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7 CENTERS FOR MEDICARE AND MEDICAID SERVICES

8 Medicare Evidence Development & Coverage

9 Advisory Committee

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16 July 25, 2018

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18 Centers for Medicare and Medicaid Services

19 7500 Security Boulevard

20 Baltimore, Maryland

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16 Carl L. Tommaso, MD

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23

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1 PANEL PROCEEDINGS

2 (The meeting was called to order at
3 8:10 a.m., Wednesday, July 25, 2018.)
4 MS. ELLIS: Good morning and welcome,
5 committee chairperson, vice chairperson,
6 members and guests. I am Maria Ellis, the
7 executive secretary for the Medicare Evidence
8 Development and Coverage Advisory Committee,
9 MedCAC. The committee is here today to discuss
10 their appraisal and recommendations regarding
11 the state of evidence for procedural volume
12 requirements, especially pertaining to surgical
13 aortic valve replacement (SAVR), transcatheter
14 aortic valve replacement (TAVR), and
15 percutaneous coronary interventions (PCIs) for
16 hospitals to begin and maintain TAVR programs.

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

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

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

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

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

6

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

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

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

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

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

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

16 Also, the committee is reminded to
17 please refrain from discussing the meeting
18 topics during breaks or lunch.
19 If you require a taxicab, there are
20 telephone numbers to local cab companies at the
21 desk outside of the auditorium.
22 Please remember to discard your trash
23 in the trash cans located outside of the room.
24 And lastly, all CMS guests attending
25 today's MedCAC meeting are only permitted in

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

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

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

14 Group.

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

9

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

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

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

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

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

10

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

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

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

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

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

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

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

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

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

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

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

11

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

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

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

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

12

1 volume requirements should be.

2 TAVR procedures are used for the
3 treatment of aortic stenosis. The procedure
4 involves a bioprosthesis, inserting a
5 bioprosthesis valve using a catheter via
6 transfemoral, transapical and transaortic
7 approaches. The valve is implanted in the

8 orifice of the native aortic valve or a failed
9 surgical bioprosthetic valve.
10 The FDA first approved TAVR in
11 November of 2011 and within six months CMS
12 established the current national coverage
13 determination. To date CMS has approved 24
14 clinical trials under the NCD to cover TAVR in
15 investigational studies that have led to FDA
16 approval of expanded indications. As expanded
17 indications are approved by the FDA, the NCD
18 provides for concurrent Medicare coverage
19 without the need to reopen the policy or adjust
20 claims processing instructions.

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

13

1 sorry, regurgitation.

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

7 indication.

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

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

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

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

5 On June 27th we opened a
6 reconsideration of the current TAVR NCD, which
7 resulted from a complete formal request. The
8 request challenges the inclusion of procedural
9 volume requirement, recommends coverage be
10 based on quality outcomes instead of non-TAVR
11 procedure volumes, and program qualifications
12 be based on physician operator education,
13 training and skill. The analysis process for
14 the reconsideration began with a 30-day comment
15 period which closes this Friday, July 27th.
16 The proposed decision is due on March 27th,
17 2019, and posting the proposed decision
18 initiates the second 30-day public comment
19 period. The final decision is due 90 days
20 after the proposed decision is posted. To
21 follow the analysis, please periodically check
22 the tracking link listed on the website, or the
23 website as listed up here. You can access
24 public comments here, and both the decisions,
25 proposed and final, will be available as well.

15

1 Thank you.

2 DR. BACH: Thank you very much, Sarah.

3 We'll have our first speaker, who's Peter

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

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

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

1 During that period of time, I drive an

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

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

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

1 catheterizations including 400 or more
2 percutaneous coronary interventions, I'll refer
3 to those as PCIs, during the prior year. Two
4 cardiac surgeons with a hundred career surgical
5 aortic valve replacements, ten of them at high
6 risk, and 25 aortic valves in the prior year or
7 50 in the past two years were required.

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

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

1 active staff, maintain a surgical volume of 20
2 surgical aortic valves per year or 40 in the
3 last two years, and continued for the hospital
4 to perform a thousand cath's and a minimum of
5 400 percutaneous coronary interventions to
6 remain a TAVR center.

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

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

1 completed.

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

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

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

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

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.

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

21

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

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

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

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

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

22

1 have made the coronary intervention procedures
2 safer.

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

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

19 This paper was from data from 1998 and

20 1999, only really five years into the stent
21 era. Even then the authors commented that
22 procedural volume was only one factor
23 contributing to outcome and that technological
24 advancements might level the field.
25 Six years later the update from these

23

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

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

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

24

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

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

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

17 and hospitals doing ten or less LVAD, left
18 ventricular assist device implants, 11 to 30,
19 31 to 50, and greater than 50 implants per year
20 were studied. If you look at the curves, the
21 blue line, which is one to ten implants per
22 year, and the green line, which is greater than
23 50 implants per year, are almost
24 superimposable. If there was truly a
25 volume-quality relationship, the greater than

25

1 50 curve should be the highest curve there, not
2 almost identical with the lowest volume center.
3 I had one of the statisticians from
4 Providence at their medical data center review
5 the data available from this article, and
6 Dr. Chiu's conclusion to me was that there
7 really is no statistical difference between the
8 highest volume and lowest volume center. Yet,
9 the conclusion of the paper was volume implies
10 quality. So again, I ask everybody to keep in
11 mind that these statements are made but they're
12 not necessarily supported by the data.

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

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

26

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

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

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

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

27

1 Now, since I've shown here that volume
2 of procedure is not predictive of quality --
3 I'm sorry, I lost my slides here.
4 As we saw with PCI becoming safer over
5 the years, we see the same sort of thing with
6 TAVR, and I initially said TAVR has become
7 safer. I just show you this graph from one
8 paper showing that the process matures. This
9 is a paper from Israel on 1,285 patients at
10 three TAVR centers in Israel between 2008 and
11 2014, showing that as the years have gone by,
12 the procedure has become safer, the need for

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

17 To get an idea about TAVR safety now,
18 we queried the ACC TAVR history for the four
19 quarters ending in quarter three 2017. Of
20 45,395 cases, only 220, which is 0.5 percent,
21 required emergency conversion to open heart
22 surgery. Annulus rupture, only 39 cases, which
23 is usually a fatal complication, but has become
24 rare due to improved understanding of valve
25 sizing, improved CT imaging and better planning

28

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

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

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

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

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

29

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

10 As TAVR has shown excellent results
11 and now has been approved not only for high
12 risk but also for intermediate risk patients,
13 surgical aortic valve volume is dropping. TAVR
14 is, as I said, a cath lab procedure, not a
15 minor modification of surgical aortic valve
16 replacement, so surgical volume should not be a
17 factor in qualification of a TAVR program.
18 Should a program performing quality TAVR stop
19 doing TAVR if their surgical volume
20 appropriately drops? Again, I would say no.
21 Again, consider the potential motivation for a
22 program to unnecessarily perform surgical
23 aortic valve replacement in order to maintain
24 their TAVR program.
25 TAVR revision with removal of the

30

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

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

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

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

31

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

7 provide.

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

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

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

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

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

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

33

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

3 Volume criteria do create barriers for

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

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

1 discuss how important quality is, which I'm

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

19 (Applause.)

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

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

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

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

1 this document in the subsequent presentations
2 today.

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

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

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

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

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

25 outcomes have been improving yearly. This is a

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1 very important concept.

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

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

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

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

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

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

21 The circles represent TAVR programs in

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

40

1 of the things you should know about this slide
2 is the average O to E (O:E) ratio was .72, not 1.0.
3 DR. BACH: I'm going to interrupt for
4 just one second, not to get you off your topic.
5 Just so everyone realizes I'm not
6 editorializing, this graph has the axes flipped
7 relative to the prior speaker. It has no
8 effect on the interpretation, but just so
9 everyone knows, volume was counted along the
10 horizontal or X axis by the prior speaker and
11 mortality was shown on the Y axis, this is the
12 other way around. That's all. Sorry for
13 interrupting, and you'll get those 15 seconds
14 back.

15 DR. BAVARIA: That's a good point,
16 thank you. Okay, where was I? On the Y axis
17 is site annual volume, as you just heard.
18 There are a few takeaway points.
19 There is undoubtedly a volume-outcome

20 relationship, it is dramatic. This initial,
21 initial 2016 analysis of the volume-outcome
22 relationship was the canary in the coal mine
23 that informed the writing committee to examine
24 quality of TAVR in the United States further.
25 96 percent, another point, 96 percent

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

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

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

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

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

5 These are a series of important
6 slides. This is the most recent data not from
7 a while back, this is hot off the press from
8 the TVT registry, it includes patients treated
9 over a one-year period ending in 2017. The
10 data was analyzed by the DCRI, an independent
11 analytic center. The outcome shown here is
12 30-day mortality, there are three plots. The
13 left is raw mortality frequency and the next
14 two on the right are mortality expressed as an
15 observed to expected ratio, the O to E (O:E) ratios. On
16 the horizontal axis is site annual volume

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

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

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

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

16 The overall trend in the last five
17 years of commercial TAVR in the United States
18 has shown a steady and meaningful improvement
19 in outcomes. These concerning signals for
20 worse low volume outcomes are buried in the
21 overall improving results because the sites
22 doing over 50 cases a year account for 84
23 percent of all cases performed in the United
24 States.
25 Finally, these results represent sites

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1 that have opened under the requirements of the
2 original NCD, including the volume thresholds
3 we currently now have in place. Reducing these
4 thresholds would be expected to create a large
5 increase in number of low volume sites,
6 potentially decreasing volumes at existing
7 sites and potentially shifting the overall
8 outcomes in the United States towards low
9 volume sites and away from much better results
10 of the higher volume programs. Reducing volume
11 standards would sacrifice quality for expansion
12 of access, without any scientific evidence that
13 584, as we speak today, centers is inadequate.

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

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

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

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

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

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1 the yellow-orange rectangles.
2 This slide is basically the same
3 concept, so I'll skip over it for time
4 purposes.
5 This slide outlines, documents quality
6 control recommendations for low volume centers
7 in the sense that we want to not close anything
8 but keep them under good quality.
9 The past few slides demonstrate that a
10 volume-outcome relationship is real,

11 programmatic TAVR volume requirements are
12 essential, quality cannot be measured at very
13 low programs, that have very low volume.
14 TAVR is a complex procedure. There is
15 a 6.5 percent need for alternate non-femoral
16 access. This is the most recent data from the
17 TVT registry. TAVR still has major morbidity
18 and mortality. There is a high risk of
19 pacemaker necessity, and there is a combined
20 intraprocedural catastrophic risk for cardiac
21 arrest, conversion to open surgery, need for
22 emergent cardiac bypass, left main coronary
23 occlusion, or aborted TAVR procedures. When
24 you add them all up, any one of the
25 catastrophic events occur in approximately two

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

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

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

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

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

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1 developing a risk-adjusted composite measure
2 which will be the basis for national public
3 reporting of TAVR outcomes in the United
4 States. This slide represents three examples
5 of the methods the TVT registry will use for
6 site and public reporting of quality metrics.
7 One of the most important goals for

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

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

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

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

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

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

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

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

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

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

5 program.

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

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

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

4 should be board eligible and certified.

5 As mentioned earlier, these
6 requirements have been liberalized. In the
7 2012 document it was actually aortic valve
8 implantation. We have liberalized those in
9 this document to include any aortic procedure
10 involving the aortic valve.

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

18 To address Dr. Pelikan's concerns, the
19 inclusion of PCI as a requirement has been
20 controversial, since PCI and TAVR are different
21 procedures for different indications. In the
22 2012 document, the inclusion of PCI was used as
23 a surrogate for an adequately sized
24 cardiovascular program including all the
25 necessary adjunctive programs. PCI is

1 important as we have found, because up to 40

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 More than half of patients undergoing

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

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1 patterns of care rather than barriers created
2 by inadequate number of U.S. centers. Further
3 study of understanding gender disparities is
4 ongoing in the TVT registry.
5 15 percent of Americans are African-
6 Americans and 17 percent are Hispanic. The
7 numbers of TAVRs from the TVT database suggest
8 that only four percent of TAVRs are performed
9 in African-Americans and 4.3 percent in
10 Hispanics.

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

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

19 that in the STS database, only 5.7 percent of

20 SAVR were African-Americans.

21 The other issue I want to discuss in

22 terms of hindrance to Americans of TAVR is a

23 lack of education of primary care in

24 understanding the pathophysiology, prognosis

25 and treatment options in patients with aortic

60

1 valve disease. This has been anecdotal and

2 there's no data available, but all clinical

3 cardiologists have patients who present with

4 end-stage hearts as a result of aortic

5 stenosis, and those patients have been followed

6 by a primary care and never been referred for

7 care. It has been said too many Americans are

8 dying from aortic stenosis. I think it better

9 that Americans who die from aortic stenosis

10 have not gotten appropriate care. Education

11 would go a long way in minimizing this problem.

12 So in conclusion, quality variability,

13 not access nor volume alone is the key

14 challenge. This document provides framework

15 for moving from volume requirements to quality

16 metrics, but adequate volume is necessary to

17 assess quality. Low volume centers should have
18 ongoing case reviews as metrics are unstable.
19 All studies should engage in ongoing
20 measurement and QI. Registry is essential to
21 assess long-term outcomes and variability
22 involving patient cohort. Evolving quality
23 would suggest external review programs to
24 understand variability.
25 Thank you very much for the

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1 opportunity to present here.
2 DR. BACH: Thank you very much.
3 (Applause.)
4 Next we'll have Dr. Martin Leon, who
5 is the AdvaMed recommended speaker. Dr. Leon
6 is a professor of medicine and director of the
7 Center for Interventional Vascular Therapy at
8 Columbia New York Presbyterian Hospital. He's
9 the founder and chairman emeritus of the
10 Cardiovascular Research Foundation of New York
11 City. Thank you, Dr. Leon.
12 DR. LEON: Thank you. Well, you've
13 been treated to a great deal of data, I'll do
14 my best not to be repetitive and to provide a
15 slightly different perspective.

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

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1 performed thousands of TAVR procedures as a
2 primary and secondary operator, and I work in a
3 center that last year did over 450 TAVR
4 procedures in a hospital system that did over
5 700 TAVR procedures.

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

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

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

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

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

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

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

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1 survival.

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

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

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

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

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

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

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

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

7 So to summarize, untreated severe

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

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

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

7 clinical indications.

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

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

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

5 Most recently we focused on
6 intermediate risk patients, and I want to share
7 with you some recent data in a late-breaking
8 trial presented at the PCR last month where
9 they looked at intermediate risk patients with
10 the most current balloon-expandable TAVR
11 system, the so-called Sapien 3, and compared
12 data from the FDA qualification study and the
13 TVT registry. So the FDA trial involved 51
14 high volume largely academic centers as part of
15 a thousand-patient study. If we scroll over to
16 the TVT registry, we now have 453 centers, low,
17 medium, high volume centers involving almost
18 9,000 patients.

19 The methodology was a propensity
20 matched analysis one to one to three of the
21 transfemoral population, very important, with
22 24 baseline covariates using a logistic
23 regression model with S3 used as the control.
24 These are the propensity matched, again in TF
25 patients, 30-day mortality and stroke outcomes.

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

4 versus the TVT registry, including all centers,

5 and the same was true for stroke.

6 And if you look at other outcomes,

7 exactly the same. As you generalize to

8 well-trained sites that have had experience

9 with TAVR whether high, medium or low volume,

10 the overall outcomes were as good as the

11 highest volume sites in the most recently

12 approved indication.

13 Certainly there are many other

14 clinical indications which we think will be

15 served by TAVR in the future, and there's no

16 question, I believe, and I think most of you in

17 the room would agree that this has been a

18 breakthrough therapy with rapid evolution of

19 technology, procedural factors, with an

20 expected significant growth that will strain

21 the capacities of many centers threatening to

22 limit TAVR access. And importantly, in the

23 current environment of strict adherence to

24 evidence-based medicine principles, careful

25 site selection, rigorous site training and

1 continuous monitoring and oversight, the

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

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

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

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

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

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

25 Similarly, if you look at this

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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

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

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

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

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

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

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

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

25 I think we all care about the patient

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

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

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

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

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

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

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

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

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

21 DR. BACH: Thank you very much.

22 (Applause.)

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

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

2 structural interventionist, and a board

3 member of the Association of Black

4 Cardiologists. Good morning.

5 DR. HORNE: Good morning. Thank you

6 for the invitation. Again, I'm here as a

7 representative, a member of the Association of

8 Black Cardiologists and as a co-chair of the

9 Structural Heart Task Force for the Association

10 of Black Cardiologists, which was actually

11 implemented three years ago when some of the

12 data that you saw previously from the TVT

13 registry showed that over a five-year period of

14 time, there was still only a 3.8 percent

15 penetrant of this particular technology within

16 the African-American community. So we've spent

17 a significant amount of time researching this,

18 and we think it's incredibly important that you

19 are giving us a platform to discuss this today.

20 I have no conflicts to report.

21 So, we look at the question that, one

22 of the questions I was asked to address is,

23 again, whether or not there are unintended

24 barriers to access created by volume

25 requirements? The simple answer to this is

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

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

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

1 to providing TAVR to underserved populations.

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

1 documented.

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

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

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

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

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

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

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

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

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

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

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

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

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1 important; based on clear objective data, based
2 on echocardiography, the prevalence was parity.
3 So the discrepancy, again, may be
4 underdiagnosis of aortic stenosis in African-
5 Americans.
6 African-Americans historically have
7 been undertreated for valvular heart disease
8 and again, I think this is important because
9 obviously this is not just in the aortic valve
10 space but also in the mitral valve space. If
11 you look at this particular trial, we saw that
12 about 1,400 adult patients who underwent
13 first-time isolated mitral valvuloplasty or
14 mitral valve replacement at two institutions
15 between 1993 and 2003, you can see that
16 African-Americans were less aggressively
17 treated.

18 We also know that -- and this is a

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

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

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

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

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

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

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

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

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

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

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

25 So, reducing access to TAVR has a

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

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

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

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

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

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

16 So, this was also shown earlier, the
17 different variations in time between diagnosis
18 and treatment is greater for TAVR patients. In
19 2016, the days between aortic stenosis
20 diagnosis and treatment for SAVR versus TAVR,
21 and you can see that there's a 134-day
22 difference between diagnosis and treatment for
23 a disease state, again, that had a one-year
24 adjusted mortality of 50 percent if not
25 treated.

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

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

10 30 SAVR annual volume requirement scenario,
11 there are ten sole community centers that would
12 be under volume thresholds, so there's a
13 potential for ten communities to be left
14 without access to appropriate therapy. It is
15 very profound, and again, our membership base
16 in the Association of Black Cardiologists is in
17 Jackson, Mississippi, Pensacola, Florida; I
18 mean, these are real communities, these are
19 real patients, and I hope that this is
20 something that we continue to discuss.

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

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

8 percent in-hospital mortality in 2017.

9 So, impact of volume requirements.

10 Volume requirements would heighten

11 socioeconomic and racial disparities. This is,

12 again, a different study, and I hope that

13 what's reassuring, because obviously the point

14 here is to only address evidence that's here in

15 the literature, and you can see that in the

16 lexicon of literature on this particular topic,

17 there actually is a significant amount of

18 information demonstrating the issue that we're

19 trying to address here. So again, for every

20 \$10,000 increase in income, the odds of

21 receiving TAVR is increased by ten percent, and

22 non-blacks were significantly more likely to

23 receive TAVR than blacks, with an odds ratio of

24 2.812.

25 And so this is the slide that I

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1 alluded to earlier. If you look at minority

2 Medicare beneficiaries and the less economic

3 stability to overcome additional barriers to

4 access healthcare services, if you look at,

5 again, the median per capita income of Medicare

6 beneficiaries by race and ethnicity in 2016,

7 you're talking about 30,000 for whites and
8 17,350 for blacks, and 13,650 for Hispanics.
9 And again the median savings, which is
10 incredibly important, you have a difference
11 that's, you know, eightfold. And so this
12 disparity is something that we can't ignore,
13 because we know that obviously economics are
14 going to influence patients who are consumers
15 in the healthcare space decision-making
16 process, and the way in which we are currently
17 constructed, this is something that these
18 patients are still having to deal with.

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

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

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

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

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

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

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

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

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

2 valve disease compared to their white
3 counterparts.
4 So, a potential solution. I would
5 argue that existing geographical barriers would
6 lead us to better geographical alignment. If
7 we look at counties where 20 percent or more
8 population is African-American and focused on
9 centers in those particular areas, then one
10 would argue that you'd have a better
11 opportunity to, again, get care to the patient
12 as opposed to putting the onus on the patient
13 to go to where the treatment is available,
14 considering other variables such as cost and
15 comfort and preference that are currently
16 limiting patients' ability to seek particular
17 care.

18 This obviously, again, is a very very
19 important article, and this was mentioned
20 earlier, that it's critical to this discussion.
21 However, I would argue that some of this data
22 was based on earlier iterations of the valve
23 when we had larger sheath sizes and you didn't
24 have development as it pertains to ability to
25 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

1 national average.

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

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

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

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

10 Thank you for your time.

11 (Applause.)

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

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

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

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

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

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

23 United States. This is my disclosure
24 statement.
25 First, I want to say on behalf of the

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

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

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

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

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

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

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

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

25 We do believe that patient and

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

19 efforts to promulgate education and educate
20 both patients and physicians.

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

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

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

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

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

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1 infrastructure for aid to regulatory
2 reimbursement colleagues.
3 Did the original NCD succeed in its
4 purpose of rational dispersion of a new
5 treatment? The huge growth in TAVR is related
6 to the treatment access of 584 sites, and the
7 professional consensus document does not close
8 those sites, as has been thought by a draft.
9 And the U.S. has the highest density of TAVR
10 sites anywhere in the world. The excellent
11 clinical results in the U.S. cited by many
12 today have occurred in the context of the
13 original requirements that include volume
14 thresholds. That should go into the decision
15 of the committee voting on these volume

16 requirements.

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

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

3 These outcomes are apparent with a
4 50-case threshold, and reducing the proposed
5 requirements would be expected to create a
6 large increase in the number of low volume
7 sites. So, Dr. Leon, do you want to marry low
8 volume SAVR sites with low volume TAVR sites,
9 and low volume TAVR sites with higher surgical
10 mortality? No.

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

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

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

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1 sites, but basic healthcare education and
2 access issues.

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

13 come up with the right solutions.
14 TAVR is not a simple procedure. 22
15 percent of patients undergoing TAVR have
16 significant in-hospital procedures. It's not
17 like simple hernia and should be distributed to
18 all hospitals. The need for a PCI threshold is
19 not related to a volume-outcome relationship,
20 it's related to the experience and expertise to
21 treat patients with severe AS and coronary
22 disease. The need of a surgical AVR threshold
23 relates to having high quality staff as an
24 option for patients to select, and having
25 surgical experience and expertise for the

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

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

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

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

24 The unintended consequence of reducing
25 standards, volume thresholds is

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

4 DR. BACH: Thank you, Dr. Carroll.

5 (Applause.)

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

10 Surgeons Council on Quality, Research and

11 Patient Safety. Dr. Shahian.

12 DR. SHAHIAN: Thank you, good morning.

13 Well, you've heard, or you will hear from other

14 presenters, that volume thresholds are simply

15 an inferior proxy to measures of quality and

16 that they should be eliminated. Quite to the

17 contrary, we believe that volume thresholds are

18 an absolute prerequisite for accurately

19 measuring direct quality. No organization in

20 health care has demonstrated a greater

21 commitment to quality measures than STS, as

22 evidenced by our largest in class number of

23 NQF-endorsed measures, most of which are

24 risk-adjusted outcomes. 65 percent of our

25 adult cardiac surgery participants publicly

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1 report these on our website, note both risk

2 adjusted and morbidity and mortality for aortic

3 valve replacement, as well as several process

4 measures for CABG.

5 This slide from our manuscript shows

6 that we are developing a similarly robust

7 portfolio of direct outcome measures for TAVR,

8 and will also institute a public reporting
9 system.

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

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

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

6 Now, you remember those very low

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

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

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

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

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

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1 threshold.

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

4 As shown in this slide for a procedure with
5 about a three percent mortality rate, to detect
6 a doubling of mortality with an alpha of about
7 five, .05, you'd need hundreds of cases to have
8 80 percent power, which many regard as
9 desirable. The smaller the sample size, the
10 more likely you are to have a Type II
11 statistical error, failure to identify a true
12 difference in performance.

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

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

1 DR. SHAHIAN: Sure. And just in case

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

10 DR. BACH: Thank you very much.

11 (Applause.)

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

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

1 stenosis. I appreciate the opportunity to
2 address the panel.

3 We're here because transcatheter
4 aortic valve replacement has been
5 transformative. We celebrate this advance, we
6 embrace the technology, and welcome the
7 innovations that make it more technically
8 reproducible and accelerate the learning curve.

9 As the technology came on line, CMS wisely
10 recognized that access to high quality care
11 demanded rational dispersion of this powerful
12 technology. The NCD has had a very very
13 positive effect by reinforcing the importance
14 of the multidisciplinary team.

15 The issue at hand here is broader than
16 the ease with which a device can be implanted
17 in an aortic annulus, the issue here is the
18 treatment of aortic stenosis in human beings.

19 The Institute of Medicine established
20 patient-centered care as one of the six
21 dimensions of healthcare quality. This
22 requires informed discussions of all options.

23 Only when all options, including surgical
24 aortic valve replacement are available with
25 high quality outcomes, can truly

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

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

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

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

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

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

25 and surgical volumes. Thank you, Marty. The

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

5 You also asked us the closely related
6 question, how confident are we in the threshold
7 of procedural volumes for the principal
8 cardiovascular surgeon? The answer is very
9 confident. The learning curve for many
10 surgical procedures has been studied and
11 published; it's remarkable how often the number
12 100 recurs. This is required to safely and
13 reliably achieve the high quality outcomes our
14 patients deserve. Remember, these are also the
15 surgeons that will be called on to rescue
16 patients from the uncommon but potentially
17 catastrophic complications of TAVR. This is
18 particularly important in institutions starting
19 up their TAVR programs where the complications
20 may occur more frequently, and especially as
21 the move to lower and lower risk patients
22 occurs. The annual volume threshold is less

23 than twice a month, again, not burdensome.

24 How confident are we in our threshold

25 SAVR procedure volumes to maintain a program?

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

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

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

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

2 Thank you.

3 DR. BACH: Thank you very much.

4 (Applause.)

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

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

20 valve patients.

21 I am a long-term survivor of Hodgkin's
22 lymphoma with radiation-induced heart valve
23 disease. My valve was replaced via TAVR in
24 2014.

25 For the past four years I've had the

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

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

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

19 MS. STRONG: Okay. My disclosures are
20 on our slide. Will that work?
21 DR. BACH: They're on the next slide?
22 Okay, great. Thank you. Sorry about that.
23 MS. SMITH: Thank you, Susan. On
24 behalf of the Heart Valve Disease Policy Task
25 Force, thank you for the opportunity to present

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1 our views on access to all appropriate
2 treatments for all heart valve disease
3 patients. These are our disclosures.
4 I was born with a bicuspid aortic
5 valve and have had three open heart surgeries.
6 Every week I'm honored to visit with patients
7 and their families to help them as they face
8 their treatment and their recovery. As an
9 organization, Mended Hearts supports more than
10 200,000 patients throughout their journey each
11 year, so we know the patient story.
12 Mended Hearts is honored to partner
13 with organizations such as the Alliance for
14 Aging Research and Heart Valve Voice. Sue
15 Passion, the president and CEO of the alliance,
16 and Marilyn Serafini, the executive director of

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

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

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

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

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

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1 continue to search for the why.

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

13 Despite good intentions, the current

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

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1 most vulnerable in our community.
2 Quality is what matters to patients,
3 not quantity. In the case of TAVR, there are
4 ample studies to help patients like me make
5 informed decisions based on our personal
6 priorities. This panel should consider the
7 more recent studies that have shown excellent
8 outcomes in both high and low volume hospitals.
9 Patients should not be put in the middle of
10 meeting annual volume requirements to maintain
11 programs.
12 Additionally, outcomes that are

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

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

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

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

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

25 (Applause.)

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

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

10 Edwards Lifesciences.

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

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

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

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

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

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1 numerically overwhelm the small difference in
2 outcome?

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

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

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

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

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

5 patients, so there are three to four times more
6 valve surgeries done in the smaller hospitals.
7 And I would ask, is there appropriate
8 representation for these hospitals in making
9 the decisions for CMS or for these guidelines?
10 Consider the TAVR patients, we've
11 heard this already. They're frequently elderly
12 and/or debilitated. Travel carries challenges,
13 including medical risks, fatigue and costs.
14 Their support system, their family members are
15 also affected by traveling, the time off from
16 work, or perhaps they can't even find time to
17 take off from work in addition to costs. The
18 need to travel is often used as a reason not to
19 pursue TAVR by symptomatic elderly patients. I
20 can just share my personal experience having
21 just moved to Monterey, California, that that
22 is an argument made by many patients, and
23 Dr. Horne has already talked about the minority
24 patients.
25 So arguments that -- I think I'm going

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

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

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

21 DR. BACH: Please wrap up.

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

1 Most key opinion leaders come from larger

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

12 (Applause.)

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

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

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

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

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

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

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

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

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

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

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

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

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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

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

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1 52 TAVRs, they've met their TAVR threshold by
2 the new requirement, but they've done 25
3 surgeries. This center is now faced with a
4 dilemma, do they do the procedure that they
5 think may be best for this patient, or do they
6 do the procedure that they need to do to meet
7 their quota. And the irony of this is in this
8 theoretical world, if they didn't meet their
9 surgical quota they would lose their TAVR
10 program but they would continue to do surgery,
11 and that just doesn't make good logical sense
12 for patients.

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

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

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

12 (Applause.)

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

19 DR. VANG: Yeah, unfortunately, Pieter

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

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

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

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

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

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

150

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

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

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

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

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

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

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

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

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

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

14 can see this in 2017, that there is no
15 difference in outcomes.
16 So as you consider the questions posed
17 to the panel, please consider the methodology
18 used in analysis regarding volume and outcome.
19 We believe the use of conventional weighted
20 averages provides a more representative and
21 accurate depiction and assessment. Thus, I
22 believe that achieving quality outcomes must be
23 balanced with appropriate patient access.
24 Other speakers have underscored the importance
25 of patient access already, so in the interest

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1 of time, I'm going to move through the next few
2 slides.
3 Thus in conclusion, we believe that
4 CMS policy making should maintain quality while
5 protecting patient access to TAVR therapy.
6 Medtronic does not believe there is sufficient
7 evidence to modify the current operator and
8 facility outcomes to the TAVR NCD at this time.
9 Thank you for the opportunity to present.
10 (Applause.)
11 DR. BACH: Thank you very much. Next
12 up is Megan Coylewright, Dr. Megan Coylewright,

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

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

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

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

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

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

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

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

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

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

25 And I would argue we haven't asked

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

8 outcomes are, they ask me to take care of them
9 there in the community. It's a different
10 experience, but it's mine to speak of, and
11 specifically I don't want to exchange best
12 patients, I want to exchange best practices.
13 And I'll just share a story with you,
14 not the patient's real name, but a real story.
15 Mrs. Richardson, who had a valve problem, and
16 she needed to have a transcatheter valve placed
17 but it was in a different valve position, and
18 in our community hospital we weren't offering
19 this yet within the research trials, so I spent
20 hours preparing the Power Point, getting the
21 slides and the films down to Boston, conference
22 calling with my partners. And she called me a
23 week after the appointment was made and said I
24 will not travel, I won't go there unless you go
25 with me. And I don't say this to boast, I say

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1 it that it matters to patients to get care in
2 their community. She died six months later of
3 heart failure.
4 And I think about many patients like
5 that who've refused to travel and how important
6 it is, and it's specifically important to

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

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

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

4 And finally, patients with low

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

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

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1 DR. BACH: Please wrap up.

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

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

14 (Applause.)

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

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1 And I apologize, I'm doing my best

2 reading. Michael Deeb, from the University of
3 Michigan.

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

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

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

4 DR. BACH: Your time is up.

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

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

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

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

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

16 DR. BACH: Thank you.

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

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

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

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

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

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

25 We've seen a transition in treating

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

8 As Dr. Joe Bavaria previously
9 presented, there is some data to suggest low
10 volume programs performing TAVRs on lower risk
11 patients are having, or might have worse
12 outcomes. I would like to argue that these
13 lower risk patients, there's an increased need
14 to have perfect outcomes in these patients.
15 Outcomes for low risk patients need to be
16 perfect, and that's why it's imperative to have
17 qualified surgeons and cardiologists involved
18 and available, and maintain strict criteria for
19 TAVR programs. If we do a TAVR on an
20 85-year-old with CAD, PAH, renal disease, COPD,
21 and a complication occurs, most surgeons would
22 be less likely to intervene. But if we do a
23 TAVR on a 60-year-old bicuspid, otherwise
24 healthy, and complications occur, we will

25 intervene and our surgical procedures can be

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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

23 80 percent of the hospitals that don't do TAVR
24 were not represented on the ACC expert
25 consensus document. I don't understand why

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1 that's the case.

2 Number three, why the focus on PCI?

3 We did 400 Watchman's in our facility, they
4 don't count. We live in a place where we have
5 less than two percent smokers, our STEMI volume
6 is down 70 percent, and somehow we get
7 penalized for being conservative for doing
8 PCIs, we don't do elective PCIs very much at
9 all. I don't think that should prohibit us
10 from doing TAVR. Thank you.

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

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

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

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

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

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

9 And the last point is the TVT
10 registry. It is taxing, our institution pays
11 about half a million dollars a year to get this
12 information. While this information is
13 important, I think it should be revisited, what
14 we should ask, how should we get the best
15 information, and who should sponsor it.
16 Institutions cannot carry that for a long
17 period of time, especially when they come to
18 400, 500 cases a year. Thank you very much.

19 DR. BACH: Thank you very much. Next

20 up is Matt Austin.

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

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

18 DR. BACH: Thank you very much. Next

19 up is Susan Peschin, and I'm sorry if I
20 mispronounced your name.
21 MS. PESCHIN: Actually, you did great.
22 I'm Sue Peschin, and I serve as president and
23 CEO of the Alliance for Aging Research, a
24 nonprofit in Washington D.C., and we have
25 received funding from Edwards Lifesciences.

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

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

24 DR. BACH: You're out of time.

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

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1 much.

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

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

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

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

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

12 I think just to finalize --

13 DR. BACH: Please wrap up.

14 DR. CUBEDDU: Yeah. One question that
15 I think we've missed all along is, we emphasize
16 the differences between one volume and low
17 volumes, and the potential impact on one or two
18 percent differences in mortality, but we have
19 lost sight of potentially the mortality among
20 many other patients that have waited three to
21 four weeks to get an appointment that are
22 living, you know, 60 or a hundred miles --
23 DR. BACH: Your time is up.
24 DR. CUBEDDU: -- away from centers
25 without TAVR access.

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1 DR. BACH: Thank you. Just
2 disclosures, please?
3 DR. CUBEDDU: I have no disclosures.
4 DR. BACH: Great, thank you very much.
5 Thank you everyone for your attention and for
6 the speakers. We're going to break for lunch.
7 We remain ahead of schedule, thank you for
8 that. We will reconvene at 12:40 in here.
9 Most important, the speakers from this
10 morning will be part of the conversation.
11 Please, speakers from this morning, if you'd
12 like to participate, and I hope you will,

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

17 (Lunch recess.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 DR. LEON: Thank you. Marty Leon.

8 Yes, we did present the in-hospital data which
9 was the only data set that we had available to
10 demonstrate those trends. I think your
11 question is an interesting one, suggesting that
12 if there's reduced length of stay, the
13 in-hospital mortality would be less simply
14 associated with reduced length of stay. I
15 don't believe that that is the case. I think
16 that those are true differences in mortality
17 that have been confirmed in innumerable other
18 data sets, including the TVT database, and
19 including a variety of randomized and other
20 clinical trials that have been developed over
21 time.

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

1 were higher risk, and progressively over time

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

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

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

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

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

5 The second thing is really more
6 important and exactly what you're talking
7 about, which is why the TVT registry is going
8 completely away from in-hospital metrics to
9 30-day metrics, and you were exactly right, it
10 had to do with length of stay. The length of
11 stay is going down, so the delta between
12 in-hospital mortality and 30-day mortality is
13 actually going up. And what's happened is that
14 for any of the procedures that we see in
15 cardiovascular surgery or medicine, the delta
16 between the hospital mortality rate and 30-day
17 mortality rate is actually the highest in TAVR,
18 it's pretty unnerving actually. So the
19 in-hospital mortality rate is basically
20 worthless and the 30-day mortality rate is
21 really really important, and so I agree with
22 your point.

23 DR. BACH: Thank you.

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

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

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

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

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

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

20 DR. BACH: You have to be quite close.

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

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

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

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

25 simulations, there's all kinds of way for

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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

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

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

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

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

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1 to correctly do the preprocedure planning that
2 was just discussed. Then there's a proctoring
3 period of as many cases as is necessary to be
4 able to demonstrate that the site has operators
5 and a functional team that can orchestrate
6 doing the procedure correctly.
7 So it is a very intense and rigorous
8 process, more intense than any other
9 interventional procedure that's ever been
10 devised in interventional cardiology, and I
11 think probably as intense as a training program
12 that you would see with surgical procedures.
13 There's also refresher courses as new
14 techniques become available, so there's an
15 ongoing process to train these centers, which I
16 think, you know, has helped to result in some
17 of the outcomes that we've observed.
18 I would never argue that there
19 shouldn't be some case volume threshold. The

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

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

11 DR. DESVIGNE-NICKENS: Thank you.

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

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

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

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1 DR. FELDMAN: Ted Feldman from SCAI.
2 Another really critical part of the volume
3 discussion both in training and in practice is
4 the management of emergencies. And in a very
5 paradoxical way as TAVR has become safer for a
6 trainee, the frequency of emergencies to learn
7 how to manage real time and to have experience
8 with has become less, and that does drive the
9 need for volume, and I would argue that after
10 training it's no different in real practice,
11 that you have to have the aggregate of
12 experience with PCI, TAVR and surgery to be
13 facile as a team to manage emergencies, and
14 those are real frequency events, so that takes
15 a lot of experience.
16 DR. BACH: Okay. Mark, please.

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

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1 better or more appropriate than the other?
2 DR. LEON: We have looked at the data
3 as exhaustively as we can. The TVT registry
4 really comprises data from two specific valve
5 types, those data are available to the
6 companies that functionally own those data, and
7 we've looked at those data sets and have
8 attempted to replicate as carefully as we can
9 the analyses that were done by the consensus
10 document, and have been unable to replicate the
11 observation that there is the kind of
12 volume-outcome relationship that would suggest
13 importantly that we increase TAVR volume
14 requirements.
15 The only way that we can get close to

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

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

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

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

22 DR. BACH: Thank you.

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

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

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

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

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

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

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

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

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

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

10 DR. BACH: Great, thank you. Eric.

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

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

20 DR. VANG: Eric Vang, with Medtronic.

21 DR. BACH: Thank you.

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

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

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

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

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

25 DR. LEON: Marty Leon, Columbia,

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

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

14 DR. BACH: Thank you. Okay.

15 Dr. Pelikan.

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

25 If we look at other procedures where

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

5 DR. BACH: Thank you. Zoltan?

6 DR. TURI: Yeah. Actually, if you

7 don't mind, although I have no TAVR conflicts,

8 I wanted to mention that I gave a talk for

9 grand rounds on PFO closure that Abbott

10 reimbursed me for, I'd rather have that out

11 there. The other is that CMS, I noticed this

12 morning, gave me a degree of Master's in Public

13 Health, which is nice, but it would be a

14 surprise to my parents who paid for my

15 education.

16 So, I want to follow up on something

17 Dr. Carroll said. Dr. Bavaria showed us the

18 observed versus expected ratio for 30-day

19 mortality. I'm fond of full disclosure slides

20 so you see every data point, and he pointed out

21 that 96 percent of those with a O to E (O:E) ratio

22 over two were in the low volume group of less than

23 a hundred cases.

24 Dr. Pelikan showed us a curve reversed

25 to some degree and said that, you know,

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1 significant numbers of hospitals doing less

2 than 50 cases had no mortality, and he said

3 well, this was a marker of high quality in

4 those institutions.

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

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

14 As I mentioned in my remarks earlier,
15 we know nothing about a program that does 30,
16 40, 45 cases and has zero mortality. Chances
17 are they're going to have a substantial number
18 of deaths in the second 50 of their first
19 hundred just by random chance. We can make no
20 inferences about their quality, and that's the
21 crux of the second argument favoring volume
22 thresholds. We simply cannot determine the
23 quality of a program that's doing 40 cases.

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

1 score of those low volume centers?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 institution exists, they should not be doing

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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

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

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

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

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

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

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

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

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

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

22 DR. BACH: Don't remind us.

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

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

5 DR. BACH: Thank you. Dr. Goldberg.

6 DR. GOLDBERG: Steve Goldberg, two
7 comments.

8 DR. BACH: Affiliation, please?

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

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

19 requirements are going to reduce access to
20 care, then that has to be factored in.
21 The second point is I wanted to
22 comment, it's been made a couple times today,
23 that in the TVT registry, that the larger
24 volume hospitals had sicker patients based upon
25 the STS risk calculation, but in fact the

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

11 DR. BACH: Thank you. Naftali?

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

14 DR. BACH: Uh-huh.

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

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

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

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

16 of non-TAVR procedures.

17 Dr. Bavaria, I was wondering that --

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

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

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

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

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

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

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1 procedure.
2 I'm not disagreeing with the quote of
3 22 percent in-hospital complications but that
4 really has not been the experience that I've
5 had. But clearly, you have to be able to deal
6 with a coronary emergency, you have to be able
7 to deal with a peripheral emergency. My only
8 point is, if a hospital does 300 or 400, or 200
9 coronary interventions a year, it doesn't
10 necessarily make that operator better at doing
11 those procedures. So I'm divorcing --
12 DR. BACH: Thank you. I'm sorry, I

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

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

23 DR. BACH: Thank you. Aloysius.

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

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

5 DR. BACH: Closer to the microphone.

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

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

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

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

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

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

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

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

8 question?

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

11 SPEAKER: None of which I'm aware.

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

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

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

7 comment than a question, but I had to get it

8 off my chest.

9 DR. BACH: Great. I apologize.

10 Naftali, you actually had two questions, the

11 second for Dr. Bavaria, so please, I apologize

12 for cutting you off.

13 MR. FRANKEL: Yes. That question was

14 if mortality indeed is increased at low volume

15 centers and if there is really no concern about

16 access, then why, if -- you concluded by being

17 very clear that you're not recommending for

18 those sites to be closed down. So if you

19 translate the low volume centers into an

20 increased risk for those patients, why is that

21 your recommendation?

22 DR. BAVARIA: I think there's two

23 answers to that question. First of all --

24 DR. BACH: Sorry, name and

25 affiliation.

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1 DR. BAVARIA: Oh, I'm sorry, Joe

2 Bavaria, co-chair of the writing committee.

3 DR. BACH: Thank you.

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

5 know for a fact based on the most recent data
6 out of the TVT database that there is a
7 volume-outcome relationship and it's quite
8 significant under 50 and very significant under
9 25, and you can see that data. And so the
10 question is, well, why not close them, you
11 know, why not kind of close them down. Our, as
12 the four societies, our job is not to close
13 down sites, our job in regarding this kind of a
14 document which is a consensus care document, is
15 to provide for remediation and provide the data
16 so that sites can get better, as Dr. Carroll
17 said.

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

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

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

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

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

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

1 MR. FRANKEL: I'm looking nationally

2 on average.

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

13 DR. BACH: Briefly.

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

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

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

6 DR. BACH: Thank you. Smadar.

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

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

23 DR. KORT: Supported by data.

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

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

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

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

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

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

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

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

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1 from Dartmouth. I'll just provide a little
2 clarification about the state of training for
3 structural heart disease in the country to
4 answer that question. We don't have
5 accreditation for training for structural heart
6 disease fellows, so Dr. Horne and I were some
7 of the early fellows that were trained. These
8 were unaccredited programs, there were not
9 specific volume requirements that are applied.
10 We look to the professional societies as well
11 as Medicare requirements when we train other
12 fellows that come to our programs, we have to
13 get funding from other spots to do that.
14 So it's different than interventional
15 cardiology training programs where this is an
16 accredited program with national curricula and
17 goals that have to be met and that are
18 accessed. So for TAVR operators that are
19 coming out of fellowship and when we're
20 training fellows, it's an unaccredited program
21 without specific guidelines, separate from what
22 Dr. Leon talked about where he's bringing in

23 attendings that have finished their

24 interventional cardiology programs.

25 DR. LEWIS: But those fellows

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1 generally have had an interventional year?

2 DR. LEON: Yes. It's usually a second

3 year of training, so the structural fellowships

4 that are currently available are not

5 accredited, yes, so they are somewhat

6 individualized, and the curriculum is really

7 based on the institutional ideas of what the

8 curriculum should be, and there are relatively

9 few of them. So you can count the number of

10 defined structural programs probably on the

11 fingers of both hands, so there are not enough

12 structural programs to treat, or to train new

13 fellows that would provide an answer to some of

14 the access issues that we've been talking

15 about. It's difficult to get this training out

16 of fellowship.

17 DR. BACH: Thanks, and now I'm going

18 to cut you off, sorry. Michael.

19 DR. CINQUEGRANI: This is a question

20 for my colleagues representing societies in

21 that while the TVT registry is well developed

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

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

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

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

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

20 for that, it doesn't go the other way around.
21 So it's kind of neophytic, but it does exist
22 and it's actually being discussed right now as
23 we speak at the board level of the STS, and
24 that should be a little more robust.
25 DR. BACH: Dan, please. No, I'm just

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1 going to allow one answer per question, sorry.
2 Dan.
3 DR. OLLENDORF: Thanks. So, I've been
4 kind of puzzling over the notion that's been
5 brought up in a couple of different
6 presentations around whether reducing or
7 eliminating volume requirements would be either
8 necessary or sufficient to address disparities.
9 So Dr. Horne, I'm wondering if I can ask a
10 question about the data you presented specific
11 to your community.
12 So, this is a community that has
13 prevalent Hispanic and African-American
14 populations, has a population that's a quarter
15 Hispanic, a quarter as African-American, but
16 the data you presented on the rate of TAVR in
17 the African-American population as being much
18 higher than is typically seen nationally is

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

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

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

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

17 with regards to language barriers and, you
18 know, in some instances inability or
19 uncomfotability with having to figure out how
20 to navigate the healthcare system.

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

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

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

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

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1 any -- I work focused on cancer, and we have
2 vast disparities there where we don't have
3 volume requirements. So, do you see a bigger
4 effect, is there a difference?
5 DR. HORNE: Unfortunately, I do.
6 Because again, we have demonstrated that
7 patients are only going to access care where
8 they are comfortable, right? And we, you know,
9 have the trend lines that show that some
10 smaller programs have had adverse outcomes and,
11 you know, it's somewhat personal. I'm pretty
12 proud of the outcomes that we've had, so some
13 smaller programs actually, I think many of us

14 have great outcomes. And again, if you're
15 going to offer the patient nothing as opposed
16 to being in a more familiar, albeit less robust
17 than maybe a critically acclaimed national
18 environment because of the way or where your
19 physicians practice, I think that the patients,
20 again, through shared decision-making, should
21 be able to have access to that information.

22 Every physician has the right to be
23 transparent with their outcomes. I tell
24 everybody we're a small center, we've done X
25 number of cases, these are our outcomes, and I

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1 think that they deserve the opportunity to make
2 that decision.

3 DR. BACH: Thank you. I'm not going
4 to -- I'm trying to get to the other questions,
5 even though I just inserted a question. Mark,
6 and then Aloysius.

7 DR. CARLSON: I'm going to ask what is
8 certainly a naive question and it may even be
9 outlandish. There has been the assertion,
10 which is understandable, that it's difficult if
11 not impossible to measure quality accurately in
12 low volume centers. And when we talk about

13 volume we're talking about not just volume, but
14 volume over time, specifically annual volume.
15 And my question has to do with, what is magical
16 about a year, why not two years? And should we
17 be focusing on time at all, or should we be
18 focusing on the absolute number of cases that
19 is required to assess quality and then assess
20 it at that point going forward repetitively?
21 Sort of like your oil changes in your car,
22 every 5,000 or 10,000 miles. It's just not
23 clear to me why one year should be the answer.
24 DR. BACH: Because that's how long it
25 takes the earth to go around the sun.

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1 DR. CARLSON: Sorry, I didn't hear
2 you.
3 DR. BACH: For a serious answer now.
4 DR. SHAHIAN: Dave Shahian, from STS.
5 Well, you're absolutely right, and you know, we
6 are looking at, a running three years is
7 probably what we're going to settle on, just to
8 address that particular issue. Your point
9 about just doing, you know, if you think you
10 need 150 cases in order to get a statistically

11 valid result, why not just wait until you have
12 that many cases. It's an option. I can't
13 think of any situation in which that's been
14 done, and there may be no good reason that it's
15 not been done, but it is --

16 DR. CARLSON: So there might be some
17 centers where you would measure it at six
18 months?

19 DR. SHAHIAN: Yeah, that's right.

20 But just to point out some other ways
21 to mitigate this small sample issue, on the
22 surgical side we've gone to composite measures,
23 and just to give you a very quick example, in
24 the development of the CABG composite, the STS
25 CABG composite, using mortality alone, which is

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1 what we've basically been talking about today,
2 we could identify one percent of providers as
3 being outliers when we first did this. When we
4 went to a composite that had more risk-adjusted
5 mortality plus the risk-adjusted occurrence of
6 any of the five major complications, we could
7 identify a total of 23 percent. We've seen the
8 same phenomenon in aortic valve, aortic valve
9 CABG composites, so that's a very powerful tool

10 for making it possible to address quality and
11 measure quality at lower volumes than we have
12 historically with a single measure like
13 mortality, and we are moving towards composites
14 in TAVR as well.

15 DR. BACH: Thank you. Anita.

16 DR. FERNANDER: So, this has been a
17 really informative and educational discussion
18 for me. As a health disparities researcher, I
19 really want to challenge my colleagues around
20 the table as well as those of you sitting in
21 the audience, and those who are on these
22 decision-making boards and committees, to
23 really rethink how you are equating quality
24 with volume. It's very very antiquated. You
25 are sitting in existing committees and boards

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1 where you are vested in focusing on volume.

2 There are research methods and
3 strategies that exist that, where gold standard
4 does not have to be focused on quantitative
5 statistics. There are strategies where you can
6 think out of the box and think creatively about
7 meaningful outcome data. Volume is not an

8 outcome data. What are you going to actually
9 extract from a volume number? What is that
10 going to tell you about how your patient is
11 doing, what their quality of life is, how other
12 social factors are being influenced, and
13 influence your patients?

14 I really am looking at this very, in
15 many ways, homogenous group of folks here who
16 are not used to thinking outside of the box and
17 who can exist in their worlds operating this
18 way until death do you part. But I would
19 really really challenge you to go back to your
20 committees, work with your colleagues, bring in
21 folk who have different views and different
22 outlooks and perspectives, to be able to treat
23 what is becoming more and more a very diverse
24 and heterogeneous patient population.

25 (Applause.)

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1 DR. CARROLL: John Carroll, ACC. I
2 totally agree. This MedCAC is focusing on
3 volume, that's CMS's decision, and that's why
4 you're heard so much about volume. Quality and
5 this broader definition of quality is very
6 important, and in the TVT registry that is one

7 of the main reasons we instituted getting this
8 patient-reported outcomes survey done in all
9 patients before, 30 days, and one year, to look
10 at what is the treatment effect in all of the
11 diversity of patients in terms of not only
12 being alive at one year, but feeling better in
13 their own words, to being more functional.
14 That's why we're also looking at
15 rehospitalization rates and whether people go
16 home after a procedure or go to a nursing home.
17 So we are trying to look at much more patient
18 centric ways of looking at therapy outcomes
19 than just, you know, complication rates,
20 et cetera. It's really about the benefit
21 that's accrued.

22 So I think we're working on that and
23 it's a challenge, because no other clinical
24 registry has looked at one-year outcomes having
25 the patient's voice as a key component of what

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1 defines success. So we're totally on board
2 with what you're thinking.

3 DR. BACH: Thank you. Naftali, did
4 you have another question? Your card's up.

5 MR. FRANKEL: Yeah, I just wanted to
6 ask Dr. Leon.

7 DR. BACH: Please.

8 MR. FRANKEL: So Dr. Leon, I looked at
9 a couple of the articles that you published as
10 part of the broader literature on this topic,
11 and obviously everywhere you look you see your
12 name, and there were a couple specific things
13 that stuck out when I was reading through them,
14 where you noted in one article, the Canadian
15 Journal on Cardiology, to quote, it's not
16 surprising that several sites have demonstrated
17 the effects of a learning curve. Experience
18 has shown to affect overall outcomes and
19 specific procedural elements.

20 Then in a JAC article, you noted, in
21 parallel with technology enhancements, patients
22 have benefited from increased operator
23 experience. A large meta-analysis from 25
24 multicenter registries and 33 single-center
25 studies found an important reduction in stroke

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1 after TAVR. These findings were associated
2 with increased operator experience. The
3 importance of operator learning curves and

4 experience, unlike other commonly used
5 interventional technology, and for example you
6 noted stents, TAVR expertise requires intensive
7 device-specific training.

8 So in your opinion, what is the
9 current learning curve, the amount of
10 procedures for TAVR in less complex as well as
11 more complex procedures that you were
12 indicating in those articles?

13 DR. LEON: Thank you. You quoted
14 several manuscripts that were in very different
15 time domains as well, and I think your points
16 are very well taken. There's no question when
17 you start a new technology like TAVR in the
18 highest risk patients, which is what the
19 original approval indications were, patients
20 who had significant comorbidities, devices that
21 were particularly high profile as I mentioned
22 earlier in the early days, 30 percent having
23 transapical access because you couldn't use a
24 transfemoral approach, certainly there's going
25 to be much more of a learning curve under those

1 circumstances.

2 So I would characterize the early days
3 versus the modern era of TAVR, where many of
4 these procedures are done in a minimalist way,
5 where crowd wisdom and group learning and
6 experiences over time have dramatically reduced
7 the learning curve for new operators. So new
8 operators being trained now have a much much
9 more shallow learning curve than we had five,
10 eight years ago when we began this process.
11 And it's for the very reasons that I mentioned.
12 We do as a group have much more experience, we
13 train them against complications to prevent
14 them, 95 percent of the patients have
15 transfemoral access, we've been able to reduce
16 sequentially many of the specific complications
17 by a combination of procedural changes and
18 technology advancement.

19 So I think the learning curve issue,
20 albeit a very important one five years ago, is
21 less significant now. I can't give you an
22 actual single number as to what is the learning
23 curve for the new operator who is being trained
24 in TAVR. Certainly I think you'd want somebody
25 who's had good experiences with 25 or 50 cases

1 as a primary operator under supervision, I
2 think that would probably encompass the
3 important aspects of a learning curve, and as
4 being part of a much larger group with more
5 experience in the other disciplines required to
6 achieve optimal outcomes.

7 MR. FRANKEL: So if you required that
8 amount, would you feel comfortable?

9 DR. LEON: I would feel comfortable,
10 yes, that people who have proper proctoring
11 with extensive training and had independent
12 operator experiences with 25 or more cases,
13 certainly, yes, I would be comfortable.

14 MR. FRANKEL: I just wanted to say
15 that that JACC article was from 2016.

16 DR. LEON: Yes, but it reflects data
17 that was accumulated from 2012 to 2014.

18 DR. BACH: And was probably under peer
19 review for two years or something.

20 MR. FRANKEL: Fair enough.

21 DR. BACH: That's the end of the panel
22 questions. A couple things. Larry, I cut you
23 off and you haven't said anything, and also,
24 you had a comment you wanted to make. Anyone
25 else, if you have comments that are concise,

1 that are additive, they don't mischaracterize
2 anyone else's comments, we're open to it. But
3 otherwise, we will be discussing things and
4 then we will tell you it is acceptable during
5 our discussions, that if we are wrong on facts
6 and you have input, we would love to hear it.

7 MR. WOOD: Just a quick comment. I
8 think that one of the challenges here is we
9 keep looking at TAVR in isolation, without
10 understanding there's a competing therapy for
11 these patients, which is surgical AVR. Closing
12 someone's TAVR program without understanding
13 that their AVR program is much better does not
14 necessarily benefit these patients. The idea
15 that if every patient who's a TAVR patient
16 leaves a hospital that got closed down and they
17 go down the street and get TAVR is a false
18 narrative. Most of these patients are going to
19 end up staying at that hospital and potentially
20 having surgery.

21 Unless we evaluate the quality of how
22 aortic valve replacement is done, then we're
23 missing the forest for the trees. And so, to
24 deal with the sample size issue, one solution
25 is to capture all of the patients' AVRs that

1 are done, and measure their O to E (O:E) ratio on how
2 they did all their AVRs, combining surgery and
3 TAVR. It would give you a larger sample size
4 and would provide patients with what they need
5 if they want to know, how well does my disease
6 get treated at this hospital, and do I get
7 proper care. Thank you.

8 DR. BACH: Thank you.

9 DR. BAVARIA: I just wanted to -- yes,
10 Joe Bavaria, co-writer. Dr. Kort's question
11 was a good one and I just wanted to, you wanted
12 an example of some data but nobody gave it to
13 you. So, one of the things that we see
14 happening regarding low volume centers,
15 et cetera, and how they relate to higher volume
16 centers and, you know, that bit that you were
17 talking about, when you have these large, like
18 ACA, or say for example the big Cleveland
19 systems, and even in our system at the
20 University of Pennsylvania where we have about
21 ten hospitals that we own, so what's happening
22 there is no good data but the health systems
23 themselves are dealing with this.

24 So you have ten open heart hospitals

25 in your system but the CEO says we're only

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1 doing TAVR in three, but the other seven are
2 getting, or have TAVR programs up to the point
3 of the procedure and then send them in in a
4 spoke and wheel fashion. So it is being
5 addressed, it's being addressed in an
6 interesting way, mostly by the burgeoning of
7 the large healthcare systems and taking care of
8 the efficiencies of that healthcare system.

9 DR. BACH: Thank you. Name and
10 affiliation, please.

11 DR. CUBEDDU: Robert Cubeddu,
12 Cleveland Clinic Florida. I want to believe
13 that the NCD guidelines and recommendations in
14 2012 really developed within an era where
15 structural heart disease was recently just
16 introduced, where operators and different
17 hospitals really didn't have any kind of
18 credentialing recommendations or guidelines,
19 and so it really has helped tremendously the
20 commercialization of this therapy. I think it
21 has evolved dramatically, and I think it's very
22 important that we're making this the next step,

23 to update, you know, the guidelines, and I do
24 think this is a very important day for all of
25 us, including our patients.

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1 With that, I'd like to say that when
2 we revise and when we come up with, or when the
3 panel does, just keep in mind the things that
4 have been discussed today, the ethnicity
5 considerations, the geographical
6 considerations, and the training consideration.
7 If I were to take Dr. Marty Leon to my hospital
8 today, he could not do TAVR. That makes no
9 sense in my mind. If I could take any of the
10 surgeons that are sitting in the front row to
11 my hospital today, they could not do TAVR.

12 And yes, we heard that the question
13 asked in the office is, well, what's your
14 experience, but my question is, what sense does
15 it make for me to jump on a plane and go up to
16 New York or go up to Boston, or drive 60 miles,
17 when you alone have trained in structural heart
18 disease, have all the structural heart
19 experience across the board from Watchman and
20 PVL, and closure with ASDs, and we do heart
21 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

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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

20 course of this discussion if things that come
21 up that are factual in nature, please, I will
22 figure out a way to integrate you into that
23 conversation.

24 But I want to ask, I will start this,
25 but the panel all knows that they're supposed

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1 to speak to one another, to ask one another
2 questions. I'll start with the central issue.
3 As this point based on the observation of the
4 data, there's strong feelings that there is not
5 a volume signal with relation to mortality. I
6 think that was a triple negative, but those are
7 in vogue now. I'll say it again. Is there a
8 solid conclusion that there is a volume-outcome
9 relationship with TAVR based on the data that
10 you've seen today? That's the question to you
11 guys, and/or, what are the remaining questions
12 that we need to tease through?

13 DR. LEWIS: So, I've kind of been
14 teasing this question in my mind, and when I
15 think about going down to a site doing one or
16 two of these, that to me makes me nervous, I
17 don't like that. It seems that emergencies
18 come up, teams work well together when they've

19 worked on a project together, but what is the
20 right number, is there a right number, and is a
21 number important at all?

22 We certainly have numbers for
23 credentialing in PCI. You can't do PCI in my
24 hospital unless you do a certain volume.

25 DR. BACH: To remind everyone in the

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1 room, as well as the panel all knows this, the
2 discussion we are having is about volume
3 essentially conceptually, it's obviously
4 numerical, but not about a specific cutoff,
5 like is it 25 or 50 or a hundred, but it's a
6 direction.

7 So can I, do your answers seem to come
8 from less of a statistical place than it came
9 from clinical experience and expertise and
10 observation, is that fair?

11 DR. LEWIS: That's fair.

12 DR. BACH: Okay. Please.

13 DR. TURI: And I'd add that when we
14 look at the data, the outliers, the unfavorable
15 outliers are clearly in the low volume patients
16 with rare -- in low volume centers with rare

17 exceptions.

18 I think I would bring in something
19 else on pilots, and there's probably no
20 organization that's more wedded to outcomes
21 than aviation, or very few, and they in fact
22 look at, in partial answer to Mark's question,
23 they look at time and the number of various
24 maneuvers that are required to maintain
25 currency, so every six months, at least the

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1 rules used to be that you do six hours of
2 instrument flying in actual conditions or
3 simulator, and six landings, and these are just
4 examples, but the idea is that you maintain
5 competence as a factor of volume. And while I
6 can't prove that that's what's led to a linear
7 decline in flying accidents, it's certainly
8 been a significant part of that.

9 DR. BACH: Dan, go ahead.

10 DR. OLLENDORF: So, I will take the
11 statistical view because it's all I can do, and
12 I guess I went into the day knowing as I do,
13 having looked at evidence for a number of
14 procedures in a number of disciplines, and I
15 know Dr. Bavaria and Dr. Carroll in their

16 comments noted this, there's been a
17 demonstrated volume-outcome relationship for a
18 number of complex procedures across a number of
19 disciplines, cardiology and non-cardiology
20 alike, so I felt like I needed to be convinced
21 that there was not a volume-outcome
22 relationship, and so that -- and I don't feel
23 convinced that there is not a volume-outcome
24 relationship.

25 Now all that being said, this is not

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1 what we're voting on today, but volume as the
2 only surrogate for quality also makes no sense
3 to me, there have to be other quality
4 indicators that could be part of a true
5 comprehensive program to understand what a
6 qualified center and what a qualified
7 practitioner looks like, but I'm -- there was
8 nothing in what was discussed today to tell me
9 that there is definitively no volume-outcome
10 relationship.

11 DR. BACH: Please.

12 DR. FERNANDER: So, not only am I
13 struggling with the volume index, but I'm also

14 struggling with this, we seem to be very
15 focused on mortality as the primary outcome.
16 It is important obviously, but I think that
17 there are other variables that also need to be
18 taken into account that have not been examined.

19 DR. BACH: I think, just to clarify, I
20 think some of the outcomes that we saw on those
21 slides included things like stroke rate and
22 other sorts of complications, as well as
23 mortality. I might be -- please correct me if
24 I'm wrong.

25 DR. FERNANDER: Also as a behavioral

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1 scientist, I'm also interested in social
2 behaviors other than, you know, stroke or
3 related illness.

4 DR. BACH: I wasn't disagreeing, I was
5 just clarifying what we did look at.

6 DR. KORT: So, my disclosures are that
7 I'm not an interventionalist, I'm an imager,
8 I'm the director of the echocardiographic
9 laboratory at Stony Brook, so I'm involved with
10 our valve center and imaging. To maintain my
11 Level III in echocardiography, I do need to
12 perform a certain number of and read a certain

13 number of studies a year to keep my lab
14 accredited as it is. Because I highly believe
15 in laboratory reputation and high quality
16 imaging, I do need to demonstrate that each one
17 of the physicians working in my lab is actually
18 reading and performing a certain number of
19 studies.

20 I'm also part of the structural
21 program at Stony Brook, I'm actually the only
22 person that is involved with those procedures
23 at Stony Brook, and I came here this morning
24 thinking that this should really not be any
25 different and there should be some volume, and

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1 again, not saying what that volume should be,
2 but there should be some volume requirement to
3 start the program and to maintain the program.

4 Obviously, and listening to some of
5 the things that were so elegantly said today, I
6 also believe that there should be some
7 provision for deviating from that requirement
8 based on expertise in the place where the
9 program is to be started, as well as geographic
10 limitations. So I would have loved CMS to look

11 into those criteria as well, and add those in
12 addition to a volume requirement.

13 DR. DESVIGNE-NICKENS: Patrice
14 Nickens, also no conflicts. You know, I agree
15 with all that has been said but I, it's really
16 quite frustrating. It feels like somehow we're
17 in this framework that doesn't seem to work
18 well for the importance of, this is a game
19 changer, such an important advance in this
20 field. And you know, volume is, as we watch
21 cardiovascular disease death rates decline and
22 we continue to do well, you know, volume is not
23 going to be a practical way of assessing much,
24 we need to do better, because that's exactly
25 what we're trying to decrease, our need to do

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1 these procedures.

2 And I guess my fear is that we can
3 answer these questions fairly well because
4 there, you know, there's a certain threshold
5 below which it wouldn't make sense, of course
6 you have to have some experience with this
7 procedure in order to have good outcomes. But
8 it does seem that it is essentially driving the
9 value of this procedure, and that's wrong.

10 And it also doesn't, it doesn't allow
11 the fact that this kind of determination
12 impairs access which, again, you know, not
13 having volumes, not even having access, it
14 doesn't allow, you know, never having a chance
15 for this procedure, which also is another way
16 of biasing outcomes if you're only doing the
17 procedures on the patients, the persons that
18 have access to it. So I hope that there's a
19 way that in answering, in going forward with
20 this, that we have an opportunity to point out
21 just how thin, while perhaps a necessary
22 condition, how insufficient volume is to assess
23 this very important breakthrough technology,
24 which we expect to continue to improve in the
25 future.

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1 DR. BACH: So Patrice, may I ask,
2 so -- and I'm not trying to ask a leading
3 question, so if you hear leadingness in it,
4 please don't. You talked about other metrics.
5 I guess the question it comes back to, we are
6 supposed to be discussing volume itself. Are
7 you saying that these other metrics are

8 superior but volume is still something that
9 matters, or that these other dimensions are
10 really where all the focus should be and that
11 volume should be, you know, left to the
12 wayside?

13 DR. DESVIGNE-NICKENS: So, I thought I
14 understood the national coverage decision
15 process, but -- and you know, we've talked
16 about competencies and, you know, learning and
17 then, you know, evaluating teams and their
18 quality. And I'm trying to make sense of what
19 we're trying to do by allowing a procedure in
20 hospitals to be covered, if this decision will
21 affect whether or not programs are able to
22 continue or how they struggle to continue and
23 again, you know, it seems that volume, it
24 certainly as the only indicator may not be
25 correct.

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1 DR. BACH: Thank you. Dan.

2 DR. OLLENDORF: I just wanted to throw
3 this into the discussion because it may
4 represent a factual statement that somebody
5 could correct if I'm getting it wrong. I think
6 someone said that -- so, the access issues are

7 multifactorial and there may be, a volume
8 requirement may be a contributor to access
9 issues, we don't have a lot of empiric data on
10 this, but there was a statement made that the
11 rate of TAVR is higher in Wyoming which has no
12 TAVR centers, than it is in Illinois which has
13 19. So residents of Wyoming are going out of
14 state and having TAVR at a higher rate than
15 residents of Illinois are having TAVR, whether
16 that's in state or out of state. So access
17 issues are critically important, but I don't
18 know that we can explain everything relative
19 only to the volume requirements.

20 DR. DESVIGNE-NICKENS: So, I don't
21 know, but I would imagine that that difference
22 that you're talking about in Wyoming has to do
23 with income and ability, you know, the ability
24 to go. So, these are actually elderly, for the
25 most part elderly patients, but being able to

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1 plane out over to where, a place to have a
2 procedure like this, would not be an option
3 for, you know, other disparate populations.

4 DR. OLLENDORF: Yeah, and I don't know

5 how the income disparities play out between the
6 two states, but that was certainly a striking
7 data point for me.

8 MS. PESCHIN: Have you ever been to
9 Jackson Hole, Wyoming? It's incredibly
10 wealthy.

11 DR. OLLENDORF: I haven't, but it's
12 not the only city.

13 MS. PESCHIN: Yeah, so you have to
14 look at what --

15 DR. BACH: I'm sorry.

16 MS. PESCHIN: Can I just say something
17 about just --

18 DR. BACH: I'm sorry. We have to have
19 a process. I made the statement that factual
20 corrections were more than welcome, but the
21 time --

22 MS. PESCHIN: I have a factual
23 correction.

24 MS. ELLIS: Ma'am, you need to
25 introduce yourself.

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1 MS. PESCHIN: I'm Sue Peschin, and I'm
2 with the Alliance for Aging Research. The data
3 that's been presented at this meeting is sort

4 of, it's blinded, we don't know anything about
5 the specific facilities. You know, they're
6 being presented in sort of like a -- and I
7 don't know if you all have seen behind the
8 scenes, you know, that these are, this is the
9 listing of the facilities that --

10 DR. BACH: But in fairness, this isn't
11 a factual correction.

12 MS. PESCHIN: It is, because you guys
13 are making assumptions based on not knowing the
14 specific facilities that we're talking about,
15 and the TVT registry doesn't reveal that
16 information.

17 DR. BACH: That's a factual statement,
18 but I'm going to cut you off. We have to --
19 I'm sorry, but this is the time, this is
20 uncomfortable for me, but that's it.

21 MS. PESCHIN: Can I just make --

22 DR. BACH: No.

23 MS. PESCHIN: Dr. Bach, can I just
24 make one more point about this whole thing?

25 DR. BACH: No.

1 MS. PESCHIN: Which is, the weird

2 thing, I think with volume that's going on, is
3 they go through massive training and there are
4 minimum requirements to start a program. They
5 should have high quality from day one when they
6 start a program. The very idea that you need a
7 certain amount of volume is basically saying
8 that it's a learn as you go process, and I
9 really hope that's not the case.

10 DR. BACH: Thank you. Naftali.

11 MR. FRANKEL: I think that one of the
12 challenges that was mentioned today, and I
13 think that there's broad consensus across the
14 board that if there were other quality metrics
15 available, if we could actually state what the
16 outcomes data, risk-adjusted data from each
17 hospital is based on outcomes rather than
18 volume, I think everyone agrees that that would
19 be preferred. The problem is that first of
20 all, that's not available, today at least,
21 publicly for sure.

22 SPEAKER: (Inaudible.)

23 DR. BACH: Let him finish his
24 sentence, please.

25 SPEAKER: (Inaudible.)

1 MR. FRANKEL: Per hospital throughout
2 the country reported to the public.

3 SPEAKER: (Inaudible.)

4 MR. FRANKEL: The public, I mean, for
5 patients. So until that information is
6 available, patients are blinded in terms of
7 determining where they should go for treatment.
8 Volumes is one of the comforts that they can
9 have, that they know that the hospital that
10 they're going to has at least that measure in
11 place. So while I think that the other
12 measures would certainly be very valuable and
13 perhaps better than what's available right now,
14 until that happens, I don't see how we can cut
15 that away from the patient in their
16 decision-making process.

17 The other side of that coin is that,
18 as was stated over and over again today, when
19 you have lower volumes, then you can't provide
20 those other, that other data, so I don't really
21 understand how it's argued that we can move
22 forward with these other metrics in lower
23 volume centers if you're not able to actually
24 quantify that data and risk adjust it in lower
25 volume sites. You know, that's something that,

1 I'm not sure if it was addressed yet, but I
2 haven't heard really an answer to that.

3 DR. BACH: Thank you. Aloysius.

4 DR. CUYJET: I think volume, if I'm
5 getting a valve replacement, I'm going to ask
6 the surgeon what their experience is, but I'm
7 also going to ask -- I'm sorry. If I'm going
8 to have an aortic valve replacement, not
9 really, just for the sake of argument, I'm
10 going to ask my own surgeon, or the
11 interventionalist if I'm having TAVR, what your
12 experience has been. I'm also going to ask him
13 where the procedure is going to be done,
14 because one of the things that hasn't been
15 discussed much is the team involved in the
16 patient care, the RNs, the NPs, PAs, physical
17 therapists, and who is leading the team. All
18 of those things are important to me as a
19 patient if I have to decide where I was going
20 to have things done.

21 So I think there needs to be -- we've
22 focused narrowly on volume for the surgeons,
23 interventionalists, structural heart person,
24 but we haven't had much discussion about all
25 the other components of the team, and I think

1 that's extremely important in terms of patient
2 experiences and patient outcomes.

3 DR. BACH: It has to be facts.

4 SPEAKER: It will be fast.

5 DR. BACH: Facts.

6 SPEAKER: Facts?

7 DR. BACH: F-A-C-T, not F-A-S-T.

8 SPEAKER: I can do facts and fast.

9 DR. BACH: Okay.

10 SPEAKER: I'm from Alabama, I speak
11 fast. With all due respect, Doctor, you said
12 this was all a play act that you're a patient,
13 you're not a patient. You have no idea what
14 it's like to be told that you're going to have
15 to have an aortic valve replacement. You have
16 all sorts of questions. There are other things
17 other than how many do you do and where did you
18 get your training, that's not it. That is not
19 the question that the patient is going to ask
20 you. It's going to be other things, it's going
21 to be will I have to travel far away, I'm too
22 sick to travel. Can I get it done here just as
23 good as I can get it done there, so that I will
24 be here in my neighborhood where my family can

25 be close to me. It's important to be with your

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1 family and have them with you when you're going
2 through a procedure like this. I love my
3 surgeons. I've been opened up three, actually
4 five times, but I love my surgeons, in fact I
5 have them up on a pedestal. I also love my
6 cardiologist, he is my hero, and my
7 relationship with my cardiologist and myself,
8 between the patient and the cardiologist to me
9 is, it's almost a holy relationship.

10 DR. BACH: Thank you very much.

11 SPEAKER: You're very welcome.

12 DR. CUYJET: What I said was you need
13 to do your homework and where you have things
14 done in addition to, I had my hip done, and I
15 did my homework before I decided who and where
16 it was going to be done.

17 The other piece of it is, travel's
18 been mentioned frequently as a factor. We need
19 to take a look at some of the children's
20 hospitals. They make provisions for families
21 to be with their kids, not always, but that
22 doesn't mean we can't do it, or make a

23 recommendation that it be done.

24 We did a study in Nassau County, Long

25 Island called Vital Signs, and travel was at

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1 the top of the list. People who didn't have
2 neighbors or family to drive them, took an hour
3 by bus, a half-hour wait in the office to be
4 seen for 15 minutes, and an hour to go back
5 home. So it's not something that should be
6 taken trivially, but it's something that we
7 should think about, alternatives to compensate
8 for folks who are reluctant to go to a better
9 place, if you will, because of the travel
10 issues.

11 DR. BACH: Can we talk more about this
12 travel issue and this balance of access and
13 qualification, and do either, you know, with
14 regard to the disparities that have been
15 described or without regard to them, where are
16 people, how is this data that we looked at, the
17 maps, et cetera, being interpreted, other
18 questions. We're soon going to have to ask
19 this question of ourselves and vote on it,
20 whether or not we believe -- and we can look at
21 the question precisely, but it relates to the

22 volume thresholds and the effect and the
23 tradeoff, if there is one, between outcomes and
24 access. So I thought it might help to talk
25 about the data we've seen so far, if there are

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1 any views. Please, Patrice?
2 DR. DESVIGNE-NICKENS: Yeah, just a
3 comment. So I didn't, I don't think I reviewed
4 specifically regarding TAVR, but there's a
5 large body of information for minority patients
6 that, you know, because of legacy of
7 discrimination, that they feel a loyalty to, if
8 you will, minority-serving institutions, often
9 despite quite high rates of, you know, poor,
10 you know, poor performance, poor quality. And
11 so I think, and I just offer that as an example
12 of a patient factor that if these, this kind of
13 procedure which is lifesaving, is offered only
14 at, you know, these quality, you know, high
15 volume centers, there's a large -- well, part
16 of it is the education among other things, but
17 you know, it's what I -- the direct result of
18 that is a large percentage of patients that
19 would never consider moving outside the

20 hospitals that treated their families, you
21 know, their relatives, you know, mothers and
22 fathers and grandparents, because they couldn't
23 go anyplace else in the past.

24 DR. CINQUEGRANI: Yeah. I don't
25 recall that we specifically heard discussions

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1 about limitations directly, or examples of
2 access, or had much, if any, data presented on
3 that today. We did have data presented on
4 times of evaluation, and I know that in our
5 program and I'm sure in all the other programs
6 have the same issue, the number of visits
7 patients have to make to go through an
8 evaluation process to receive TAVR, and
9 certainly that would have a negative impact on
10 access. If you live a distance from a program,
11 the closest one you have available to you, or
12 perhaps in quotes, the best one that you have
13 available to you, the times, the number of
14 times you have to return to that program would
15 have a major impact on your ability to access
16 the program.

17 DR. BACH: Yeah, I actually think, did
18 I hear the number 11 visits?

19 DR. CINQUEGRANI: Yeah.

20 DR. BACH: Is that right? You know,
21 do you have a fact for us?

22 MR. WOOD: We have a fact. We did
23 this analysis, and the average TAVR patient has
24 13 to 15 visits before they have their TAVR
25 procedure, and this is why it's not just

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1 traveling that one day of their procedure and
2 their hospital stay, it's traveling for all the
3 workups, and most hospitals do their own
4 workups, they're not going to take other
5 people's work. So this travel issue isn't a
6 one-time thing, it's an ongoing issue.

7 DR. BACH: Thank you. Fact.

8 DR. TOMMASO: Tommaso, writing
9 committee. I can tell you that maybe they're
10 having 13 visits but in our institution they're
11 doing six to eight of them a day, so it's not
12 like they're going back and forth 13 times. We
13 compress it and get everything done in the
14 shortest period of time that we can. So yes,
15 they may be having 13 visits, but it's not 13
16 days.

17 DR. BACH: Got it, thank you. It's
18 got to be additive.
19 DR. BAVARIA: Yes. The slide says
20 it's from the time of diagnosis of the aortic
21 stenosis, not from the time of the
22 decision-making process towards SAVR or TAVR.
23 DR. BACH: Got it, thank you. Mark.
24 DR. CARLSON: Are you interested in
25 anecdotes in the absence of evidence?

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1 DR. BACH: Just as long as you
2 remember that the plural of anecdote is not
3 data, yes.
4 DR. CARLSON: So, I'm a native of
5 Kansas, and I have a friend with a 95-year-old
6 farmer, active farmer still, father, in Garden
7 City, Kansas. And he's a physician, the son is
8 a physician in Kansas City. He called me up
9 and told me that his father had critical aortic
10 stenosis and they were talking to him about
11 this new experimental procedure, which is the
12 one we're discussing today. So Garden City,
13 Kansas is about 400 to 450 miles from Kansas
14 City, or it's some distance to Denver where
15 John Carroll would be, and it might be a little

16 bit closer to Wichita, and you can get the
17 procedure in all of those places. But they
18 chose to go eight-and-a-half hours or whatever
19 it was by car, with a 92-year-old man at that
20 point, to the University of Kansas, and I think
21 there were two or three visits before they made
22 arrangements.

23 But what I can tell you, if it were
24 not that his son was a physician, if it were
25 not that his son knew me and I told him that

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1 this wasn't as crazy as it might have sounded,
2 he never would have gone and gotten the
3 procedure, just never would have taken the next
4 step. And there are -- there aren't many
5 people in Garden City, Kansas who have those
6 kinds of connections to be able to connect the
7 dots, and eight-and-a-half hours is a long
8 distance for a 92-year-old man who's having
9 angina, lightheadedness and periodic bouts of
10 hypotension. Thanks for enduring that.

11 DR. BACH: I'm sorry about that. Go
12 ahead.

13 DR. TURI: But the question is, do you

14 recommend that there be a TAVR program in
15 Garden City, Kansas?
16 DR. CARLSON: I'm not recommending
17 that, nor am I dissenting against it, but I
18 think it's key to understand, as many have
19 alluded to, the complexity of the issues that
20 exist geographically. And I've heard that the
21 density, and John, you might be able to address
22 this, the density of centers in the United
23 States is greater than anywhere else in the
24 world. It wasn't clear to me whether that's
25 density by population or density by geographic

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1 area.

2 DR. CARROLL: Population.

3 DR. CARLSON: Population. So it's a
4 much more complex situation when you've got a
5 country the size of ours, with populated areas
6 and very rural areas.

7 DR. GOLDBERG: Steve Goldberg, from
8 Monterey. I just want to say that your
9 anecdote is my life experience in a larger area
10 than Garden City, but that is a very very
11 common type of a scenario and we, you know, one
12 small anecdote was a patient we decided was too

13 high risk for us, we sent him up to a major
14 academic medical center a couple hours away.
15 They evaluated the patient and I called to find
16 out what they thought, and they said oh, you
17 didn't hear, he drove back home and died.

18 And so, I don't think that it's
19 appropriate for an anecdote like that to drive
20 things, but that is the real world.

21 DR. BACH: Thank you very much. Other
22 comments on this access issue? Please,
23 Naftali. I'm sorry, the time for public
24 comment is over. I'm sorry.

25 MR. FRANKEL: What I was wondering is,

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1 do we know that in areas, let's say a 50-mile
2 radius, and you don't have a site available,
3 and obviously for those that are elderly or
4 there's other restrictions, it is a barrier for
5 them to travel further. Do we know that right
6 now, that if the criteria was changed, that
7 those are the locations where we would have
8 centers opening up, and not in the concentrated
9 saturated areas that we're hearing about over
10 and over? And I guess you can't say a blanket

11 yes, but in a marked way, is there going to be
12 a dramatic improvement on that front in those
13 areas?

14 DR. BACH: So that's a question of
15 fact. We saw maps with changes in standards
16 and cutoffs, changing centers that could be
17 opened. So, is this an answer to that
18 question?

19 DR. TOMMASO: I was just going to --
20 Tommaso, writing committee. I was going to
21 refer you to the map I had with the red stars
22 which were the new programs that had opened in
23 the last two years. 50 percent of them were in
24 relatively rural small urban areas which
25 improved access to care. The other 50 percent

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1 were on top of existing programs. If we had
2 taken all of those programs and put them in the
3 rural area, we wouldn't have had people having
4 to drive eight hours. But conversely, in those
5 rural areas, like Wyoming, those people are
6 used to driving.

7 MR. FRANKEL: Okay, but obviously
8 there are restrictions.

9 DR. TOMMASO: I was just in Wyoming.

10 In Gillette they go to Billings to do their

11 grocery shopping.

12 MR. FRANKEL: Okay. Given that there

13 can be, you know, elderly patients that are not

14 able to do that.

15 DR. BACH: We'll do a fact check on

16 whether people do drive more in Wyoming.

17 DR. PELIKAN: They do, that's a fact.

18 But here is the fact. 50 miles is not the

19 barrier, it's not the only barrier. So in an

20 urban center where there's 20 million living,

21 getting in and being seen and getting the

22 procedure done is also a barrier. And if we

23 have a small number of hospitals, I can tell

24 you where I'm doing TAVR is backed up sometimes

25 three to five weeks to even get a date to do a

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1 TAVR because they're so busy. If we open up to

2 low risk patients, patients are going to have

3 to wait longer and longer if we do not allow

4 more centers to open.

5 DR. CARLSON: Yeah, I just want to

6 agree with Peter. I practiced in Cleveland for

7 20 years, and there were people who would not

8 cross the bridge over the Cuyahoga River, and
9 there were people who would not go from one
10 side of an interstate to the other, and there's
11 nothing we're going to do to change that.

12 DR. BACH: Thank you. Let's just get
13 back to the facts. Go ahead.

14 DR. DEHMER: Well, we can't really
15 predict what would happen if one TAVR center is
16 opened, but you can have lessons from the past,
17 and this was a story that I know I was involved
18 with, with the proliferation of PCI centers.
19 And there's a collection of literature that
20 showed that once there were expanded
21 indications for PCI centers all driven by the
22 need to have more STEMI centers, and then STEMI
23 centers couldn't survive unless they did
24 elective centers, they looked at what happened
25 after that. And most of the new STEMI centers

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1 didn't end up in rural areas where they needed
2 to provide MI care, they all happened clustered
3 around existing centers because it was kind of
4 a me too philosophy that existed. So I think
5 the caution is if you open this up, are the new
6 TAVR centers really going to be produced or

7 open up where they're most needed, and we've
8 heard over and over again that they're most
9 needed in the Garden City, Kansas area, and in
10 other more rural areas or other places where
11 individuals have socioeconomic challenges.

12 DR. BACH: Thank you. Dan. Is your
13 mic on?

14 DR. OLLENDORF: Thanks, Mark. So,
15 we're not going to solve all because we could
16 end up locating centers where it's perceived
17 that communities are underserved, if it's too
18 much of a geographic burden, but that's not
19 going to get rid of all the disparities. We
20 haven't even talked about the gender disparity
21 which is plainly evident here, right, so women
22 who need this procedure at higher rates are
23 getting it at lower rates. So, I'm just not
24 sure which direction we're headed in. We need
25 to acknowledge that disparities exist and there

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1 may be remedies on the payment side, and maybe
2 the societies can do something about this, but
3 I'm just not sure where to go with this.

4 DR. BACH: Great, thank you. Did you

5 have another comment?

6 DR. CUYJET: I had just a comment.

7 You know, we can identify problems, whether

8 it's travel, loyalty to a primary care provider

9 or cardiologist, but we need to think about

10 what are collectively referred to as the social

11 determinants of health. There's different ways

12 to solve problems, and one of them might be

13 more TAVR centers, but that might not be the

14 answer. We need to figure out what people are

15 resisting, what's inhibiting them from

16 accessing appropriate care and to see what the

17 solutions are to the problem. That's not part

18 of this discussion but it is something that we

19 should begin to think about.

20 DR. BACH: Patrice, do you have

21 another question or is your card, that's a

22 legacy? Okay.

23 I'm not the only one who should be

24 asking the questions. Do you have questions of

25 one another? With an eye to the next phase,

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1 I'm going to take you into a set of questions

2 that are on the sheet next, so in this general

3 discussion, do you have questions for one

4 another? Okay. So, all right.

5 So the next phase of this is -- all

6 right. The next phase of this is the voting so

7 let me just, two things. One is, I want,

8 because I think this is a rich discussion, so

9 I'm going to put things out of order a little

10 bit, which is that on the back half of your

11 voting question page you'll see what's called

12 the additional discussion topics. We're going

13 to actually start there and we're going to

14 discuss these issues in whatever wholesome

15 manner we feel we can. These do not require

16 votes, but the Agency is listening to our

17 conversation and trying to figure out a number

18 of different things, including what is known or

19 what our conclusions are about what is known,

20 what the right next questions are, and to

21 remind everyone, that we are here discussing a

22 national coverage decision that was called

23 coverage under evidence development. It is a

24 mechanism that CMS can use to gather more

25 information at some level through the course of

1 coverage, so we should keep in mind that we

2 should lay out what we think the Agency should
3 go figure out, and they have some tools at
4 their disposal to arrange for doing that.
5 So we're going to start there, and
6 then I will return with more instructions about
7 the voting questions when we get to them. So
8 to that end, these are specific questions, I
9 think we've sort of covered them, sort of
10 haven't, but I do want to go through the
11 question on the table which we've already
12 started to ask, is do volume requirements
13 create unintended barriers to TAVR based on any
14 of the following, geographic location, gender,
15 ethnicity, race, socioeconomic status, provider
16 preference, which is explained in depth there
17 but as was explained several times, I trust my
18 doctor, I want to go to the doctor or hospital
19 I feel comfortable with, and the hospital
20 setting.

21 And so in no particular order, or
22 collectively, I want to start a discussion
23 around this, and I've already brought it up a
24 couple of times in a couple of different ways.

25 The critical phrasing in that question

1 is the verb create, is it the volume
2 requirements that create these problems? And I
3 would say that the counterfactual is, absent
4 the volume requirements, these problems would
5 certainly not vanish, or maybe they would
6 vanish, but that's not what we're asking
7 ourselves, it's would they be diminished, given
8 the assumption that all of the gaps are bad.

9 Let me ask, did anyone see any
10 evidence that was overwhelming that they'd
11 create any of these dimensions of problems? I
12 could start with the other end too.

13 DR. CUYJET: I'll start. I don't
14 think it's the fundamental issue. I'll go back
15 to, I mentioned the CABG study, you can go to
16 the 1995 New England Journal article where
17 there was a conference, I think it was over 500
18 primary care providers. They had two sets of
19 actors, one set is white, one is age 55, the
20 other age 70. The other set was black, again
21 55 and 70 years of age, and the providers were
22 given different scenarios describing anginal
23 pain. The recommendations were less aggressive
24 for the black patients and less aggressive for
25 the female patients.

1 So I think this is a fundamental issue
2 which, again, is beyond the scope of this
3 conversation. So just having more centers,
4 like the old build it and they will come, I
5 don't think applies. I think if we really want
6 to make meaningful change, there has to be a
7 more profound analysis of what the issues are
8 that inhibit patients from seeking care,
9 whether they're legitimate, and if so, what
10 alternatives can we offer to them, and if
11 they're not legitimate, the reasons they're not
12 seeking care.

13 DR. BACH: Thank you. There must be
14 other views on this, or similar views. Go
15 ahead, please.

16 DR. DEHMER: So, I have benefitted
17 from a lot of education today from the various
18 speakers plus the other panel members, and I
19 would walk away from this saying there are
20 unintended barriers to receiving TAVR care, and
21 a lot of other care in all sorts of other
22 areas. That said, however, I don't think it's
23 volume alone, I think I've heard a lot about
24 different feelings that different groups have
25 about where they want to get the care, and

1 that's not solely a function of volume, I think
2 that's a much bigger issue that's going to
3 require really education for the whole
4 community, or the whole body of patients that
5 we've heard have severe symptomatic aortic
6 stenosis, that many of them don't get the care
7 because they probably don't realize how
8 important it is, and that something can be done
9 for them. So are there barriers, I would say
10 yes. Are they totally related to volume, no.

11 DR. BACH: Thank you.

12 DR. KORT: I think that the word
13 create is a very strong word. I think that
14 volume can contribute to barriers for
15 everything that is really listed there, A
16 through G, but I would have used the word
17 contribute as opposed to create, and again,
18 keeping in mind that it's not the only factor.

19 DR. BACH: I'll take that edit even
20 though I'm not allowed to edit the question. I
21 think the question is, is there a causal
22 effect, and I think it's completely fine to use
23 a softer term for it.

24 MR. FRANKEL: I think that Dr. Horne's

25 presentation really highlighted the fact that

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1 you have these other very significant
2 variables, the under-referrals, with the actual
3 preference of patients not to seek treatment,
4 which I think just to echo, really highlights
5 the need for better patient education regarding
6 what's available and what the potential
7 outcomes are if they make use of that. And the
8 fact that there's such a severe problem of
9 under-referrals, I think is another issue
10 that's not patient education, that might be
11 partially the referring physician's education,
12 but these are obviously core components that
13 are underlying those barriers to care.

14 Is it possible that volume takes a
15 part of this, yes, but it seems to be, based at
16 least on the data that was presented, that it's
17 secondary to other problems that are really
18 much more reflective in the disparities that
19 exist.

20 DR. BACH: Thank you. Greg, are you
21 waiting to say something? No? Okay, I'm
22 sorry.

23 Can I ask about gender? Did we see
24 any data that volume creates or contributes to
25 the gender gap that we saw today? Can I ask a

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1 factual question about gender, because I don't
2 know the disease literature well enough? Is it
3 the case that the at risk, the rate of women at
4 risk or who are eligible for the condition
5 would suggest a higher rate amongst women than
6 we see? Yes? I'm seeing nods.

7 UNIDENTIFIED SPEAKER:
8 (Unintelligible.) 50 percent of women.

9 DR. BACH: But is the prevalence of
10 this particular valvular disease listed by age
11 equivalent across gender?

12 SPEAKER: (Unintelligible.)

13 DR. BACH: Okay, great, thank you for
14 that clarification. So back to my question.
15 Did we see evidence that volume contributes or
16 creates this gender gap?

17 DR. TURI: No, I think that was the
18 weakest of the parameters that are up to there
19 in terms of any potential correlation to
20 volume. The question, the volume is almost
21 certainly only one factor in whatever barriers

22 might be set up by that. The other end is with
23 the patient that, I don't want to pick on
24 Garden City, but will a patient that's in an
25 area that's far from a TAVR center really

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1 benefit from having a low volume center in
2 terms of outcomes, and I think that's something
3 that we may, that remains unanswered.

4 DR. BACH: Yeah. So one of the things
5 I try to do is make sure we're on a level set,
6 so just to clarify, I haven't heard from anyone
7 that they think volume is the only factor,
8 right, so I think we all collectively are
9 telling the Agency what seems logical, which is
10 that these are multifactorial things, but we
11 are focusing this conversation, which everyone
12 is doing a great job of doing, on this one
13 particular operational question. I'm also not
14 asking a question about magnitude because I
15 don't think we can easily get to that. But you
16 know, of course there are other factors.

17 Factual only, please?

18 DR. HORNE: So, Aaron Horne,
19 Association of Black Cardiologists. I guess

20 specifically, he said that he thinks volume is
21 a secondary issue in terms of the criteria
22 that's set up, but everybody on the panel has
23 acknowledged that there's an underdiagnosis and
24 an undertreatment of aortic stenosis in the
25 African-American population, and so by

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1 continuing to do the same thing, I think that
2 that demonstrates that the criteria in itself
3 isn't about creating, as opposed to being a
4 secondary causal relationship, right, because
5 we've shown over five years that that number
6 has not changed, the 3.8 percent, and we all
7 agree that it's underdiagnosed, undertreatment,
8 so therein, I would argue that it is directly
9 affecting it.

10 DR. BACH: Thank you for that comment.
11 Just to paraphrase, my characterizing them as
12 independent factors I think is what's being
13 objected to, they are interrelated factors over
14 time, and I appreciate the comment.

15 Socioeconomic status, just to go
16 through this list, I'm in no particular order,
17 volume standards creating gaps related to
18 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

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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

17 about what's good, you know, what the training
18 programs require, you know, and why the numbers
19 are what they are, and you know, maybe that's
20 something that we could try to minimize, but
21 nevertheless, it is, you know, we're trying to
22 define the people process, and that is probably
23 not a good thing.

24 DR. BACH: The point is taken, and
25 remember, the Agency is going to take into

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1 account our discussion around these things,
2 including important points like that one.

3 We're talking about SES, that's the
4 topic, subtopic.

5 DR. OLLENDORF: Yes.

6 DR. BACH: Okay.

7 DR. OLLENDORF: Although I may throw
8 in everything else too. The frustration for me
9 is that, so, if we go back to the world before
10 TAVR existed, all of these were barriers to
11 good cardiology care, so there were disparities
12 around all of these to good cardiology care, so
13 I am still not even convinced that there's an
14 interrelated association or contribution of
15 volume requirements to either creating or

16 exacerbating these barriers, I'm unconvinced.

17 I think the way to try to deal with
18 this is some sort of a demonstration project
19 with some sort of volume requirement still in
20 place around the other things that could be
21 done to address improved referral rates,
22 improved education to patients and families,
23 locate centers in underserved areas,
24 geographically or based on race and ethnicity,
25 and see what happens with that demonstration

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1 project, and then decide whether volume is a
2 contributing factor or not. I can't think of
3 it any other way.

4 DR. BACH: Okay, thank you. Some
5 other ones, I'm going to push a couple
6 together, not that we shouldn't talk about each
7 of them, but things like the geographic
8 location and the hospital setting or structured
9 community versus academic, that those things,
10 that they're creating unintended barriers along
11 those dimensions? Not a lot of discussion. Go
12 ahead.

13 DR. CUYJET: Well, I'll make two

14 comments. One, if you look at the healthcare
15 systems, they're private systems, they're
16 safety net systems, so you really need to map
17 where patients are getting their care. And
18 there's an economic underpinning with it.
19 Before I shifted to administrative medicine I
20 was at a safety net, the safety net for Nassau
21 University, but they're able to negotiate for
22 reimbursement rates that are much lower than
23 what Northwell, which is the biggest healthcare
24 system in New York State, can negotiate,
25 because they have the power of size and volume.

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1 So economics play a part in what procedures are
2 done, the volume and the access, so that needs
3 to be looked at. And so where patients, you
4 know, when Northwell started open heart and
5 transplant programs, it was in this paper for
6 Long Island and every other media access they
7 could get, so it was really well publicized.
8 Nassau University Medical Center, if they have
9 any marketing budget, it's nowhere in
10 comparison to Northwell. So there are other
11 factors that play into the dynamics.
12 The other thing that's of interest for

13 the folks from Harvard who developed the
14 implicit association test, I don't know how
15 many people are familiar with that, when I was
16 chair of medicine at NUMC, I brought the
17 attendees in, directed them to the website,
18 because everybody swore they had no biases.
19 Then they took the test and we came back and
20 had a little discussion. There are other
21 factors that people don't even consider that go
22 into the decision-making process, both among
23 patients and providers, so there's a whole
24 universe of questions to ask and answers to
25 determine. So this whole thing with volume as

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1 a barrier, it may or may not be, because it
2 really depends where patients are referring
3 their primary and tertiary care.
4 DR. BACH: Thank you. In discussions
5 we've talked about race, ethnicity came up at
6 one point as well, happy to talk about that
7 more, it's obviously come up as an issue.
8 Generally the panel sense, individuals on the
9 panel sense about to what extent volume
10 requirements contribute to or create

11 disparities in TAVR access based on either, if
12 I can lump them together, race or ethnicity, or
13 both. I appreciate we've had a lot of
14 discussion on this already, so I'm not trying
15 to, this isn't causing a vacuum in CMS's
16 records. Patrice, did you have something?
17 DR. DESVIGNE-NICKENS: I was just
18 trying to think in some of the solutions that
19 were suggested today about many of the things
20 Ron said, the realm of what this process would
21 do, but when we talk about volume, we're
22 talking about patients. If we put in patient
23 characteristics, they should be high risk
24 patients, there should be gender equity, there
25 should be race, you know, commensurate with the

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1 population, you know. In other words, volume
2 would be, are, you know, the centers doing this
3 can not be able to hand-pick patients. I don't
4 think that's ever intended but if you look at
5 the population that, you know, if you look at
6 the numbers, and particularly that rise in the
7 use of TAVR over time, it looked like, you
8 know, the early days of PCI, you know, a
9 tenfold change in how many patients are being

10 reached appropriately for this procedure, and
11 when you see the minority participation in that
12 rise was negligent, it was absolutely flat over
13 that period. So maybe, you know, again, we
14 could at least ask the physicians, because
15 disparity means that the, you know, it's the
16 health outcomes from one group that was
17 different from another group just on the basis
18 of race, and so if you don't have access to
19 these procedures, you are forcing the
20 disparities so there is a causal, you know,
21 there is that causal relationship, I think.

22 DR. BACH: Thank you very much.

23 Sandy.

24 DR. LEWIS: The challenge as we move
25 forward is that a lot of programs are nearly

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1 maxed out on their ability to perform
2 additional TAVR programs and TAVR procedures,
3 so that as we look forward, there's got to be
4 some consideration for where we're going to be,
5 and it seems to me that volumes of AVR total is
6 probably not something that's on our question
7 list but maybe should be thought about if we're

8 talking about volumes, and ability to build new
9 programs. If this procedure proceeds the way
10 interventional cardiology has over the last 30
11 years, we are going to see huge demand that I'm
12 not sure our current settings are going to be
13 able to provide.

14 There's a need for a hybrid room, a
15 team. I'm not sure why there are still two
16 surgeons on a team, maybe there should be two
17 structural cardiologists on a team. These are
18 things we haven't talked about, but when we're
19 talking about volume and the makeup of a TAVR
20 program, I would think about these things.

21 DR. BACH: Thanks.

22 DR. FELDMAN: Just as a point of fact,
23 there are no --

24 DR. BACH: Name and affiliation,
25 please.

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1 DR. FELDMAN: Oh, Ted Feldman,
2 representing SCAI. There's no data to suggest
3 the programs are maxed out on increasing
4 volume.

5 DR. BACH: Thank you.

6 DR. TURI: Could I just add one

7 geography issue to the race issue, in which I
8 have no specific expertise, but I built a TAVR
9 program in Camden, New Jersey, which has a very
10 large African-American population, and we
11 noticed this disparity almost from the
12 beginning. So I'm just saying it's not, it's
13 clearly more than just geographic availability.
14 i mean, I think Dr. Horne's slide showing the
15 geography, geographic issues, was compelling,
16 but it is just another sign of how there are
17 many other factors.

18 DR. BACH: Thank you, Zoltan. Yes?

19 DR. DESVIGNE-NICKENS: So, something
20 that Dr. Leon mentioned, that the penetration
21 is very poor, and if we are, as we should need
22 to be, more successful because of the improved
23 outcomes from the procedure, it certainly
24 suggests that we need to do something about
25 education, et cetera, that this is, you know,

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1 this is underdiagnosed, undertreated, and that
2 the procedure is probably underutilized.

3 DR. BACH: Great, thank you.

4 Okay. I'm going to draw this section

5 to a close, I'm going to take an unscheduled
6 five-minute break because everyone's been
7 sitting here for two-plus hours having to put
8 up with me. When we get back at three o'clock,
9 we're going to go to the voting, and I'm going
10 to begin with instructions on how to do it.
11 That's in five minutes. Thank you.

12 (Recess from 2:57 to 3:03 p.m.)

13 DR. BACH: We're going to get started
14 please. I know it's been a long day, but --
15 okay.

16 Maria, are there instructions for
17 using the phone, does everyone know how to do
18 that?

19 MS. ELLIS: Yes.

20 DR. BACH: All right. We're going to
21 now do the voting and let me just, a couple of
22 things. One is we are using a new system, I
23 don't get to vote so I have no idea how to do
24 it, but Maria is going to explain it, I hope,
25 but let me say something about the voting.

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1 The questions cannot be altered. We
2 can discuss them for points of clarification,
3 and the objective is to have us all voting on

4 the same question, all understanding it the
5 same way, and having CMS understand our
6 comprehension of it.

7 The other thing I want to say, and
8 these things are difficult, I know in many
9 cases, but our goal is to do our best to
10 refine, be accurate, and then everyone will get
11 an opportunity to vote, in fact it's a
12 requirement to state your vote as well as the
13 electronic thing, as well as the paper ballot,
14 it's a fully redundant system, but also to
15 explain your vote, which allows, if you will,
16 to add a texture to it.

17 I want to say something about some of
18 these questions, and I won't identify
19 particular ones, but you may find along the way
20 that some of the questions feel like questions
21 where we didn't get much today that helps
22 inform the answer. And so I want to point out
23 that it is perfectly okay to vote, and I'm not
24 telling you what your vote should be, but to
25 express, to measure your confidence in this

1 statement both along the dimensions of how you

2 interpret what data you saw as well as the
3 absence of data. So it's okay, for example, to
4 have relatively no confidence if you got no
5 information. You have a chance to then clarify
6 the origin of your vote after you explain it,
7 you can say I voted this way because of X or Y,
8 or whatever X and Y is.

9 That said, Maria, can you, our
10 newfound technology thing?

11 MS. ELLIS: Yes. So instead of using
12 the clicker, we are basically, the panel
13 members, the voting panel members, they will be
14 using either their smart phones or laptops to
15 cast their votes, and once they cast their
16 votes and everyone casts their votes, it's
17 going to show up on the screen, so that's the
18 only difference. Instead of using the clickers
19 that we normally used in the past, but
20 sometimes they get stuck and a vote is not
21 cast, we decided to try something different.

22 And again, the scores will be
23 available after the meeting.

24 DR. BACH: Do they know how to do it?

25 MS. ELLIS: Yes, I'm sorry. Panel

1 members, there are instructions inside your
2 folder. They're only for you, so you guys are
3 the only ones with the instructions. The poll
4 is closed. There you go, the poll should be
5 open.

6 DR. BACH: Okay, I'm going to read the
7 first question, you can enter it
8 electronically, please record it on your sheet,
9 and I will then poll you one by one to both ask
10 your vote and if you want to add any context to
11 it.

12 So the first question is -- but before
13 you vote, if there are questions of
14 clarification around the question as stated,
15 please voice those.

16 The first question is, how confident
17 are you that there is sufficient evidence that
18 a certain threshold of SAVR procedural volumes
19 must be required for hospitals without previous
20 TAVR experience to begin a TAVR program?

21 DR. TURI: Just for clarification,
22 that means you believe there should be a
23 threshold, not the number, or you don't believe
24 there's any fixed number, just that you believe
25 there should be a number.

1 DR. BACH: Yes, you can believe
2 there's a number, perhaps a fixed one or not.
3 The question is, if you will, a directional
4 one, do you believe that there should be,
5 sufficient evidence that some threshold should
6 be required?

7 (The panel voted and votes were
8 recorded by staff.)

9 DR. BACH: Is that everybody?

10 MS. ELLIS: Waiting for one more
11 person. There we go.

12 DR. BACH: Great, that's everyone, and
13 I'll start at the end this time, and I'll just
14 try and fluctuate. Patrice, would you state
15 your vote, record it on a piece of paper, and
16 if you want to add any explanation, you can,
17 you're not required to.

18 DR. DESVIGNE-NICKENS: I voted three,
19 I do think that some threshold is important. I
20 don't think it should be, it remains to be
21 qualified.

22 DR. BACH: Thank you. Mark, and just
23 to clarify, Mark's vote does not count for the
24 scoring, but his views are still recorded and
25 his vote is still heard.

1 DR. CARLSON: On this one I voted --

2 DR. BACH: Oh, I'm sorry, and also
3 Patrice's, I'm sorry. Go ahead.

4 DR. CARLSON: Okay. On this one I
5 voted one. I did that because I didn't see
6 evidence that there was a correlation for SAVR
7 and TAVR, and I also heeded the warnings in two
8 or three of the presentations about the perils
9 of being a patient in need of aortic valve
10 replacement who appears in December to a
11 hospital that is seeking to make the threshold
12 for SAVR and already made their threshold for
13 TAVR.

14 DR. BACH: Okay, thank you. Zoltan.

15 DR. TURI: From my standpoint there
16 wasn't a number, but just that, for the kinds
17 of, for what you need a surgeon for to start a
18 program, without hard evidence, I nevertheless
19 felt that there was, there are plenty of data
20 on surgical competence and volume, so I thought
21 there was high level of evidence that to start
22 a program, you need at least some reasonable
23 volume of surgical experience.

24 DR. BACH: What was your vote?

25 DR. TURI: It was a five.

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1 DR. BACH: Great, thanks. Dan, and
2 please keep your answers concise.

3 DR. OLLENDORF: So, I voted four,
4 because I do agree that there is evidence that
5 a threshold of procedural volume has to be
6 required, and within a hospital without a
7 previous TAVR program, I felt that SAVR was the
8 closest proxy, but because it was a proxy, I
9 didn't go for a five.

10 DR. BACH: Sandy?

11 DR. LEWIS: I voted three. I didn't
12 see a lot of evidence today about SAVR volumes
13 and starting programs, but I have this sense
14 that somebody should know their way around the
15 aorta to be involved in a TAVR startup, so
16 answering the question of sufficient evidence,
17 I wasn't convinced that we saw a lot of
18 evidence about this.

19 DR. BACH: Thank you. Smadar?

20 DR. KORT: I voted five. I still feel
21 that to start, and I think that there is enough
22 data to show that to start a TAVR program, you

23 need to be in a place that knows how to take
24 care of sick patients with severe aortic
25 stenosis and take care of them in the cath lab

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1 or in the hybrid room or something, that's
2 something that needs to take place, and that
3 includes also the nurses and the technicians
4 and everyone around who takes care of these
5 patients.

6 DR. BACH: Naftali?

7 MR. FRANKEL: I also voted five for
8 similar reasons. First of all, that with a new
9 TAVR program, the background and experience of
10 the surgeons certainly could be useful in
11 situations where things do go wrong, obviously
12 that happens less and less now, but I would
13 want the patients to have the confidence that
14 that's in place as a safety net in case that
15 occurs. And also from the team approach, that
16 one of the things that we saw with volumes is
17 it's not always the volume of the individual
18 physician but the hospital as a whole because
19 of their experience when they have more
20 volumes, so I think that would be a practical,
21 practically helpful as well, to have that

22 construct in place when the TAVR program began.

23 DR. BACH: Thank you. Anita?

24 DR. FERNANDER: Based on the evidence

25 presented today, I voted a one.

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1 DR. BACH: Greg?

2 DR. DEHMER: My vote was four. I
3 think the key phrase is sufficient evidence. I
4 think we'd all be very comfortable voting if
5 there were multiple randomized trials that told
6 us what exactly number we should use, if it's
7 50, 30, or a hundred, but we don't have that.
8 Failing that kind of evidence, I think it's
9 important to fall back on the opinion of
10 experts, and fortunately we do have such a
11 document that has been crafted, and I put a lot
12 of weight on that. I know if I had some
13 dreadful disease and there was no randomized
14 trial that really defined my therapy, I would
15 be grateful for what, the advice of a panel of
16 experts, and we have that, and I think there
17 is, using that as a standard, there is
18 sufficient evidence.

19 DR. BACH: Thanks. Michael.

20 DR. CINQUEGRANI: Five. SAVR is an
21 important component of any aortic valve
22 treatment program, and a certain volume
23 threshold should exist.

24 DR. BACH: Aloysius?

25 DR. CUYJET: I voted two. I haven't

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1 seen any evidence that surgical replacement of
2 aortic valve correlates without competency in
3 TAVR, so that's my vote.

4 DR. BACH: Question number two, how
5 confident are you that there is sufficient
6 evidence that a certain threshold of PCI
7 procedural volumes must be required for
8 hospitals without previous TAVR experience to
9 begin TAVR programs?

10 Any questions of clarification? I'm
11 going to guess there aren't, but if there are?
12 No. Please go ahead and vote.

13 (The panel voted and votes were
14 recorded by staff.)

15 DR. BACH: Do we have everyone?

16 MS. ELLIS: Yes, everyone has voted.

17 DR. BACH: Aloysius?

18 DR. CUYJET: Again, low confidence

19 again, because I haven't seen any evidence that
20 the volume and experience with PCI procedures
21 correlates with TAVR outcomes.

22 DR. BACH: You said low confidence,
23 that's a one, right?

24 DR. CUYJET: I voted two.

25 DR. BACH: A two, all right, thank

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1 you. Please make sure you also document your
2 votes on the yellow sheets, you might as well
3 do that right now so no one otherwise loses
4 track. Michael?

5 DR. CINQUEGRANI: Four.

6 DR. BACH: Greg?

7 DR. DEHMER: Almost the same rationale
8 as my previous answer, I voted a four.

9 DR. BACH: Anita?

10 DR. FERNANDER: Again, based on
11 today's evidence, one.

12 DR. BACH: Naftali?

13 MR. FRANKEL: I voted three, only
14 because specific to PCI, you know, there's
15 another option of other proficiencies for
16 procedures other than PCI that were discussed

17 today, so if PCI was the only criteria then I
18 would lean more on the side of a five, but I
19 took a more moderate approach because I'm
20 assuming that that's not the only metric that
21 we would be looking at.

22 DR. BACH: Thanks. Smadar?

23 DR. KORT: I voted five for the same
24 reasons that I mentioned before.

25 DR. BACH: Thank you. Sandra?

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1 DR. LEWIS: I voted four. The reason
2 I didn't go to five was that I didn't think
3 that we heard a lot of evidence today, but on
4 the other hand, I have had a patient who broke
5 a piece of calcium off left main during a
6 procedure, I've had several patients who've
7 needed both PCI and valve implantation, so the
8 skills are in the background material.

9 DR. BACH: Thank you. Dan?

10 DR. OLLENDORF: I voted four, very
11 similar rationale to last time, not a perfect
12 proxy but a proxy nonetheless.

13 DR. BACH: Zoltan?

14 DR. TURI: Four, same rationale as
15 Naftali.

16 DR. BACH: Mark?

17 DR. CARLSON: One, similar rationale.

18 I didn't see data that established a clear

19 correlation.

20 DR. BACH: Thank you. Patrice?

21 DR. DESVIGNE-NICKENS: Yeah, I voted

22 two. I moved more away from feeling that there

23 was good evidence for this.

24 DR. BACH: All right, thank you, and

25 I'll remind everyone, please record your votes

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1 on your yellow sheets.

2 Question number three, how confident

3 are you that the benefits of meeting

4 procedural, that is SAVR or PCI, volume

5 requirements to begin a TAVR program outweigh

6 the harms of limiting access to TAVR to only

7 hospitals that meet volume requirements?

8 (The panel voted and votes were

9 recorded by staff.)

10 DR. BACH: Okay, the mean is 3.11,

11 I'll start at the end. Patrice?

12 DR. DESVIGNE-NICKENS: I voted a two

13 for this. I do think that the risk-benefit is

14 really questionable.

15 DR. CARLSON: One. I didn't see any
16 data that really compared this and looked at an
17 association.

18 DR. TURI: Five. This didn't ask
19 about evidence, this asked about how confident
20 we were, so I thought it was a little easier to
21 answer.

22 DR. BACH: Dan?

23 DR. OLLENDORF: I voted five.

24 DR. BACH: Sandra?

25 DR. LEWIS: I voted one. Certainly

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1 the experience at Cleveland Clinic Florida
2 stood out in my mind for what we heard today.

3 DR. BACH: Smadar?

4 DR. KORT: I voted three for this one.

5 I was torn right in the middle.

6 DR. BACH: Naftali?

7 MR. FRANKEL: I voted two.

8 DR. BACH: Anita?

9 DR. FERNANDER: I voted three, because
10 the question did not ask about evidence
11 received today.

12 DR. DEHMER: I voted three.

13 DR. BACH: Michael?
14 DR. CINQUEGRANI: Four.
15 DR. BACH: Aloysius?
16 DR. CUYJET: I voted two again, for
17 the same reasons for questions one and two, and
18 the technology's advancing and if the system
19 worked as well as it's supposed to, we wouldn't
20 have disparities in gender and ethnicity.
21 DR. BACH: Great, thank you. We're
22 going to move on to hospital -- are there any
23 questions from the panel about any of this
24 process? Okay.
25 We're going to move on to hospital

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1 requirements to maintain a TAVR program, a
2 different domain of questions. Number four,
3 how confident are you that there is sufficient
4 evidence that a certain threshold of SAVR
5 procedural volumes must be required for
6 hospitals with TAVR experience to maintain
7 their TAVR programs?
8 (The panel voted and votes were
9 recorded by staff.)
10 DR. BACH: Aloysius?

11 DR. CUYJET: It's getting boring, but
12 two again, same reason, I haven't seen any
13 evidence to support the question.

14 DR. CINQUEGRANI: Five.

15 DR. BACH: You need to speak into the
16 microphone.

17 DR. CINQUEGRANI: I'm sorry. Five.

18 DR. DEHMER: Four.

19 MR. FRANKEL: Five, with the same
20 rationale.

21 DR. BACH: Anita?

22 DR. FERNANDER: Two.

23 DR. KORT: I voted three. I think
24 that as the TAVR program grows, the SAVR volume
25 is expected to go down, and that should not be

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1 a reason to close programs or not to meet
2 requirements.

3 DR. LEWIS: I voted two for the same
4 reason.

5 DR. BACH: Dan?

6 DR. OLLENDORF: I voted four using
7 logic basically symmetrical to starting a
8 program.

9 DR. TURI: I voted five based on the

10 surgical data, and also with the understanding
11 that the actual number divined may decrease,
12 but there should be some threshold.

13 DR. CARLSON: I voted one because if
14 quality cannot be accurately measured in lower
15 annual volume centers, then it follows that we
16 do not have sufficient evidence to determine
17 whether or not those centers are high or low
18 quality, and thus, whether they should be
19 allowed to continue a program.

20 DR. BACH: Patrice?

21 DR. DESVIGNE-NICKENS: So I actually,
22 I hit two, I meant to hit three, there's
23 nothing I can do to change that? I have it
24 correctly on my voting sheet. I had a similar
25 rationale to number one, that I don't think

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1 there's a sufficient amount of information.

2 DR. BACH: Okay, got it, thank you.

3 DR. DESVIGNE-NICKENS: I have what I
4 wanted on the yellow sheet, if that matters.

5 DR. BACH: I have good news and bad
6 news. The good news is it doesn't matter, the
7 bad news is your vote doesn't count.

8 MS. ELLIS: But you do still say your
9 vote.

10 DR. BACH: Question five, how
11 confident are you that there is sufficient
12 evidence that a certain threshold of PCI
13 procedural volumes must be required for
14 hospitals with TAVR experience to maintain
15 their TAVR programs?

16 (The panel voted and votes were
17 recorded by staff.)

18 DR. BACH: Has everyone voted? Is
19 there anyone who hasn't voted? There we go,
20 thank you.

21 MS. ELLIS: One second.

22 DR. BACH: So the mean is there,
23 everyone's voted. Patrice, go ahead, please.

24 DR. DESVIGNE-NICKENS: Yes, again I
25 voted two. I don't think there's sufficient

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1 evidence to maintain the requirements for
2 volume.

3 DR. BACH: Thanks. Mark?

4 DR. CARLSON: One, for the same
5 reasons.

6 DR. BACH: Zoltan?

7 DR. TURI: Four, same rationale as

8 question two.

9 DR. BACH: Dan?

10 DR. OLLENDORF: Four, same reasons as

11 before.

12 DR. BACH: Sandy? Yes.

13 The first two votes don't count on the

14 tabulation, and I tried to explain that at the

15 beginning. So they're not included in the

16 averages, but people still get to vote and the

17 votes are still recorded, and then CMS

18 processes them, deals with them. Thank you.

19 DR. LEWIS: Three, based on there's

20 not a lot of data, but then expert opinion.

21 DR. KORT: Three, because again, I

22 want to make sure that programs that started

23 have the ability to maintain the program.

24 MR. FRANKEL: Three, reflective of the

25 last question, and also a little bit somewhat

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1 more confidence that the TAVR program already

2 in place, that those that are actually the TAVR

3 operators would have the proficiency to perform

4 PCIs supposedly.

5 DR. BACH: Great. Anita?
6 DR. FERNANDER: Two.
7 DR. BACH: Greg?
8 DR. DEHMER: Four.
9 DR. BACH: Mike?
10 DR. CINQUEGRANI: Five.
11 DR. CUYJET: This verse is the same as
12 the first, two.
13 DR. BACH: Question number six, how
14 confident are you that the benefits of meeting
15 procedural, that is a SAVR, TAVR, PCI, volume
16 requirements to maintain a TAVR program
17 outweigh the harms of limiting access to TAVR
18 to only hospitals that meet volume
19 requirements?
20 (The panel voted and votes were
21 recorded by staff.)
22 DR. BACH: Great, 3.44. Aloysius?
23 DR. CUYJET: I voted three on this
24 one. It's changing the landscape to
25 technology, and skill sets for TAVR are going

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1 to continue to improve, so I think about
2 limited access by appropriate volume
3 requirements for the other procedures.

4 DR. BACH: Michael?

5 DR. CINQUEGRANI: Four.

6 DR. BACH: Greg?

7 DR. DEHMER: Four.

8 DR. BACH: Anita?

9 DR. FERNANDER: Two.

10 DR. BACH: Naftali?

11 MR. FRANKEL: Mine says your answer,
12 no response received, although I voted, so was
13 it calculated?

14 MS. ELLIS: Yes.

15 MR. FRANKEL: So four, and I would
16 hope that there would be public reporting
17 attached to any consideration of
18 liberalization, I just wanted to throw that out
19 there if that's under consideration, just to
20 publicly report the actual volume study.

21 DR. BACH: Smadar?

22 DR. KORT: I voted five again, knowing
23 that there are other metrics that we should
24 look into, but without talking about the
25 specific volumes, there should be some volume

2 DR. LEWIS: I voted one because I just
3 don't like putting them all together like this.

4 DR. BACH: Dan?

5 DR. OLLENDORF: Five, same rationale
6 as with the programs starting up.

7 DR. BACH: Zoltan?

8 DR. TURI: Same thing, five, same
9 rationale.

10 DR. CARLSON: One, same rationale.

11 DR. DESVIGNE-NICKENS: Two, similar
12 rationale.

13 DR. BACH: Question number seven, to
14 begin performing TAVR -- now we're talking
15 about operator requirements. To begin
16 performing TAVR, how confident are you that
17 there is sufficient evidence that a certain
18 threshold of SAVR and TAVR procedural volumes
19 must be required for the principal
20 cardiovascular surgeon on a TAVR heart team?

21 DR. TURI: Can I ask a point of
22 information?

23 DR. CANOS: Yes.

24 DR. BACH: Yes.

25 DR. TURI: So, this suggests that the

1 surgeon to start the program will have to have
2 done both SAVRs and TAVRs, right? In other
3 words, if we felt that it was just SAVRs -- I
4 mean, I know the question can't be changed, but
5 how would you address that if that was the
6 opinion?

7 DR. BACH: That's how I would
8 interpret the question as well.

9 DR. TURI: So it has to be both SAVR
10 and TAVR, or if you feel that it should be SAVR
11 volumes but not necessarily TAVR volumes --

12 DR. BACH: All right. So this gets
13 into when I said we can't change a question but
14 we should all vote on the same question, and we
15 can ask for CMS guidance on this, but we may
16 not get it. I think we can decide whether or
17 not we are voting for the sum of SAVR and TAVR,
18 but maybe not necessarily both for any
19 particular surgeon, or alternatively, both SAVR
20 and TAVR within surgeons.

21 I guess the question to the panel is,
22 which one is more helpful to the Agency to
23 answer? Because I agree it's ambiguous.

24 PANELIST: Will you state the first
25 option again?

1 DR. BACH: Sorry. So, the question
2 could be interpreted as having a threshold of
3 both SAVR and TAVR within a particular surgeon
4 to qualify, or it could be interpreted as the
5 sum of their SAVR and TAVR experience, even if
6 they have zero of one of them. Those are
7 different questions. I would prefer we choose
8 which one we answer, I don't feel like I have
9 the clinical expertise to make that choice, but
10 is it -- Greg, go ahead.

11 DR. DEHMER: Yeah, it says the
12 principal cardiovascular surgeon, so I assume
13 that to mean the surgeon who will be involved
14 in the TAVR procedure.

15 DR. BACH: Right, so is there a
16 question, is there sufficient evidence that a
17 certain threshold of SAVR and TAVR procedural
18 volumes, meaning -- so you would say that that
19 would, we should interpret that as both the
20 SAVR and TAVR experience within that surgeon,
21 right?

22 DR. DEHMER: Yes.

23 DR. BACH: Okay, I'm fine with that.
24 Is there any disagreement?

25 DR. TURI: Yeah. I mean, I think if

1 the surgeon has done 300 SAVRs and no TAVRs,
2 that that should not preclude it, as long as
3 there's experience.

4 DR. BACH: That's an interpretation,
5 but are you comfortable voting on the question
6 of whether or not CMS should be requiring both
7 within the surgeon?

8 DR. TURI: Well, again, I don't know
9 if requiring both means that they will have to
10 have a threshold of TAVR experience.

11 DR. BACH: Hold on. All right,
12 clarification. The intent is, as Zoltan's
13 question suggested, it's either/or, so I guess
14 experience around the aortic valve. All right.
15 Given that clarification, do people feel like
16 they can answer question seven. Okay, go
17 ahead.

18 (The panel voted and votes were
19 recorded by staff.)

20 (Inaudible discussion off the record.)

21 DR. BACH: Okay. While we figure this
22 out, please record your vote on paper for
23 question seven and I'm going to poll everyone,
24 and maybe in the middle of this we will figure

25 this out, otherwise we can do it the old

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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?

23 MS. JENSEN: Well, not Tamara, but

24 Dr. Dehmer voted four.

25 DR. CINQUEGRANI: Five.

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1 DR. CUYJET: Three.

2 DR. TURI: So, the question came up on

3 our computers, so --

4 MS. JENSEN: Why don't we try to

5 revote on that one, just try to vote on what

6 you just said, please revote.

7 DR. BACH: And to clarify, Tamara is

8 reading Greg Dehmer's votes, she's not voting.

9 Okay we're good.

10 Question eight, to begin performing

11 TAVR, how confident are you that there is

12 sufficient evidence that a certain threshold of

13 structural heart disease procedural volumes

14 must be required for the principal

15 interventional cardiologist on a TAVR heart

16 team?

17 (The panel voted and votes were

18 recorded by staff.)

19 DR. BACH: You still have polling

20 closed?

21 MS. JENSEN: Yeah, we're still working

22 on it.

23 DR. BACH: Okay. Could you please
24 record your votes on the paper?

25 DR. LEWIS: Could I ask a clarifying

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1 question?

2 DR. BACH: Absolutely.

3 DR. LEWIS: So it's just procedural,
4 structural heart disease procedural volumes, no
5 specific procedures?

6 DR. BACH: That's correct, that's how
7 I read it as well.

8 DR. LEWIS: Okay.

9 (The remainder of the hearing, from
10 3:38 to 3:48 p.m., was not transcribed due to a
11 loss of audio recording.)

12 (From the video recording, it appeared
13 that the panel announced their votes on
14 question eight, voted and announced their votes
15 on question nine, and then there were closing
16 remarks from Dr. Bach.)

17 (The meeting adjourned at 3:48 p.m.)

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1 STATE OF MARYLAND SS:

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3 I, Paul A. Gasparotti II, a Notary Public of
4 the State of Maryland, do hereby certify that I
5 transcribed from audio file the proceedings to
6 the best of my ability in the foregoing-entitled
7 matter; and I further certify that the foregoing
8 is a full, true and correct statement of such
9 proceedings and a full, true and correct
10 transcript of the audio files produced.

11 IN WITNESS WHEREOF, I have subscribed my name
12 on this 10th day of August, 2018.

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19 My commission expires: September 3, 2019

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