- all right. The next phase of this is the voting so let me just, two things. One is, I want, because I think this is a rich discussion, so I'm going to put things out of order a little bit, which is that on the back half of your voting question page you'll see what's called the additional discussion topics. We're going to actually start there and we're going to discuss these issues in whatever wholesome manner we feel we can. These do not require votes, but the Agency is listening to our conversation and trying to figure out a number of different things, including what is known or what our conclusions are about what is known, what the right next questions are, and to remind everyone, that we are here discussing a national coverage decision that was called coverage under evidence development. It is a mechanism that CMS can use to gather more information at some level through the course of

coverage, so we should keep in mind that we

should lay out what we think the Agency should go figure out, and they have some tools at their disposal to arrange for doing that.

So we're going to start there, and then I will return with more instructions about the voting questions when we get to them. So to that end, these are specific questions, I think we've sort of covered them, sort of haven't, but I do want to go through the question on the table which we've already started to ask, is do volume requirements create unintended barriers to TAVR based on any of the following, geographic location, gender, ethnicity, race, socioeconomic status, provider preference, which is explained in depth there but as was explained several times, I trust my doctor, I want to go to the doctor or hospital I feel comfortable with, and the hospital setting.

And so in no particular order, or collectively, I want to start a discussion around this, and I've already brought it up a couple of times in a couple of different ways.

The critical phrasing in that question

is the verb create, is it the volume requirements that create these problems? And I would say that the counterfactual is, absent the volume requirements, these problems would certainly not vanish, or maybe they would vanish, but that's not what we're asking ourselves, it's would they be diminished, given the assumption that all of the gaps are bad.

Let me ask, did anyone see any evidence that was overwhelming that they'd create any of these dimensions of problems? I could start with the other end too.

DR. CUYJET: I'll start. I don't think it's the fundamental issue. I'll go back to, I mentioned the CABG study, you can go to the 1995 New England Journal article where there was a conference, I think it was over 500 primary care providers. They had two sets of actors, one set is white, one is age 55, the other age 70. The other set was black, again 55 and 70 years of age, and the providers were given different scenarios describing anginal pain. The recommendations were less aggressive for the black patients and less aggressive for the female patients.

So I think this is a fundamental issue which, again, is beyond the scope of this conversation. So just having more centers, like the old build it and they will come, I don't think applies. I think if we really want to make meaningful change, there has to be a more profound analysis of what the issues are that inhibit patients from seeking care, whether they're legitimate, and if so, what alternatives can we offer to them, and if they're not legitimate, the reasons they're not seeking care.

DR. BACH: Thank you. There must be other views on this, or similar views. Go ahead, please.

DR. DEHMER: So, I have benefitted from a lot of education today from the various speakers plus the other panel members, and I would walk away from this saying there are unintended barriers to receiving TAVR care, and a lot of other care in all sorts of other areas. That said, however, I don't think it's volume alone, I think I've heard a lot about different feelings that different groups have about where they want to get the care, and

that's not solely a function of volume, I think that's a much bigger issue that's going to require really education for the whole community, or the whole body of patients that we've heard have severe symptomatic aortic stenosis, that many of them don't get the care because they probably don't realize how important it is, and that something can be done for them. So are there barriers, I would say yes. Are they totally related to volume, no.

DR. BACH: Thank you.

DR. KORT: I think that the word create is a very strong word. I think that volume can contribute to barriers for everything that is really listed there, A through G, but I would have used the word contribute as opposed to create, and again, keeping in mind that it's not the only factor.

DR. BACH: I'll take that edit even though I'm not allowed to edit the question. I think the question is, is there a causal effect, and I think it's completely fine to use a softer term for it.

MR. FRANKEL: I think that Dr. Horne's

presentation really highlighted the fact that

you have these other very significant variables, the under-referrals, with the actual preference of patients not to seek treatment, which I think just to echo, really highlights the need for better patient education regarding what's available and what the potential outcomes are if they make use of that. And the fact that there's such a severe problem of under-referrals, I think is another issue that's not patient education, that might be partially the referring physician's education, but these are obviously core components that are underlying those barriers to care.

Is it possible that volume takes a part of this, yes, but it seems to be, based at least on the data that was presented, that it's secondary to other problems that are really much more reflective in the disparities that exist.

DR. BACH: Thank you. Greg, are you waiting to say something? No? Okay, I'm sorry.

Can I ask about gender? Did we see any data that volume creates or contributes to the gender gap that we saw today? Can I ask a

factual question about gender, because I don't know the disease literature well enough? Is it the case that the at risk, the rate of women at risk or who are eligible for the condition would suggest a higher rate amongst women than we see? Yes? I'm seeing nods.

UNIDENTIFIED SPEAKER: (Unintelligible.) 50 percent of women.

DR. BACH: But is the prevalence of this particular valvular disease listed by age equivalent across gender?

SPEAKER: (Unintelligible.)

DR. BACH: Okay, great, thank you for that clarification. So back to my question. Did we see evidence that volume contributes or creates this gender gap?

DR. TURI: No, I think that was the weakest of the parameters that are up to there in terms of any potential correlation to volume. The question, the volume is almost certainly only one factor in whatever barriers

might be set up by that. The other end is with the patient that, I don't want to pick on Garden City, but will a patient that's in an area that's far from a TAVR center really

benefit from having a low volume center in terms of outcomes, and I think that's something that we may, that remains unanswered.

DR. BACH: Yeah. So one of the things I try to do is make sure we're on a level set, so just to clarify, I haven't heard from anyone that they think volume is the only factor, right, so I think we all collectively are telling the Agency what seems logical, which is that these are multifactorial things, but we are focusing this conversation, which everyone is doing a great job of doing, on this one particular operational question. I'm also not asking a question about magnitude because I don't think we can easily get to that. But you know, of course there are other factors.

Factual only, please?

DR. HORNE: So, Aaron Horne, Association of Black Cardiologists. I guess

specifically, he said that he thinks volume is a secondary issue in terms of the criteria that's set up, but everybody on the panel has acknowledged that there's an underdiagnosis and an undertreatment of aortic stenosis in the African-American population, and so by

continuing to do the same thing, I think that that demonstrates that the criteria in itself isn't about creating, as opposed to being a secondary causal relationship, right, because we've shown over five years that that number has not changed, the 3.8 percent, and we all agree that it's underdiagnosed, undertreatment, so therein, I would argue that it is directly affecting it.

DR. BACH: Thank you for that comment. Just to paraphrase, my characterizing them as independent factors I think is what's being objected to, they are interrelated factors over time, and I appreciate the comment.

Socioeconomic status, just to go through this list, I'm in no particular order, volume standards creating gaps related to socioeconomic status, and again, not a hundred

19 percent responsible, but directionally.
20 Please, Patrice.
21 DR. DESVIGNE-NICKENS: Just to
22 comment, as we go through these, you know, my
23 reaction is to become increasingly dissatisfied
24 with them, so I think create is not quite the
25 right way to put this, maybe contribute, but as

1 we go through these, each of these, the answer
2 is a little bit yes, you know, sort of. And
3 the more you go through these, you know, it's
4 just, it continues an unintended barrier. If
5 you need volume to have these quality
6 procedures available, all of these issues, you
7 know, sort of create a choke point for each of
8 these groups for different reasons. And if we
9 continue in this same pattern, we're, you know,
10 the geographic problems associated with volume
11 are not, we're not, I don't see how, you know,
12 how does it get solved by saying, well, volume
13 has problems, but it's okay.
14 And so, you know, I think it's clear
15 that, you know, that the threshold number may
16 be lower, and we've had a lot of discussion

about what's good, you know, what the training programs require, you know, and why the numbers are what they are, and you know, maybe that's something that we could try to minimize, but nevertheless, it is, you know, we're trying to define the people process, and that is probably not a good thing.

DR. BACH: The point is taken, and remember, the Agency is going to take into

account our discussion around these things, including important points like that one.

We're talking about SES, that's the topic, subtopic.

DR. OLLENDORF: Yes.

DR. BACH: Okay.

DR. OLLENDORF: Although I may throw in everything else too. The frustration for me is that, so, if we go back to the world before TAVR existed, all of these were barriers to good cardiology care, so there were disparities around all of these to good cardiology care, so I am still not even convinced that there's an interrelated association or contribution of volume requirements to either creating or

exacerbating these barriers, I'm unconvinced.

I think the way to try to deal with this is some sort of a demonstration project with some sort of volume requirement still in place around the other things that could be done to address improved referral rates, improved education to patients and families, locate centers in underserved areas, geographically or based on race and ethnicity, and see what happens with that demonstration

project, and then decide whether volume is a contributing factor or not. I can't think of it any other way.

DR. BACH: Okay, thank you. Some other ones, I'm going to push a couple together, not that we shouldn't talk about each of them, but things like the geographic location and the hospital setting or structured community versus academic, that those things, that they're creating unintended barriers along those dimensions? Not a lot of discussion. Go ahead.

DR. CUYJET: Well, I'll make two

comments. One, if you look at the healthcare systems, they're private systems, they're safety net systems, so you really need to map where patients are getting their care. And there's an economic underpinning with it. Before I shifted to administrative medicine I was at a safety net, the safety net for Nassau University, but they're able to negotiate for reimbursement rates that are much lower than what Northwell, which is the biggest healthcare system in New York State, can negotiate, because they have the power of size and volume.

So economics play a part in what procedures are done, the volume and the access, so that needs to be looked at. And so where patients, you know, when Northwell started open heart and transplant programs, it was in this paper for Long Island and every other media access they could get, so it was really well publicized. Nassau University Medical Center, if they have any marketing budget, it's nowhere in comparison to Northwell. So there are other factors that play into the dynamics.

The other thing that's of interest for

the folks from Harvard who developed the implicit association test, I don't know how many people are familiar with that, when I was chair of medicine at NUMC, I brought the attendees in, directed them to the website, because everybody swore they had no biases. Then they took the test and we came back and had a little discussion. There are other factors that people don't even consider that go into the decision-making process, both among patients and providers, so there's a whole universe of questions to ask and answers to determine. So this whole thing with volume as

a barrier, it may or may not be, because it really depends where patients are referring their primary and tertiary care.

DR. BACH: Thank you. In discussions we've talked about race, ethnicity came up at one point as well, happy to talk about that more, it's obviously come up as an issue. Generally the panel sense, individuals on the panel sense about to what extent volume requirements contribute to or create

disparities in TAVR access based on either, if I can lump them together, race or ethnicity, or both. I appreciate we've had a lot of discussion on this already, so I'm not trying to, this isn't causing a vacuum in CMS's records. Patrice, did you have something?

DR. DESVIGNE-NICKENS: I was just trying to think in some of the solutions that were suggested today about many of the things Ron said, the realm of what this process would do, but when we talk about volume, we're talking about patients. If we put in patient characteristics, they should be high risk patients, there should be gender equity, there should be race, you know, commensurate with the

population, you know. In other words, volume would be, are, you know, the centers doing this can not be able to hand-pick patients. I don't think that's ever intended but if you look at the population that, you know, if you look at the numbers, and particularly that rise in the use of TAVR over time, it looked like, you know, the early days of PCI, you know, a tenfold change in how many patients are being

reached appropriately for this procedure, and when you see the minority participation in that rise was negligent, it was absolutely flat over that period. So maybe, you know, again, we could at least ask the physicians, because disparity means that the, you know, it's the health outcomes from one group that was different from another group just on the basis of race, and so if you don't have access to these procedures, you are forcing the disparities so there is a causal, you know, there is that causal relationship, I think.

DR. BACH: Thank you very much. Sandy.

DR. LEWIS: The challenge as we move forward is that a lot of programs are nearly

maxed out on their ability to perform additional TAVR programs and TAVR procedures, so that as we look forward, there's got to be some consideration for where we're going to be, and it seems to me that volumes of AVR total is probably not something that's on our question list but maybe should be thought about if we're

talking about volumes, and ability to build new programs. If this procedure proceeds the way interventional cardiology has over the last 30 years, we are going to see huge demand that I'm not sure our current settings are going to be able to provide.

There's a need for a hybrid room, a team. I'm not sure why there are still two surgeons on a team, maybe there should be two structural cardiologists on a team. These are things we haven't talked about, but when we're talking about volume and the makeup of a TAVR program, I would think about these things.

DR. BACH: Thanks.

DR. FELDMAN: Just as a point of fact, there are no --

DR. BACH: Name and affiliation, please.

DR. FELDMAN: Oh, Ted Feldman, representing SCAI. There's no data to suggest the programs are maxed out on increasing volume.

DR. BACH: Thank you.

DR. TURI: Could I just add one

geography issue to the race issue, in which I have no specific expertise, but I built a TAVR program in Camden, New Jersey, which has a very large African-American population, and we noticed this disparity almost from the beginning. So I'm just saying it's not, it's clearly more than just geographic availability. i mean, I think Dr. Horne's slide showing the geography, geographic issues, was compelling, but it is just another sign of how there are many other factors.

DR. BACH: Thank you, Zoltan. Yes?

DR. DESVIGNE-NICKENS: So, something that Dr. Leon mentioned, that the penetration is very poor, and if we are, as we should need to be, more successful because of the improved outcomes from the procedure, it certainly suggests that we need to do something about education, et cetera, that this is, you know,

this is underdiagnosed, undertreated, and that the procedure is probably underutilized.

DR. BACH: Great, thank you.

Okay. I'm going to draw this section

to a close, I'm going to take an unscheduled five-minute break because everyone's been sitting here for two-plus hours having to put up with me. When we get back at three o'clock, we're going to go to the voting, and I'm going to begin with instructions on how to do it. That's in five minutes. Thank you.

(Recess from 2:57 to 3:03 p.m.)

DR. BACH: We're going to get started please. I know it's been a long day, but -- okay.

Maria, are there instructions for using the phone, does everyone know how to do that?

MS. ELLIS: Yes.

DR. BACH: All right. We're going to now do the voting and let me just, a couple of things. One is we are using a new system, I don't get to vote so I have no idea how to do it, but Maria is going to explain it, I hope, but let me say something about the voting.

The questions cannot be altered. We can discuss them for points of clarification, and the objective is to have us all voting on

the same question, all understanding it the same way, and having CMS understand our comprehension of it.

The other thing I want to say, and these things are difficult, I know in many cases, but our goal is to do our best to refine, be accurate, and then everyone will get an opportunity to vote, in fact it's a requirement to state your vote as well as the electronic thing, as well as the paper ballot, it's a fully redundant system, but also to explain your vote, which allows, if you will, to add a texture to it.

I want to say something about some of these questions, and I won't identify particular ones, but you may find along the way that some of the questions feel like questions where we didn't get much today that helps inform the answer. And so I want to point out that it is perfectly okay to vote, and I'm not telling you what your vote should be, but to express, to measure your confidence in this

statement both along the dimensions of how you

interpret what data you saw as well as the absence of data. So it's okay, for example, to have relatively no confidence if you got no information. You have a chance to then clarify the origin of your vote after you explain it, you can say I voted this way because of X or Y, or whatever X and Y is.

That said, Maria, can you, our newfound technology thing?

MS. ELLIS: Yes. So instead of using the clicker, we are basically, the panel members, the voting panel members, they will be using either their smart phones or laptops to cast their votes, and once they cast their votes and everyone casts their votes, it's going to show up on the screen, so that's the only difference. Instead of using the clickers that we normally used in the past, but sometimes they get stuck and a vote is not cast, we decided to try something different.

And again, the scores will be available after the meeting.

DR. BACH: Do they know how to do it?

MS. ELLIS: Yes, I'm sorry. Panel

members, there are instructions inside your folder. They're only for you, so you guys are the only ones with the instructions. The poll is closed. There you go, the poll should be open.

DR. BACH: Okay, I'm going to read the first question, you can enter it electronically, please record it on your sheet, and I will then poll you one by one to both ask your vote and if you want to add any context to it.

So the first question is -- but before you vote, if there are questions of clarification around the question as stated, please voice those.

The first question is, how confident are you that there is sufficient evidence that a certain threshold of SAVR procedural volumes must be required for hospitals without previous TAVR experience to begin a TAVR program?

DR. TURI: Just for clarification, that means you believe there should be a threshold, not the number, or you don't believe there's any fixed number, just that you believe there should be a number.

DR. BACH: Yes, you can believe there's a number, perhaps a fixed one or not. The question is, if you will, a directional one, do you believe that there should be, sufficient evidence that some threshold should be required?

(The panel voted and votes were recorded by staff.)

DR. BACH: Is that everybody?

MS. ELLIS: Waiting for one more person. There we go.

DR. BACH: Great, that's everyone, and I'll start at the end this time, and I'll just try and fluctuate. Patrice, would you state your vote, record it on a piece of paper, and if you want to add any explanation, you can, you're not required to.

DR. DESVIGNE-NICKENS: I voted three, I do think that some threshold is important. I don't think it should be, it remains to be qualified.

DR. BACH: Thank you. Mark, and just to clarify, Mark's vote does not count for the scoring, but his views are still recorded and his vote is still heard.

DR. CARLSON: On this one I voted --

DR. BACH: Oh, I'm sorry, and also Patrice's, I'm sorry. Go ahead.

DR. CARLSON: Okay. On this one I voted one. I did that because I didn't see evidence that there was a correlation for SAVR and TAVR, and I also heeded the warnings in two or three of the presentations about the perils of being a patient in need of aortic valve replacement who appears in December to a hospital that is seeking to make the threshold for SAVR and already made their threshold for TAVR.

DR. BACH: Okay, thank you. Zoltan.

DR. TURI: From my standpoint there wasn't a number, but just that, for the kinds of, for what you need a surgeon for to start a program, without hard evidence, I nevertheless felt that there was, there are plenty of data on surgical competence and volume, so I thought there was high level of evidence that to start a program, you need at least some reasonable volume of surgical experience.

DR. BACH: What was your vote?

DR. TURI: It was a five.

DR. BACH: Great, thanks. Dan, and please keep your answers concise.

DR. OLLENDORF: So, I voted four, because I do agree that there is evidence that a threshold of procedural volume has to be required, and within a hospital without a previous TAVR program, I felt that SAVR was the closest proxy, but because it was a proxy, I didn't go for a five.

DR. BACH: Sandy?

DR. LEWIS: I voted three. I didn't see a lot of evidence today about SAVR volumes and starting programs, but I have this sense that somebody should know their way around the aorta to be involved in a TAVR startup, so answering the question of sufficient evidence, I wasn't convinced that we saw a lot of evidence about this.

DR. BACH: Thank you. Smadar?

DR. KORT: I voted five. I still feel that to start, and I think that there is enough data to show that to start a TAVR program, you

need to be in a place that knows how to take care of sick patients with severe aortic stenosis and take care of them in the cath lab

or in the hybrid room or something, that's something that needs to take place, and that includes also the nurses and the technicians and everyone around who takes care of these patients.

DR. BACH: Naftali?

MR. FRANKEL: I also voted five for similar reasons. First of all, that with a new TAVR program, the background and experience of the surgeons certainly could be useful in situations where things do go wrong, obviously that happens less and less now, but I would want the patients to have the confidence that that's in place as a safety net in case that occurs. And also from the team approach, that one of the things that we saw with volumes is it's not always the volume of the individual physician but the hospital as a whole because of their experience when they have more volumes, so I think that would be a practical, practically helpful as well, to have that

construct in place when the TAVR program began.

DR. BACH: Thank you. Anita?

DR. FERNANDER: Based on the evidence presented today, I voted a one.

DR. BACH: Greg?

DR. DEHMER: My vote was four. I think the key phrase is sufficient evidence. I think we'd all be very comfortable voting if there were multiple randomized trials that told us what exactly number we should use, if it's 50, 30, or a hundred, but we don't have that. Failing that kind of evidence, I think it's important to fall back on the opinion of experts, and fortunately we do have such a document that has been crafted, and I put a lot of weight on that. I know if I had some dreadful disease and there was no randomized trial that really defined my therapy, I would be grateful for what, the advice of a panel of experts, and we have that, and I think there is, using that as a standard, there is sufficient evidence.

DR. BACH: Thanks. Michael.

DR. CINQUEGRANI: Five. SAVR is an important component of any aortic valve treatment program, and a certain volume threshold should exist.

DR. BACH: Aloysius?

DR. CUYJET: I voted two. I haven't

seen any evidence that surgical replacement of aortic valve correlates without competency in TAVR, so that's my vote.

DR. BACH: Question number two, how confident are you that there is sufficient evidence that a certain threshold of PCI procedural volumes must be required for hospitals without previous TAVR experience to begin TAVR programs?

Any questions of clarification? I'm going to guess there aren't, but if there are? No. Please go ahead and vote.

(The panel voted and votes were recorded by staff.)

DR. BACH: Do we have everyone?

MS. ELLIS: Yes, everyone has voted.

DR. BACH: Aloysius?

DR. CUYJET: Again, low confidence

again, because I haven't seen any evidence that the volume and experience with PCI procedures correlates with TAVR outcomes.

DR. BACH: You said low confidence, that's a one, right?

DR. CUYJET: I voted two.

DR. BACH: A two, all right, thank

you. Please make sure you also document your votes on the yellow sheets, you might as well do that right now so no one otherwise loses track. Michael?

DR. CINQUEGRANI: Four.

DR. BACH: Greg?

DR. DEHMER: Almost the same rationale as my previous answer, I voted a four.

DR. BACH: Anita?

DR. FERNANDER: Again, based on today's evidence, one.

DR. BACH: Naftali?

MR. FRANKEL: I voted three, only because specific to PCI, you know, there's another option of other proficiencies for procedures other than PCI that were discussed

today, so if PCI was the only criteria then I would lean more on the side of a five, but I took a more moderate approach because I'm assuming that that's not the only metric that we would be looking at.

DR. BACH: Thanks. Smadar?

DR. KORT: I voted five for the same reasons that I mentioned before.

DR. BACH: Thank you. Sandra?

DR. LEWIS: I voted four. The reason I didn't go to five was that I didn't think that we heard a lot of evidence today, but on the other hand, I have had a patient who broke a piece of calcium off left main during a procedure, I've had several patients who've needed both PCI and valve implantation, so the skills are in the background material.

DR. BACH: Thank you. Dan?

DR. OLLENDORF: I voted four, very similar rationale to last time, not a perfect proxy but a proxy nonetheless.

DR. BACH: Zoltan?

DR. TURI: Four, same rationale as Naftali.

DR. BACH: Mark?

DR. CARLSON: One, similar rationale. I didn't see data that established a clear correlation.

DR. BACH: Thank you. Patrice?

DR. DESVIGNE-NICKENS: Yeah, I voted two. I moved more away from feeling that there was good evidence for this.

DR. BACH: All right, thank you, and I'll remind everyone, please record your votes

on your yellow sheets.

Question number three, how confident are you that the benefits of meeting procedural, that is SAVR or PCI, volume requirements to begin a TAVR program outweigh the harms of limiting access to TAVR to only hospitals that meet volume requirements?

(The panel voted and votes were recorded by staff.)

DR. BACH: Okay, the mean is 3.11, I'll start at the end. Patrice?

DR. DESVIGNE-NICKENS: I voted a two for this. I do think that the risk-benefit is

really questionable.

DR. CARLSON: One. I didn't see any data that really compared this and looked at an association.

DR. TURI: Five. This didn't ask about evidence, this asked about how confident we were, so I thought it was a little easier to answer.

DR. BACH: Dan?

DR. OLLENDORF: I voted five.

DR. BACH: Sandra?

DR. LEWIS: I voted one. Certainly

the experience at Cleveland Clinic Florida stood out in my mind for what we heard today.

DR. BACH: Smadar?

DR. KORT: I voted three for this one. I was torn right in the middle.

DR. BACH: Naftali?

MR. FRANKEL: I voted two.

DR. BACH: Anita?

DR. FERNANDER: I voted three, because the question did not ask about evidence received today.

DR. DEHMER: I voted three.

DR. BACH: Michael?

DR. CINQUEGRANI: Four.

DR. BACH: Aloysius?

DR. CUYJET: I voted two again, for the same reasons for questions one and two, and the technology's advancing and if the system worked as well as it's supposed to, we wouldn't have disparities in gender and ethnicity.

DR. BACH: Great, thank you. We're going to move on to hospital -- are there any questions from the panel about any of this process? Okay.

We're going to move on to hospital

requirements to maintain a TAVR program, a different domain of questions. Number four, how confident are you that there is sufficient evidence that a certain threshold of SAVR procedural volumes must be required for hospitals with TAVR experience to maintain their TAVR programs?

(The panel voted and votes were recorded by staff.)

DR. BACH: Aloysius?

DR. CUYJET: It's getting boring, but two again, same reason, I haven't seen any evidence to support the question.

DR. CINQUEGRANI: Five.

DR. BACH: You need to speak into the microphone.

DR. CINQUEGRANI: I'm sorry. Five.

DR. DEHMER: Four.

MR. FRANKEL: Five, with the same rationale.

DR. BACH: Anita?

DR. FERNANDER: Two.

DR. KORT: I voted three. I think that as the TAVR program grows, the SAVR volume is expected to go down, and that should not be

a reason to close programs or not to meet requirements.

DR. LEWIS: I voted two for the same reason.

DR. BACH: Dan?

DR. OLLENDORF: I voted four using logic basically symmetrical to starting a program.

DR. TURI: I voted five based on the

surgical data, and also with the understanding that the actual number divined may decrease, but there should be some threshold.

DR. CARLSON: I voted one because if quality cannot be accurately measured in lower annual volume centers, then it follows that we do not have sufficient evidence to determine whether or not those centers are high or low quality, and thus, whether they should be allowed to continue a program.

DR. BACH: Patrice?

DR. DESVIGNE-NICKENS: So I actually, I hit two, I meant to hit three, there's nothing I can do to change that? I have it correctly on my voting sheet. I had a similar rationale to number one, that I don't think

there's a sufficient amount of information.

DR. BACH: Okay, got it, thank you.

DR. DESVIGNE-NICKENS: I have what I wanted on the yellow sheet, if that matters.

DR. BACH: I have good news and bad news. The good news is it doesn't matter, the bad news is your vote doesn't count.

MS. ELLIS: But you do still say your vote.

DR. BACH: Question five, how confident are you that there is sufficient evidence that a certain threshold of PCI procedural volumes must be required for hospitals with TAVR experience to maintain their TAVR programs?

(The panel voted and votes were recorded by staff.)

DR. BACH: Has everyone voted? Is there anyone who hasn't voted? There we go, thank you.

MS. ELLIS: One second.

DR. BACH: So the mean is there, everyone's voted. Patrice, go ahead, please.

DR. DESVIGNE-NICKENS: Yes, again I voted two. I don't think there's sufficient

evidence to maintain the requirements for volume.

DR. BACH: Thanks. Mark?

DR. CARLSON: One, for the same reasons.

DR. BACH: Zoltan?

DR. TURI: Four, same rationale as question two.

DR. BACH: Dan?

DR. OLLENDORF: Four, same reasons as before.

DR. BACH: Sandy? Yes.

The first two votes don't count on the tabulation, and I tried to explain that at the beginning. So they're not included in the averages, but people still get to vote and the votes are still recorded, and then CMS processes them, deals with them. Thank you.

DR. LEWIS: Three, based on there's not a lot of data, but then expert opinion.

DR. KORT: Three, because again, I want to make sure that programs that started have the ability to maintain the program.

MR. FRANKEL: Three, reflective of the last question, and also a little bit somewhat

more confidence that the TAVR program already in place, that those that are actually the TAVR operators would have the proficiency to perform PCIs supposedly.

DR. BACH: Great. Anita?

DR. FERNANDER: Two.

DR. BACH: Greg?

DR. DEHMER: Four.

DR. BACH: Mike?

DR. CINQUEGRANI: Five.

DR. CUYJET: This verse is the same as the first, two.

DR. BACH: Question number six, how confident are you that the benefits of meeting procedural, that is a SAVR, TAVR, PCI, volume requirements to maintain a TAVR program outweigh the harms of limiting access to TAVR to only hospitals that meet volume requirements?

(The panel voted and votes were recorded by staff.)

DR. BACH: Great, 3.44. Aloysius?

DR. CUYJET: I voted three on this one. It's changing the landscape to technology, and skill sets for TAVR are going

to continue to improve, so I think about limited access by appropriate volume requirements for the other procedures.

DR. BACH: Michael?

DR. CINQUEGRANI: Four.

DR. BACH: Greg?

DR. DEHMER: Four.

DR. BACH: Anita?

DR. FERNANDER: Two.

DR. BACH: Naftali?

MR. FRANKEL: Mine says your answer, no response received, although I voted, so was it calculated?

MS. ELLIS: Yes.

MR. FRANKEL: So four, and I would hope that there would be public reporting attached to any consideration of liberalization, I just wanted to throw that out there if that's under consideration, just to publicly report the actual volume study.

DR. BACH: Smadar?

DR. KORT: I voted five again, knowing that there are other metrics that we should look into, but without talking about the specific volumes, there should be some volume

requirements.

DR. LEWIS: I voted one because I just don't like putting them all together like this.

DR. BACH: Dan?

DR. OLLENDORF: Five, same rationale as with the programs starting up.

DR. BACH: Zoltan?

DR. TURI: Same thing, five, same rationale.

DR. CARLSON: One, same rationale.

DR. DESVIGNE-NICKENS: Two, similar rationale.

DR. BACH: Question number seven, to begin performing TAVR -- now we're talking about operator requirements. To begin performing TAVR, how confident are you that there is sufficient evidence that a certain threshold of SAVR and TAVR procedural volumes must be required for the principal cardiovascular surgeon on a TAVR heart team?

DR. TURI: Can I ask a point of information?

DR. CANOS: Yes.

DR. BACH: Yes.

DR. TURI: So, this suggests that the

surgeon to start the program will have to have done both SAVRs and TAVRs, right? In other words, if we felt that it was just SAVRs -- I mean, I know the question can't be changed, but how would you address that if that was the opinion?

DR. BACH: That's how I would interpret the question as well.

DR. TURI: So it has to be both SAVR and TAVR, or if you feel that it should be SAVR volumes but not necessarily TAVR volumes --

DR. BACH: All right. So this gets into when I said we can't change a question but we should all vote on the same question, and we can ask for CMS guidance on this, but we may not get it. I think we can decide whether or not we are voting for the sum of SAVR and TAVR, but maybe not necessarily both for any particular surgeon, or alternatively, both SAVR and TAVR within surgeons.

I guess the question to the panel is, which one is more helpful to the Agency to answer? Because I agree it's ambiguous.

PANELIST: Will you state the first option again?

DR. BACH: Sorry. So, the question could be interpreted as having a threshold of both SAVR and TAVR within a particular surgeon to qualify, or it could be interpreted as the sum of their SAVR and TAVR experience, even if they have zero of one of them. Those are different questions. I would prefer we choose which one we answer, I don't feel like I have the clinical expertise to make that choice, but is it -- Greg, go ahead.

DR. DEHMER: Yeah, it says the principal cardiovascular surgeon, so I assume that to mean the surgeon who will be involved in the TAVR procedure.

DR. BACH: Right, so is there a question, is there sufficient evidence that a certain threshold of SAVR and TAVR procedural volumes, meaning -- so you would say that that would, we should interpret that as both the SAVR and TAVR experience within that surgeon, right?

DR. DEHMER: Yes.

DR. BACH: Okay, I'm fine with that. Is there any disagreement?

DR. TURI: Yeah. I mean, I think if

the surgeon has done 300 SAVRs and no TAVRs, that that should not preclude it, as long as there's experience.

DR. BACH: That's an interpretation, but are you comfortable voting on the question of whether or not CMS should be requiring both within the surgeon?

DR. TURI: Well, again, I don't know if requiring both means that they will have to have a threshold of TAVR experience.

DR. BACH: Hold on. All right, clarification. The intent is, as Zoltan's question suggested, it's either/or, so I guess experience around the aortic valve. All right. Given that clarification, do people feel like they can answer question seven. Okay, go ahead.

(The panel voted and votes were recorded by staff.)

(Inaudible discussion off the record.)

DR. BACH: Okay. While we figure this out, please record your vote on paper for question seven and I'm going to poll everyone, and maybe in the middle of this we will figure

25 this out, otherwise we can do it the old

1 fashioned way. Has anyone not yet voted on
2 number seven?
3 DR. KORT: I haven't.
4 DR. BACH: No, not on your phone, on
5 the sheet. Can you just record your vote,
6 please, I will poll you based on the sheet, and
7 then we'll figure out what happens here.
8 Patrice.
9 DR. DESVIGNE-NICKENS: I voted four.
10 DR. CARLSON: Two.
11 DR. TURI: I voted five based on the
12 evidence of the surgical procedures.
13 DR. BACH: Dan?
14 DR. OLLENDORF: Five.
15 DR. BACH: Sandra?
16 DR. LEWIS: Four.
17 DR. BACH: Smadar?
18 DR. KORT: Five.
19 MR. FRANKEL: Five.
20 DR. BACH: Anita?
21 DR. FERNANDER: Three.
22 DR. BACH: Tamara?

MS. JENSEN: Well, not Tamara, but Dr. Dehmer voted four.

DR. CINQUEGRANI: Five.

DR. CUYJET: Three.

DR. TURI: So, the question came up on our computers, so --

MS. JENSEN: Why don't we try to revote on that one, just try to vote on what you just said, please revote.

DR. BACH: And to clarify, Tamara is reading Greg Dehmer's votes, she's not voting. Okay we're good.

Question eight, to begin performing TAVR, how confident are you that there is sufficient evidence that a certain threshold of structural heart disease procedural volumes must be required for the principal interventional cardiologist on a TAVR heart team?

(The panel voted and votes were recorded by staff.)

DR. BACH: You still have polling closed?

MS. JENSEN: Yeah, we're still working

on it.

DR. BACH: Okay. Could you please record your votes on the paper?

DR. LEWIS: Could I ask a clarifying

question?

DR. BACH: Absolutely.

DR. LEWIS: So it's just procedural, structural heart disease procedural volumes, no specific procedures?

DR. BACH: That's correct, that's how I read it as well.

DR. LEWIS: Okay.

(The remainder of the hearing, from 3:38 to 3:48 p.m., was not transcribed due to a loss of audio recording.)

(From the video recording, it appeared that the panel announced their votes on question eight, voted and announced their votes on question nine, and then there were closing remarks from Dr. Bach.)

(The meeting adjourned at 3:48 p.m.)

STATE OF MARYLAND SS:

I, Paul A. Gasparotti II, a Notary Public of the State of Maryland, do hereby certify that I transcribed from audio file the proceedings to the best of my ability in the foregoing-entitled matter; and I further certify that the foregoing is a full, true and correct statement of such proceedings and a full, true and correct transcript of the audio files produced.

IN WITNESS WHEREOF, I have subscribed my name on this 10th day of August, 2018.

My commission expires: September 3, 2019