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7 CENTERS FOR MEDICARE AND MEDICAID SERVICES

8 Medicare Evidence Development & Coverage

9 Advisory Committee

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16 August 30, 2017

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18 Centers for Medicare and Medicaid Services

19 7500 Security Boulevard

20 Baltimore, Maryland

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1 Panelists

2 Acting Committee Chair
Aloysius B. Cuyjet, MD, MPH

3 Acting Committee Co-Chair (voting)
4 Marcel Salive, MD, MPH

5 MedCAC Members
Karen Albright, DO, MPH
6 Doug Campos-Outcalt, MD, MPA
Marc Mora, MD
7 Daniel A. Ollendorf, PhD
Renee Williams, MD
8 Adolph J. Yates, Jr., MD
Diana Zuckerman, PhD

9 Industry Representative
10 Robert J. Hilkert, MD, FACC, FAHA

11 Guest Panel Members
Martha W. Betz, PhD
12 Samuel Klein, MD
Dana A. Telem, MD, MPH, FACS, FASMBS
13 Bruce M. Wolfe, MD, FACS, FASMBS

14 Invited Guest Speakers
Orestis Panagiotou, MD, PhD
15 Thomas Trikalinos, MD, PhD
David Arterburn, MD, MPH, FACP
16 Eric J. DeMaria, MD, FACS, FASMBS
Kimberly Marschhauser, PhD
17 Joe Nadglowski

18 CMS Liaison

August 30th MEDCAC Meeting Panel Proceedings JS and LA
Lori Ashby, MA

19
Executive Secretary
20 Maria Ellis
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1 PANEL PROCEEDINGS

2 (The meeting was called to order at

3 8:06 a.m., Wednesday, August 30, 2017.)

4 MS. ELLIS: Good morning and welcome,

5 acting committee chairperson, members and

6 guests. I am Maria Ellis, the executive

7 secretary for the Medicare Evidence Development

8 and Coverage Committee known as MedCAC. The

9 committee is here today to discuss
10 recommendations regarding the appraisal of the
11 state of evidence for health outcomes in the
12 Medicare population for surgical and endoscopic
13 procedures for weight loss.

14 The following announcement addresses
15 conflict of interest issues associated with
16 this meeting and is made part of the record.
17 The conflict of interest statutes prohibit
18 special government employees from participating
19 in matters that could affect their or their
20 employers' financial interests. Each member
21 will be asked to disclose any financial
22 conflicts of interest during their
23 introduction. We ask in the interest of
24 fairness that all persons making statements or
25 presentations disclose if you or any member of

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1 your immediate family owns stock or has another
2 formal financial interest in any company,
3 including an Internet or e-commerce

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4 organization, that develops, manufactures,
5 distributes and/or markets consulting, evidence
6 reviews or analyses, or other services related
7 to bariatric procedures, including surgical,
8 laparoscopic and endoscopic, with or without
9 devices. This includes direct financial
10 investment, consulting fees and significant
11 institutional support. If you have not already
12 received a disclosure statement, they are
13 available on the table outside of the
14 auditorium.

15 We ask that all presenters please
16 adhere to their time limits. We have numerous
17 presenters to hear from today and a very tight
18 agenda, and therefore, cannot allow extra time.
19 There is a timer at the podium that you should
20 follow. The light will begin flashing when
21 there are two minutes remaining and then turn
22 red when your time is up.

23 Please note that there is a chair for
24 the next speaker, and please proceed to that
25 chair when it is your turn. We ask that all

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1 speakers addressing the panel please speak
2 directly into the mic and state your name.

3 For the record, voting members present
4 for today's meeting are Dr. Karen Albright,
5 Dr. Doug Campos-Outcalt, Dr. Marc Mora,
6 Dr. Daniel Ollendorf, Dr. Marcel Salive.
7 Dr. Renee Williams, Dr. Adolph Yates, Jr., and
8 Dr. Diana Zuckerman. A quorum is present and
9 no one has been recused because of conflicts of
10 interest.

11 The entire panel, including nonvoting
12 members, will participate in the voting. The
13 voting results will be available on our website
14 following the meeting. I ask that all panel
15 members please speak directly into the mic.

16 This meeting is being webcast via CMS
17 in addition to the transcriptionist. By your
18 attendance you are giving consent to the use
19 and distribution of your name, likeness and
20 voice during the meeting. You are also giving
21 consent to the use and distribution of any
22 personally identifiable information that you or
23 others may disclose about you during today's

24 meeting. Please do not disclose personal
25 health information.

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

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

18 Please remember to discard your trash

19 August 30th MEDCAC Meeting Panel Proceedings JS and LA
in the trash cans located outside of this room.

20 And lastly, all CMS guests attending
21 today's MedCAC meeting are only permitted in
22 the following areas of the CMS single site:
23 The main lobby, the auditorium, the lower level
24 lobby, and the cafeteria. Any persons found in
25 any other area other than those mentioned will

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1 be asked to leave the conference and will not
2 be allowed back on CMS property again.

3 And now, I would like to turn the
4 meeting over to Ms. Lori Ashby.

5 MS. ASHBY: Thank you and good
6 morning, everyone. I'd like to welcome our
7 panel, our invited speakers and everybody else
8 in attendance here today. This is a topic
9 that's very important to the population that we
10 serve, the Medicare population. There are so
11 many individuals I see in the room here with us,
12 so thank you so much for being here.

13 We have a very tight agenda today, we
14 look forward to this meeting, and without

15 further ado I would like to turn the meeting
16 over to our esteemed chair, Dr. Aloysius
17 Cuyjet. Thank you, Dr. Cuyjet.

18 DR. CUYJET: Good morning. I don't
19 know about the esteemed part, but welcome
20 everybody. I guess this is my fifth MedCAC
21 meeting and they've all been interesting in
22 terms of the presentations and discussions, and
23 they've all addressed important questions for
24 the Medicare population, so I really ask
25 everyone to pay attention to the presentations.

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1 There will be some back and forth with
2 questions at some point, and at the end of the
3 day we'll be asked for some recommendations
4 based on what the presentations support. Thank
5 you.

6 We are going to start by introducing
7 the panel members.

8 DR. ALBRIGHT: I am Karen Albright,
9 I'm from the University of Alabama at

10 August 30th MEDCAC Meeting Panel Proceedings JS and LA
Birmingham.

11 MS. ELLIS: I'm sorry. When the panel
12 members introduce yourselves, could you please
13 disclose your financial interests?

14 DR. CUYJET: I have no disclosures.

15 DR. ALBRIGHT: I have no relevant
16 financial disclosures.

17 DR. CAMPOS-OUTCALT: Doug
18 Campos-Outcalt, University of Arizona College
19 of Public Health. I have no conflicts.

20 DR. MORA: Good morning, everybody.
21 I'm Marc Mora from Kaiser Permanente in
22 Washington, and I have no conflicts of interest
23 to disclose.

24 DR. OLLENDORF: Good morning. Dan
25 Ollendorf with the Institute for Clinical and

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1 Economic Review in Boston. We receive
2 institutional support, we do evidence synthesis
3 and economic evaluations, and we have dealt
4 with bariatric and obesity-related topics in
5 the past. No other conflicts to disclose.

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6 DR. SALIVE: Good morning, I'm Marcel
7 Salive, from the National Institute on Aging,
8 which is part of NIH, and I have no conflicts.

9 DR. WILLIAMS: Good morning, I'm Renee
10 Williams, from the New York University School
11 of Medicine. I own stock in Boston Scientific,
12 and I have no other conflicts to disclose.

13 DR. YATES: Adolph Yates, University
14 of Pittsburgh Medical Center. No conflicts of
15 a financial nature.

16 DR. ZUCKERMAN: Diana Zuckerman,
17 National Center for Health Research. I have
18 stock in Johnson & Johnson.

19 DR. HILKERT: Good morning all, Bob
20 Hilkert from Novartis Pharmaceutical. I am the
21 industry representative to the panel and I'm a
22 full-time employee of Novartis Pharmaceutical
23 Corporation.

24 DR. BETZ: Good morning, I'm Martha
25 Betz, I'm a biomedical engineer and I have

1 August 30th MEDCAC Meeting Panel Proceedings JS and LA
nothing to disclose.

2 DR. KLEIN: Sam Klein, Washington
3 University School of Medicine in St. Louis. I
4 am a shareholder and consultant for Inspire
5 Bioethics and also receive grant support from
6 Johnson & Johnson for metabolic studies in
7 obesity, and a consultant for Janssen
8 Pharmaceuticals.

9 DR. TELEM: I'm Dana Telem at the
10 University of Michigan, and I'm a consultant
11 for Medtronic.

12 DR. WOLFE: I'm Bruce Wolfe from
13 Oregon Health and Science University in
14 Portland. No disclosures.

15 DR. CUYJET: All right. The first
16 presentation comes from Sarah Fulton, and
17 before she starts, could the next speaker
18 please occupy the chair that Maria pointed out?
19 Thank you.

20 MS. FULTON: Good morning. My name is
21 Sarah Fulton, I'm an analyst in the Coverage
22 and Analysis Group here at CMS. Thank you all
23 for joining today's meeting. We're looking
24 forward to a productive discussion around this

August 30th MEDCAC Meeting Panel Proceedings JS and LA
25 very important and complex topic.

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1 Medicare currently has two national
2 coverage determinations for services related to
3 treatment for comorbid conditions related to
4 obesity. NCD 100.1, bariatric surgery for
5 treatment of morbid obesity, covers open and
6 laparoscopic Roux-en-Y gastric bypass, open and
7 laparoscopic biliopancreatic diversion duodenal
8 switch or gastric reduction duodenal switch,
9 and laparoscopic adjustable gastric banding.
10 Eligible beneficiaries must have a BMI of 35 or
11 greater, at least one comorbidity related to
12 obesity, and have been previously unsuccessful
13 with medical treatment for obesity.

14 NCD 100.1 also non-covers treatment
15 for obesity alone, supplemental fasting as a
16 general treatment for obesity, open adjustable
17 gastric banding, open sleeve gastrectomy, open
18 and laparoscopic vertical banded gastroplasty,
19 intestinal bypass surgery, and gastric balloon
20 for treatment of obesity.

21 Under this NCD and for beneficiaries
22 with a BMI of 35 or greater and at least one
23 comorbidity related to obesity, and who have
24 been previously unsuccessful with medical
25 treatment for obesity, Medicare administrative

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1 contractors have discretion to determine
2 coverage for standalone laparoscopic sleeve
3 gastrectomy for the treatment of comorbid
4 conditions related to obesity. The MACs also
5 have discretion to determine coverage for any
6 bariatric surgery procedures not specifically
7 covered or noncovered through an NCD.

8 NCD 210.12, intensive behavioral
9 therapy for obesity, covers intensive
10 behavioral therapy consisting of dietary
11 assessment and intensive behavioral counseling
12 and behavioral therapy to promote sustained
13 weight loss through high intensity
14 interventions on diet and exercise for
15 beneficiaries with a BMI of 30 or greater.

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16 Beneficiaries must be competent and alert at

17 the time of counseling, and counseling must be
18 provided in a primary care setting and by a
19 primary care physician or other primary care
20 practitioner.

21 CMS covers one face-to-face visit
22 during the first month of services, one
23 face-to-face visit every other -- I'm sorry --
24 one face-to-face visit each week for the first
25 month of services, one face-to-face visit every

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1 other week for months two through six, and then
2 one face-to-face visit every month for the last
3 six months of the program, should the
4 beneficiary achieve a weight loss of three
5 kilograms during the first six months of
6 services.

7 Despite evidence assessing surgical
8 bariatric therapies, evidentiary questions
9 remain regarding clinically meaningful health
10 outcomes for Medicare beneficiaries and
11 informed decision-making for patients. It's

12 important to identify the information
13 beneficiaries need to make informed treatment
14 decisions with their providers. As such, it is
15 important to facilitate meaningful health
16 outcomes to address outstanding evidentiary
17 questions so as to inform Medicare coverage
18 policies and, very importantly, to assist
19 beneficiaries in making informed decisions with
20 their providers about their own care.

21 This figure from Boyd Swinburn and
22 colleagues' first article in a series on
23 obesity from Lancet in 2011 highlights the
24 complexity of obesity and the wide range of
25 influencing factors that depending upon each

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1 individual's situation, may encourage or impede
2 improvements and reductions in the prevalence
3 of obesity.

4 The purpose of today's meeting is to
5 obtain recommendations from the MedCAC
6 regarding the appraisal of the state of

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7 evidence for health outcomes in the Medicare
8 population for surgical and endoscopic
9 procedures for weight loss. Of particular
10 importance is the identification of evidence
11 gaps related to treatments for obesity and
12 related comorbidities, and discussion of
13 efforts aimed at patient-centered care.

14 Today we will discuss clinical study
15 endpoints and patient outcomes, both weight
16 loss and non-weight loss-related, duration of
17 intervention effects, evidence gaps, how these
18 elements impact patient decision-making, and
19 how to provide support for patient
20 decision-making.

21 In the afternoon session the panel
22 will vote and provide additional discussion on
23 the following questions. When voting, one is
24 equivalent to low confidence and five is
25 equivalent to high confidence.

1 Voting question number one. How
2 confident are you that the following are

3 meaningful primary health outcomes in research
4 studies of bariatric surgery? A, weight loss;
5 B, postoperative complications; C, diabetes and
6 other health outcomes; E, respiratory outcomes;
7 F, musculoskeletal outcomes; and G, quality of
8 life.

9 Voting question number two. How
10 confident are you that there is sufficient
11 evidence for an intervention, to include open
12 and laparoscopic surgeries and endoscopic
13 procedures, where the benefit outweighs the
14 harm for: Short-term weight loss, defined as
15 two years or less from surgery; mid-term weight
16 loss, defined as more than two but less than
17 five years from surgery; long-term weight loss,
18 more than five years after surgery.

19 For outcomes listed in question one
20 with voting scores greater than 2.5, how
21 confident are you that there is sufficient
22 evidence for an intervention, to include open
23 and laparoscopic surgeries and endoscopic
24 procedures, where the benefit outweighs the
25 harm for: Short-term outcomes, mid-term

1 outcomes and long-term outcomes.

2 Voting question number four. How
3 confident are you that the predictors of
4 success in the Medicare population, such as
5 patient characteristics and pre- and
6 post-procedure standards of care, for any
7 bariatric therapy is known?

8 There is additional discussion, list
9 the predictors of success and the corresponding
10 strength of evidence.

11 There are three additional discussion
12 questions for the day. One, discuss important
13 evidence gaps that have not been previously or
14 sufficiently addressed. Two, discuss any known
15 treatment disparities. Three, considering both
16 existing and new procedures and devices as well
17 as potential barriers to care, discuss any
18 mechanisms that might be supported by CMS that
19 would more quickly generate an improved
20 evidence base that would underpin improved care
21 and decision-making for the Medicare population

22 August 30th MEDCAC Meeting Panel Proceedings JS and LA
affected by obesity.

23 Thank you.

24 DR. CUYJET: Our next presenter is

25 Dr. Eric DeMaria.

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1 DR. DEMARIA: Good morning. My name
2 is Eric DeMaria, I'm a bariatric surgeon in
3 Richmond, Virginia, and an officer, an elected
4 officer of the American Society for Metabolic
5 and Bariatric Surgery. My assignment was to
6 talk about surgical and endoscopic procedures
7 and to present evidence.

8 My disclosures are essentially
9 speaking honoraria from several companies
10 involved in the field.

11 So, I have been given a broad
12 assignment, to begin with the basics of
13 bariatric surgeries, and proceed all the way to
14 the highest available level of evidence
15 supporting issues with those procedures. We're
16 going to talk about procedure outcomes,
17 durability, safety, survival issues. We're

18 going to focus on comorbidity treatment issues
19 and we're going to talk about quality and
20 patient safety. We're going to also touch on
21 some of the newer treatments, including the
22 endoscopic treatments that have been mentioned.

23 Obesity is a chronic disease. There
24 are a number of major healthcare organizations
25 that have come out to state this emphatically,

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1 including our American Medical Association in
2 2013. From the endocrine society we see that
3 it is one of the most common and costly chronic
4 disorders worldwide; estimates suggest that in
5 the United States obesity affects one-third of
6 adults and accounts for up to one-third of
7 total mortality and is concentrated among lower
8 income groups, and affects children as well as
9 adults. This disease requires treatment and
10 we're going to talk about various
11 interventions, and also the concept of a
12 continuum of care for obese persons.

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13 Now, this is the bariatric surgery 101
14 portion of my talk. This is the four most
15 commonly done surgical procedures, and we're
16 going to mention two terms that underpin the
17 classic understanding of procedures,
18 malabsorption, which involves intestinal bypass
19 to some extent to decrease nutrient absorption,
20 to the concept of restriction, which is gastric
21 surgery to reduce the gastric eating capacity.
22 So this profile of procedures from left to
23 right from the duodenal switch operation
24 through to the adjustable gastric band is
25 increasing levels of restriction and decreasing

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1 levels of malabsorption. Again, I'm talking in
2 a classic sense and I'll explain that more in a
3 minute.

4 Typically restrictive procedures have
5 less weight loss than malabsorption procedures,
6 so there's a spectrum of outcomes there. And
7 then also, one of the reasons behind the
8 development of restrictive properties was to

9 try and reduce surgical risk and long-term
10 nutritional risk in the patient population, so
11 the more restrictive, typically the less risk
12 of malnutrition, for example.

13 Well, there is obviously a continuum
14 of the disease of obesity, and our focus with
15 surgery has traditionally been on the body mass
16 index of 40 or greater patient population, but
17 there's a large population of patients in the
18 lower range of BMI from 30 to 40, and this is
19 perhaps where the procedures like the
20 intragastric balloon, the endoscopic procedures
21 and the less invasive procedures fit as seen
22 here, as new FDA-approved interventions. And
23 I'm going to cluster those procedures now to
24 the right on that spectrum of care because they
25 tend to demonstrate overall less weight loss

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1 than the invasive surgical procedures, but at
2 the same time potentially demonstrate lower
3 risk of complications, better safety profiles,

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4 so that's in my view where they fit on the
5 spectrum of care.

6 Well, I mentioned the classic terms of
7 restriction and malabsorption, and there is an
8 active discussion in our specialty as to
9 whether those terms are even appropriate today,
10 because what we have learned is that there are
11 metabolic and physiologic mechanisms that
12 underlie the effectiveness of these procedures,
13 specifically in the area of gut hormones that
14 are affected by most of the procedures that we
15 use today.

16 Interestingly, on the list is the idea
17 that you can consume lower calories but
18 preserve your energy expenditure, which is
19 notably different than most diet approaches to
20 weight loss treatment. And of course, the
21 emerging evidence in the microbiome that what
22 we do to the gut may actually influence the
23 microbiome, which will lead to changes in body
24 weight.

25 So this is some evidence talking about

1 diets from the television show that obviously
2 received a lot of attention, The Biggest Loser,
3 and this is an example of what was published
4 regarding the six-year outcomes of those
5 individuals from the TV program who had drastic
6 weight loss induced by diet and exercise. And
7 as we look at the results of 30 weeks versus
8 six years, what you will see is that there is
9 one individual that demonstrated persistent
10 successful weight loss, as opposed to the
11 metabolic adaptation phenomenon that led to
12 weight regain in every other individual who had
13 the motivation to appear on television to lose
14 weight. That individual was the one individual
15 who underwent bariatric surgery in this cohort
16 of patients.

17 So we have a spectrum of gut hormones
18 that are affected by our GI surgical
19 procedures, and this is beyond the scope of
20 this presentation to go into great detail, but
21 they have effects on society, they have effects
22 on the GI tract, and they have effects on the
23 central nervous system, that probably underpin

24 our surgical treatment methodologies.

25 And Lee Kaplan, from Harvard, has

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23

1 spent a lot of time and effort studying the
2 mechanisms, again beyond the scope of our
3 presentations today, but it is very likely that
4 our concepts of restriction are actually
5 misleading. For example, sleeve gastrectomy,
6 seen on the right here in this slide, one would
7 think that this would delay gastric emptying
8 and be a restrictive procedure; however, we
9 actually see accelerated gastric emptying,
10 accelerated nutrient exposure to the small
11 bowel, and therefore, changes in the gut
12 hormones which tend to support weight loss over
13 time.

14 So, let's plunge into outcome data now
15 that we've had that whirlwind introduction to
16 bariatric surgical procedures, and let's look
17 at long-term outcomes with the various
18 procedures. This is a study I'm going to refer

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19 to repeatedly this morning, the Swedish Obese
20 Subjects study from Sweden, which is a
21 prospective controlled interventional study of
22 bariatric surgery. The reason to focus on this
23 is our focus here will be on long-term
24 outcomes, and this study has been going on now
25 for many years in Sweden.

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1 So right off the bat, we see a
2 difference in survival between the control
3 population and the surgically treated
4 population, with an adjusted hazard ratio of
5 0.71 for the surgically treated patients. Now
6 here is an example of the surgical procedures
7 that were done in that trial, showing that
8 banding and vertical banded gastroplasty,
9 specifically VBG, an operation that is no
10 longer performed, were the main procedures.
11 But you can see the example of weight loss that
12 we have here, persistence of a 20 percent loss
13 of body weight in the banding category, and
14 closer to 30 percent long term in the gastric

15 bypass treated population. And an effect on
16 comorbidities was long term, with the reduction
17 in diabetes in the surgically treated cohort
18 most notably.

19 When we look at the various results
20 that have been published from the SOS trial, we
21 see a reduction in mortality that did not
22 matter if the BMI was above or below the median
23 BMI of the patient population, a reduction in
24 cardiovascular mortality, a dramatic reduction
25 in cancer mortality in this study, and diabetes

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25

1 prevention with a hazard ratio of a 0.2 to 0.25
2 percent range.

3 So, this is not the only study that
4 looks at long-term outcomes regarding survival.
5 Christou, from Canada, looked at survival long
6 term, found an 89 percent reduction in
7 mortality in the surgically treated cohort
8 compared to the nonsurgical cohort.

9 And Flum in the United States, in

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10 Washington State, a 33 percent reduction in

11 death after four years.

12 Adams' study in Utah in the United
13 States is extremely meaningful as far as
14 survival, an adjusted mortality decrease of 40
15 percent in the surgically treated cohort of
16 patients, a reduction in coronary artery
17 disease of 56 percent, diabetes of 92 percent,
18 and cancer of 60 percent in that study.

19 So let's go on to look at weight loss
20 and comorbidity outcomes of the commonly
21 performed procedures, and emphasize the
22 long-term follow-up that we have available. So
23 in reviewing the literature for the procedure
24 of gastric bypass and focusing on studies that
25 have five or more years of follow-up, within

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1 the last five years we identified 38 peer
2 reviewed publications that demonstrate a range
3 of weight loss, excess weight loss between 50
4 and 72 percent, total body weight loss in the
5 range of 19 to 35 percent, and the follow-up

6 range from five to 14 years postop.

7 So I'm going to give you some
8 representative studies here that reflect the
9 body of evidence that we have with the gastric
10 bypass, this is a procedure by Himpens showing
11 the weight loss results over time going out to
12 nine years. The excess BMI loss, 56.2 percent,
13 diabetes resolution 80 percent, and new onset
14 diabetes in 27 percent, and no link between
15 weight regained and the idea of new onset
16 diabetes from this trial.

17 Here's 10- to 13-year data looking at
18 134 patients at ten or more years after gastric
19 bypass with reduction of excess weight in the
20 range of 59 percent, diabetes of 58 percent,
21 dyslipidemia is 46 percent, and hypertension is
22 46 percent, and you can see the weight loss
23 result curve there.

24 11-year results in 384 patients after
25 primary gastric bypass. You can see the excess

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1 BMI points lost on the Y axis of the graph

2 going out to as much as 17 years after gastric

3 bypass surgery, with a reduction in diabetes of

4 72 percent, triglyceridemia of 62 percent.

5 Shifting gears a little bit to the

6 vertical sleeve gastrectomy procedure, although

7 a newer procedure in the bariatric spectrum of

8 procedures, we have recently reviewed this and

9 found ironically the same number, 38 peer

10 reviewed studies that provide five or more

11 years of follow-up available in over 2,000

12 patients. The excess weight loss with this

13 procedure ranged from 37 to 86 percent, and

14 this is a table just showing the various

15 studies and the weight loss results. I don't

16 know if I can use this as a pointer, but the

17 weight loss at the end of the follow-up period

18 is listed, and ranges from 40 percent excess

19 weight loss up into the 80 percent or more

20 range in these trials, and they're all listed

21 individually here and here on this slide. I

22 know it's a busy slide. Everyone should

23 hopefully have copies of the presentation for

24 you to peruse at your leisure.

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1 we actually have some randomized control trial
2 data from this procedure and there are now 17
3 studies in the surgical literature that provide
4 ten-year follow-up outcomes of adjustable
5 gastric band procedure.

6 So here's one of the randomized trials
7 looking at gastric band surgery in overweight
8 patients, not obese, and this is just given as
9 an example of the lower BMI cohort of patients
10 with 30 to 40 range, and that top left graph
11 demonstrates the weight changes in the surgical
12 arm with significant weight reduction, and this
13 was diabetic patients, so in the second graph
14 at the top right you see the hemoglobin A1c
15 depressed significantly by the surgical
16 treatment of these patients.

17 There has been a randomized controlled
18 trial comparing the adjustable gastric band to
19 the Roux-en-Y gastric bypass procedure, and
20 this is an example of the weight loss data in

21 the top graph here, but to summarize, the
22 Roux-en-Y gastric bypass was found to be
23 superior to the band in terms of excess weight
24 loss, 76 percent versus 46 percent at ten-year
25 follow-up. The bypass had a higher early

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1 complication rate than the band at eight
2 percent versus zero. And there are some
3 potentially lethal long-term effects of gastric
4 bypass; as I had mentioned previously, the risk
5 profile is higher with that type of procedure
6 versus the gastric banding procedure.

7 Here is a study looking at
8 reoperations, a systematic review looking at
9 reoperations in the adjustable gastric banding
10 population. The reoperation rate with the
11 gastric band is 23 percent at the end of
12 long-term follow-up in this review article, and
13 that is seen in the right-hand graph. You see
14 the explantation rate at 23 percent with this
15 long-term follow-up study. Excess weight loss

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16 in the 40 to 50 percent range in this long-term
17 study.

18 The Swedish adjustable gastric
19 banding, the ten-year experience has been
20 reported to be similar. Here is data out to
21 seven and eight years after that procedure,
22 with BMI averaging in the range of 30 with that
23 trial here.

24 And then complications were the focus
25 of this study looking at 785 patients. A rate

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1 of esophagitis of 29 percent was the greatest,
2 most frequent complication, then about 10
3 percent port problems and so forth on down the
4 line. Again, this is information you should
5 have to be able to review in more detail.

6 And then reoperations for such
7 problems, pouch dilation, port problems, band
8 migration, in the range of about five to six
9 percent.

10 Just a couple more studies. The red
11 here is loss to follow-up, the black lines are

12 band removals seen at a single center over the
13 course of up to 16 years after surgery. There
14 is a progressive increase in the removal of the
15 adjustable gastric bands over time.

16 Here's another where the red line is
17 the band removal rate out to 19 years after
18 adjustable gastric banding, and therefore,
19 clearly one could draw the conclusion that
20 banding does not work for every patient.

21 So, another identified group that
22 potentially is problematic with the adjustable
23 gastric band is the high BMI population. This
24 study of the super obese, 186 patients with a
25 BMI of 50 or greater looking at band removal,

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1 and you can see a progressive increase over
2 time out to 14 years after surgery.

3 In addition, there has been a
4 publication from the Michigan group looking
5 specifically at Medicare, both population and
6 expenditures, for the adjustable gastric band,

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7 and what you see on the bottom left, that
8 phenomenon is the costs for application of the
9 adjustable gastric band, and the dark bar is
10 the index procedures, the white part of the bar
11 is the reoperative procedures, and you can see
12 a shift with decreasing the index procedure
13 costs and an increase in the reoperative costs.
14 Overall the costs have declined over the years,
15 probably as the adjustable gastric band begins
16 to assume its appropriate frequency in the
17 obese population as compared to some years ago
18 where it was widely applied.

19 To complete the four procedures, the
20 duodenal switch, 14 studies now published with
21 more than five-year follow-up, 3,700 patients
22 followed from five to 20 years. Excess weight
23 loss ranging from 63 to 93 percent, and then a
24 subset of super obese patients, BMI greater
25 than 40, demonstrating an excess weight loss

1 greater than 64 percent, which is significant
2 as far as how effective this operation is for

3 the super obese.

4 Again, the same kind of very busy
5 table looking at the outcomes of the duodenal
6 switch for the various studies that I've just
7 summarized very briefly, and you can see the
8 long-term follow-up demonstrates 60 to 90
9 percent reduction of excess weight in this
10 population.

11 There are randomized trials looking at
12 duodenal switch compared to, for example here,
13 gastric bypass, and typically the result is as
14 seen here, where the weight loss is somewhat
15 superior with the duodenal switch operation,
16 carried out to a long-term follow-up here of
17 50 -- I'm sorry -- 60 months follow-up.

18 So let's transition a little bit into
19 comorbidities. This is referring back to the
20 SOS trial data looking at remission of type 2
21 diabetes, the control group in green, the
22 surgical cohort in blue, and out to ten years.
23 So there's a significant decrease in the
24 incidence of diabetes and an increase in the
25 remission of diabetes in the surgically treated

1 cohort.

2 Another interesting finding in the
3 prevention of new onset diabetes, a protective
4 effect of surgical treatment versus the control
5 cohort of patients as seen here.

6 This is a look at both microvascular
7 and macrovascular complications of diabetes
8 from the SOS data showing the various control
9 and surgically treated groups and how they
10 differentiate. On the left is microvascular
11 and diabetes complications and on the right is
12 macrovascular complications, so a benefit of
13 surgical treatment.

14 This is the 11 randomized trials
15 looking at surgical versus medical treatment of
16 type 2 diabetes with a total N of 794 patients,
17 and you can see the various remission criteria
18 listed in terms of hemoglobin A1c for the most
19 part in these studies. The far right is the
20 attainment of the goal of remission as defined
21 by A1c, and one striking feature of these

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22 trials is how infrequently the control group
23 attains the goal of remission. The highest
24 rate in these studies is 16 percent -- I'm
25 sorry -- 23 percent of the nonsurgically

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1 treated control group attained the remission
2 objective, as opposed to the surgically treated
3 arm where the results typically are in the
4 range of 50 to 70 percent attaining the goal of
5 diabetes remission, so fairly compelling high
6 level evidence of the benefit of surgical
7 treatment for diabetes versus medical
8 treatment.

9 One representative study we'll spend a
10 moment on is the five-year results of the
11 STAMPEDE trial, and here we have three arms in
12 this randomized trial, medical therapy, gastric
13 bypass, and vertical sleeve gastrectomy. Both
14 bypass and sleeve demonstrated superiority in
15 terms of attainment of hemoglobin A1c less than
16 six percent, the bypass group 29 percent, the
17 sleeve 23 percent, the medical treatment group

18 five percent, and often this was done without
19 medications.

20 As you can see in the second row, the
21 hemoglobin A1c less than six percent, none of
22 the medical treatment group attained that
23 clearly, the bypass 22 percent, the sleeve 15
24 percent, both of these outcomes significant.

25 Hemoglobin A1c over the course of five

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1 years, the top line is the medical treatment
2 cohort, the gastric bypass and sleeve are
3 clustered at the lower ends with more dramatic
4 reductions in hemoglobin A1c persistent out to
5 five years. And of course this is in the
6 setting of significant weight loss, so here's
7 the change in body mass index found in the
8 medical group with very little change, and then
9 the surgical groups, the two surgical cohorts
10 of band and -- sorry -- of bypass and sleeve,
11 demonstrating significant weight loss.

12 And then just another interesting

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13 observation, it doesn't seem to matter if your
14 body mass index is in the classic range for
15 surgical treatment of a BMI of 35 or more, or
16 less than 35 in the presence of diabetes. The
17 surgically treated groups are seen at the
18 bottom, the medical treatment groups are seen
19 at the top of this graph, and there is no
20 difference between the two BMI ranges studied.

21 Adverse events were at a low rate in
22 the surgically treated population despite the
23 invasiveness of surgery.

24 So here's a meta-analysis summary of
25 all studies of metabolic surgery that have

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1 looked at diabetes, 94 studies, nearly 95,000
2 surgical patients. Studies that have BMI less
3 than 35 are clustered at the top. Studies
4 where the body mass index is in the more
5 traditional range for bariatric surgery at 35
6 or greater, the diabetes remission rate, 71
7 percent in the classic group and then in the
8 low BMI population it was 72 percent, really no

9 difference in diabetes outcome between the two
10 BMI groups.

11 The AHRQ has done a systematic review
12 of this that I'm not going to spend much time
13 on, just supporting the idea that diabetes
14 treatment is potentially beneficial with the
15 low BMI patient population. So here is, again,
16 the odds ratio of diabetes remission in the 11
17 randomized trials of surgeries versus
18 medications or lifestyle change, on the right
19 you can see as you go down this list the BMI is
20 ascending, and there's the division between BMI
21 less than 35 and more than 35, again, really no
22 difference. To the right is the outcomes that
23 favor the surgical treatment, and that is true
24 of every study that has looked at this
25 question, surgical superiority is similar in

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1 BMI less than 35 and greater than 35.

2 The American Diabetes Association and
3 45 other diabetes treatment organizations

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4 around the world have endorsed some changes in
5 their recommendations regarding consideration
6 of surgery for treatment of the comorbidity of
7 diabetes, metabolic surgery for type 2 diabetes
8 should be recommended for patients with BMI
9 greater than or equal to 40 regardless of
10 glycemic control, recommended for patients with
11 BMI greater than or equal to 35 with
12 inadequately controlled hyperglycemia, which
13 unfortunately is all too common the case today
14 in our country, considered for lower body mass
15 index patients with inadequately controlled
16 hyperglycemia in the BMI of 30 to 34.99 range.

17 And then the specific mention of the
18 Asian population in which diabetes tends to
19 begin at lower levels of BMI, with a BMI as low
20 as 27.5 for those patients who have inadequate
21 control of hyperglycemia. So, a treatment
22 algorithm has changed with the institution of
23 new ADA guidelines that favor the idea of at
24 least consideration of surgery to treat this
25 metabolic disease at lower BMI levels.

1 So in conclusion, the evidence for
2 metabolic surgery for type 2 diabetes is very
3 good and supported by randomized controlled
4 trials, and we have these widely endorsed
5 international guidelines that included
6 evidence-based recommendations for surgery to
7 treat diabetes and other comorbidities.

8 And this has been considered by other
9 payers. The California Technology Assessment
10 Forum has considered surgery for diabetes in
11 BMI less than 35 patients, and their panel
12 voted unanimously that the evidence is adequate
13 to demonstrate the net health benefit of
14 bariatric surgery is greater than conventional
15 weight loss management.

16 So, turning now to the comorbidity of
17 cardiovascular disease, surgical weight loss
18 impacts cardiovascular disease by a number of
19 mechanisms. Odds ratio here for various
20 outcomes from a cardiovascular standpoint, here
21 seen is an odds ratio of comparing nonsurgical
22 controls and mortalities for patients who had
23 bariatric surgery, of 0.48; a reduction in MI in

24 the odds ratio of 0.46; stroke, 0.49, with
25 various studies.

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1 Here is a look at fatal cardiovascular
2 events. Seen on the left-hand side over time,
3 the hazard ratio in the surgically treated
4 group, 0.56, and total cardiovascular events,
5 less impressive at 0.83.

6 And in this table, which is very busy,
7 I understand, the top line in each of the two
8 sections is the surgery yes versus no, outcome
9 for cardiovascular events, seen on the top left
10 in the middle is MI, and on the right is
11 stroke. The hazard ratio for cardiovascular
12 events, 0.47 for surgery compared to no surgery
13 in this compilation of data, so quite a bit of
14 evidence that surgery reduces the
15 cardiovascular risk in patients who have been
16 treated that way.

17 Heart failure is a big issue in the
18 United States, more than four million

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19 hospitalizations for heart failure, a 20 to 50
20 percent readmission rate, and when you look at
21 outcomes from a cardiac function standpoint,
22 you see improvements in the ejection fraction
23 in the surgically treated cohort
24 postoperatively. And then here's a look at
25 weight loss and heart failure with the

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1 procedure of gastric bypass compared to
2 lifestyle and medication treatments, and a
3 significant decrease in the issues related to
4 heart failure with the surgical treatment
5 group. And then this is a look at emergency
6 department visits and hospitalizations for
7 heart failure. The line down the middle is the
8 division line of bariatric surgery being
9 applied, so a fairly significant decrease in
10 the rate of ED visits or hospitalization for
11 heart failure exacerbations in the 24 months
12 following bariatric surgery.

13 Let's turn our attention, I know this
14 seems like a whirlwind, believe me, I'm

15 exhausted trying to do this, but let's turn to
16 cancer. There is obviously cancers that have a
17 strong obesity link in terms of their
18 development, and intentional weight loss is
19 emerging as a strategy for cancer therapy as
20 well as cancer prevention.

21 So we'll look here at the SOS study
22 again, we keep reverting back to this. There's
23 a difference between males and females in terms
24 of reduction of cancer. On the right is the
25 female patient population from that study

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1 looking at, the cumulative cancer index is
2 depressed by surgical treatment.

3 This is particularly noteworthy
4 because we're talking about the older
5 population with the far right-hand of this
6 diagram, looking at non-gastric bypass compared
7 to gastric bypass, this is the data from Utah
8 in the United States, and a very significant
9 reduction in the hazard ratio of cancer in the

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10 surgically treated cohort. Again, it tends to

11 be in some studies more prevalent in females,
12 but in this study as well, included with males.

13 So again, I've identified here the age
14 55 to 74 population, this is from Utah once
15 again. Overall, a reduction in all-cause risk
16 of mortality, but specifically cancer-related
17 deaths, the hazard ratio is 0.54 in the
18 surgically treated cohort of patients.

19 So, let's look at a meta-analysis of
20 cancer. Six observational studies comparing
21 the relative risk of cancer in bariatric
22 surgery patients versus controls. Again, a
23 striking positive outcome for the female
24 patient population with the relative risk being
25 0.68 for women versus men.

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1 And here you see a graphical
2 representation of the data from this review
3 showing particularly a relative risk reduction
4 in females, as seen on the left side of this
5 diagram.

6 So, endometrial cancer, just to refer
7 to a couple of the well-known obesity-related
8 cancers, bariatric surgery is associated with a
9 71 percent risk reduction for uterine cancer.
10 And here is a look at adenocarcinomas of the
11 esophagus where there's a relationship with
12 body mass index, this is the incidence of
13 esophageal carcinoma related to body mass index
14 in males and females.

15 And then a meta-analysis looking at
16 colorectal cancer incidence, which was
17 significantly lower versus non-operated obese
18 individuals, so the relative risk was 0.73
19 percent, with a 27 percent lower risk of
20 colorectal cancer in the bariatric surgery arm.

21 And liver cancer, 61 percent lower
22 prevalence of liver cancer compared to those
23 patients who have no history of bariatric
24 surgery, and very significant.

25 So now we'll turn briefly to quality

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1 and patient safety, which has been a major
2 focus of work for the bariatric surgery
3 specialty in recent years, and I will introduce
4 you to this graph which you may or may not have
5 seen looking at mortality. This is the
6 University Hospital Consortium data going back
7 to 2002 to 2009. This was a period of dramatic
8 reduction in risk for bariatric surgery, going
9 from four percent to one-half of one percent
10 over the course of a few years.

11 This is Medicare data looking at the
12 same issue, mortality. The dividing line here
13 is the 2006 national coverage decision, and you
14 can see a general decrease over the same
15 general period of time in mortality. And in
16 fact if you try to superimpose these two lines,
17 you'll see something that we commonly see, is
18 that the Medicare population is well
19 represented by some of our other cohorts of
20 data. The red dots here are the Medicare
21 outcomes on mortality, the red line is the NCD
22 time period in 2006. So you see these things
23 line up, it's an overall reduction in
24 significant risk of complications over the

25 August 30th MEDCAC Meeting Panel Proceedings JS and LA
course of time.

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1 And here's some more Medicare data
2 looking at 2010 gastric bypass specifically
3 where the mortality was 0.2 percent, and this
4 compares favorably with various other commonly
5 done procedures, including most notably
6 cholecystectomy, and having a higher mortality
7 than gastric bypass surgery in the United
8 States.

9 We have this study looking at the
10 elderly, which is a Medicare eligible
11 population. Typically studies of the elderly
12 patient reveal a higher rate of comorbidity in
13 the older patient population undergoing
14 bariatric surgery. And for example, you can
15 see a twofold increase on the left-hand graph
16 in the incidence of diabetes at nearly 50
17 percent in the elderly group, but pretty safe
18 surgery overall on the right. The serious
19 morbidity rate, 1.3, and the in-hospital
20 mortality is 0.11 percent in the elderly

21 patient group, so pretty acceptable outcomes.

22 So, there's probably a lot of reasons
23 why this has happened, including a shift to
24 less invasive surgery over the course of time
25 in our country, but all of these issues are

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1 true improved patient optimization, taking care
2 to do good patient selection and having
3 multidisciplinary teams, but the underpinning
4 of all this from our perspective is the process
5 of accreditation. So, there are now 845
6 centers that participate in our national
7 accreditation program in bariatric surgery,
8 they represent 49 of the 50 states, and we do
9 site visits to authenticate the data, the data
10 is collected by trained registrars.

11 Here's some of the data, this is
12 calendar year 2016. The mortality rate for 783
13 sites and 186,000, just about, cases, 0.11
14 percent, so very very safe, and this is real
15 world data, this is national data in the United

16 August 30th MEDCAC Meeting Panel Proceedings JS and LA
States, and this is particularly relevant to
17 our discussion today in the Medicare eligible
18 population where we've divided by procedure and
19 we've divided by age greater than or equal to
20 65.

21 And just to hit some of the highlights
22 here, even with gastric bypass, that is a more
23 complex surgical procedure in the age over 65
24 patient population, this is 2016 calendar year,
25 0.3 percent, so very acceptable. Remember, the

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1 benchmark of cholecystectomy mortality is 0.9
2 percent. Very safe surgery, one of the safest
3 surgical procedures you can have done.
4 So, I'm going to skip through this
5 very quickly because my time is running short,
6 but we have reviewed the issue of accreditation
7 in a number of studies, and also a
8 meta-analysis looking at outcomes. We see
9 unaccredited centers have higher complication
10 rates, higher mortality rates, and unaccredited
11 status is a positive predictor of complications

12 in our review of data.

13 So here's 13 studies. Basically only
14 two studies suggest there's no difference in
15 outcomes between accredited and nonaccredited
16 centers, so we strongly support the idea of
17 participation in the accreditation program to
18 improve the outcomes of bariatric surgery, and
19 other major payers in the United States do
20 require this as part of their approach to
21 approval for bariatric surgery.

22 Now one of the more exciting things
23 that we've done now with this quality program
24 with accreditation is to actually begin
25 national studies to try and impact outcomes,

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1 and the first project completed was the DROP
2 project, Decreasing Readmissions Through
3 Opportunities with MBSAQIP, and we piloted in
4 five centers and then applied the concepts of
5 reducing readmissions to 128 representative
6 hospitals, and I'll show you some of the data

7 August 30th MEDCAC Meeting Panel Proceedings JS and LA
here.

8 What we most notably saw was a
9 significant decrease in the post-sleeve
10 gastrectomy readmission rate. In the last
11 quarter of the study it was down 27 percent,
12 and you can see that on the right-hand graph in
13 the four quarters of the study, one through
14 four, there is a little bit of a rolling effect
15 where it took some time to actually begin to
16 impact practices but, again, sleeve
17 gastrectomy, a fairly significant decline in
18 readmission rates over the course of this
19 approach, and during this period of time there
20 was no change in morbidity of any of the
21 procedures, but just the decrease in
22 readmissions. We found that enacting a
23 discharge phone call and postop visit with the
24 surgeon and a nutritionist were the most
25 important things that decreased readmissions.

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1 I'm going to touch now briefly on some
2 of these newly FDA-approved interventions. I'm

3 going to focus this part of my talk on the
4 intragastric balloon, but there is information
5 here on the vBloc and the AspireAssist, and I
6 know we have speakers later that are going to
7 cover these in more detail. But we are in a
8 situation where we have this device that has
9 been around before, and actually CMS has an
10 exclusion to the concept of intragastric
11 balloon treatment where this device is placed
12 in the stomach endoscopically. Newer devices
13 will not require endoscopic placement, but
14 there are some data to suggest the benefit of
15 this at least in a short-term outcome
16 perspective.

17 82 publications on the Orbera device
18 with nearly 7,000 patients. Total body weight
19 loss at six months, 13 percent, with some
20 degree of maintenance of that weight loss. The
21 balloon is removed at six months, with some
22 persistence of the weight loss effect beyond
23 the six-month period. And I know for sure that
24 the gastroenterologists are going to talk about
25 this to some extent, but here is a

1 meta-analysis of the various studies which
2 averaged 25 percent excess weight loss with the
3 device.

4 And I mentioned before that one of the
5 appeals of the intragastric balloon is the
6 safety profile, which is very significant
7 compared to more invasive surgical procedures
8 in terms of outcomes, so, meta-analysis data
9 available to talk about.

10 I'm going to skip the AspireAssist for
11 now, it is an FDA-approved method for weight
12 loss.

13 I'm going to wrap up now with some of
14 the barrier to care information that we have,
15 and here's a look at the number of surgical
16 procedures we estimate to occur annually in the
17 United States and the various procedures. We
18 estimate that there are nearly 16 million
19 individuals that qualify for bariatric surgery
20 based on the traditional qualifications that we
21 have in our field. The penetration rate for

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22 surgical treatment, however, remains at about
23 the one percent level, so we are not treating
24 the epidemic of obesity very well with surgical
25 approaches.

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1 So, to try and gain some information
2 into why this may be, we supported a national
3 poll and called Americans to ask them about
4 their attitudes towards obesity and treatment
5 options. So, obesity and cancer were tied as
6 the top biggest concerns for patients.
7 Patients did not identify themselves
8 appropriately on average in terms of being
9 candidates for surgery, they did not consider
10 themselves obese even though their
11 self-reported statistics would put them in the
12 obese group. And the American public believed
13 that losing weight on one's own through diet
14 and exercise is the way to do it, surgical
15 treatment was way down on the list. And this
16 disturbing statistic, this was the percent of
17 Americans who were surgically eligible whose

18 doctors suggested surgery, only 12 percent. So
19 I think you could argue that we are to some
20 degree failing our patient population by not
21 giving good discussion of treatment options.

22 So, I think with our physician
23 colleagues, we have perhaps knowledge issues,
24 what's going on in bariatric surgery, the very
25 safe nature of the procedure, their awareness

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1 of these facts, their behavior, whether they
2 really in today's economic challenged world, do
3 they have time to have these discussions with
4 patients and what are their priorities. But we
5 have enacted what we call the Obesity
6 Collaborative Care Summit where we try to work
7 with other societies and develop their
8 knowledge of bariatric surgery treatments and
9 other obesity treatments.

10 So in conclusion, I hope I've
11 convinced you in this whirlwind tour that
12 bariatric surgery is safe, I hope I've

August 30th MEDCAC Meeting Panel Proceedings JS and LA
13 convinced you that bariatric surgery is
14 effective. It actually improves survival.
15 There are procedures routinely covered by
16 health insurance that have no survival
17 benefits, such as joint replacement surgery.
18 There isn't a payer in the United States that
19 denies joint replacement surgery, and they
20 can't even claim a survival benefit.

21 We improve health through bariatric
22 surgery and we improve quality of life, yet
23 only one percent of eligible people are treated
24 on an annual basis in the United States. And
25 you could argue that our one percent

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1 penetration of the population suggests that
2 we're to some degree irrelevant at the current
3 time in the treatment of the obesity epidemic,
4 and I would certainly like to see that change
5 in the future.

6 Thank you very much for the
7 opportunity to present.

8 DR. CUYJET: Thank you, Dr. DeMaria.

9 (Applause.)

10 DR. CUYJET: Our next presenter is
11 from Brown University, and you'll have to help
12 me out with the last name.

13 DR. TRIKALINOS: Hello. My name is
14 Tom Trikalinos, I am from Brown, and together
15 with my colleague Orestis Panagiotou, I am
16 going to present the AHRQ funded technology
17 assessment. We have nothing to disclose.

18 Obesity is prevalent in the Medicare
19 population and it's prevalent to such an extent
20 that a substantial number of Medicare
21 beneficiaries meet the NIH criteria for
22 bariatric therapy. To be specific, when we
23 refer to Medicare population in this technology
24 assessment we refer to people who are aged 65
25 or older, or younger than 65 but have a

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1 disability or end-stage renal disease.

2 The technology assessment is based on
3 a systematic review of the evidence, and the

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4 idea is to describe the evidence base that is
5 pertinent to Medicare eligible patients who
6 undergo bariatric surgery, bariatric therapy.
7 It is guided by five key questions that I'm
8 going to review briefly now.

9 The first key question has to do with
10 mechanisms, pathophysiologic mechanisms by
11 which the bariatric procedures act, and we are
12 not going to talk about it. Dr. DeMaria
13 summarized some of them.

14 The second key question is about
15 developing an evidence map. An evidence map is
16 a general description of studies, of patients
17 who receive bariatric surgeries, bariatric
18 therapy and are, and these categories are
19 applicable to the Medicare population, and in
20 this general description we describe the
21 characteristics of the patients, the
22 interventions, and the outcomes that have been
23 studied.

24 The third key question has to do with
25 outcomes related weight loss. It has several

1 parts. We are interested in the effectiveness
2 of different bariatric procedures. We are
3 interested in patient- and intervention-level
4 modifiers on the effects of bariatric
5 procedures. We are also interested in the
6 frequency and predictors of failing to achieve
7 at least minimal weight loss. And, we are
8 interested in the effects of revisional
9 bariatric therapies on weight outcomes.

10 The fourth key question is analogous
11 to the third but pertains to non-weight
12 outcomes. We are interested in comparative
13 effectiveness and safety of bariatric
14 therapies, and also effect modifiers or set of
15 facts.

16 Finally, key question five has to do
17 with whether the effects of bariatric therapies
18 on known weight loss outcomes are mainly direct
19 or are mainly mediated by weight loss.

20 In every systematic review we have to
21 identify, we have to define how we select
22 studies, and we usually do that by specifying
23 the populations, interventions, comparators,

24 outcomes, timings and settings of the eligible
25 studies. These are our eligibility criteria

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1 and I am going to review them briefly.

2 In terms of populations, because we
3 are interested in the Medicare population, we
4 have limited ourselves to studies where the
5 mean age or median age is above 55 years, or to
6 studies that have included patients with
7 disabilities or patients with end-stage renal
8 disease. We exclude pediatric populations and
9 pregnant women. We focused on studies that
10 have a mean or median age above 55 years
11 because generally studies that include patients
12 who are exclusively above 65 are rare and
13 because the majority of people, the patients
14 who receive Medicare, who receive bariatric
15 therapies and are Medicare eligible do so for
16 reasons of disability, are patients who are in
17 Medicare because of disability.

18 In terms of interventions, we

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19 considered bariatric therapy to be any
20 procedure that results in an anatomic or a
21 functional change of the gastrointestinal
22 system, whether or not a device is placed.
23 These procedures, these therapies may be done
24 with surgery, either open or through
25 laparoscopy, or they may be done

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1 endoscopically.
2 We are interested in comparing
3 bariatric procedures with other bariatric
4 procedures, or with pharmacological, behavioral
5 and nutritional treatments, or with no
6 treatment or sham treatment.
7 In terms of outcomes, the technology
8 assessment is interested in all clinical
9 outcomes, but for the purpose of this meeting,
10 of interest is weight loss, postoperative
11 complications, and metabolic, cardiovascular,
12 respiratory and musculoskeletal outcomes, and
13 quality of life.
14 We are interested in studies that are

15 pertinent to the current setting, so we
16 included studies that have been conducted after
17 the 2000s. We are including studies that have
18 been done in research settings such as
19 randomized trials, and also studies that use
20 real world evidence, or have been done with
21 routinely collected data.

22 We are interested in estimating causal
23 effects, causal treatment effects, and for
24 these types of estimations, the randomized
25 trial is the gold standard. This is because

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1 randomization ensures that in expectation, the
2 compared groups are similar in the distribution
3 of effect modifiers that have been measured or
4 aren't measured. Therefore, any difference in
5 the outcome can be ascribed to the difference
6 in the treatments.

7 However, we are also reviewing
8 nonrandomized studies. The issue here is that
9 on average, the compared groups are likely to

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10 differ in the distribution of effect modifiers,

11 and these differences had to be accounted for.

12 If these differences are not accounted for in
13 the analysis or design, we are going to have
14 biased estimates of treatment effects.

15 To operationalize what studies are
16 admissible to get information for causal
17 treatment effects, we have these falling into
18 two criteria. So a study is admissible if it
19 has an explicitly comparative scope and if the
20 study has taken at least some minimal effort to
21 balance confounders and other prognostic
22 factors between the compared groups. This
23 minimal effort could have been done by a
24 design, in the optimal case these are
25 randomized trials. If it's not randomized,

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1 it's through matching or analysis, for example
2 a statistical model.

3 We do not use non-comparative studies
4 to make inferences or estimates about causal
5 treatment effects but we, because the evidence

6 is relatively sparse in the Medicare eligible
7 population, we do report results from known
8 comparative studies for restricted purposes.

9 We are interested in studies of
10 predictive models, and to describe their
11 eligibility we first defined what we mean by
12 predictive models. So we are very generous and
13 we say that we take as predictive model
14 anything, any function that maps variables,
15 equal variables at baseline which are the
16 predictors to be outcomes, which are the
17 outcomes. Evidence study designs are, we want
18 to call them studies. We want studies that
19 fully report the predictive models for such
20 thing as bariatric surgery with respect to
21 weight loss, and also we demand that predictors
22 are measured at baseline.

23 We have excluded all studies that
24 don't focus on associations.

25 We searched broadly, we searched over

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1 ten sources, including bibliographic databases,
2 registries of studies and scientific
3 information packages, and we have rated the
4 strength of the evidence of the associated
5 evidence base for the specific conclusion
6 statements. We do that by evaluating four
7 domains, the risk of bias, the consistency,
8 precision, directness and applicability of the
9 evidence that is accompanying the specific
10 statements, the specific conclusion statements.

11 Briefly speaking, the strength of
12 evidence is graded into rates, rates of high,
13 moderate or low, dependent on how confident we
14 are that the evidence base gives an effect that
15 is close to the true effect. There is also a
16 rating of insufficient if there is no evidence
17 that supports a specific conclusion.

18 And I think that here I will turn it
19 to Orestis to go on and describe the actual
20 results.

21 DR. PANAGIOTOU: Hello everybody. My
22 name is Orestis Panagiotou, I'm also from the
23 Brown EPC Center. I have no conflicts of
24 interest, and I will pick up where Tom left by

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25 describing the results, the actual results of

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1 our systematic review and technology

2 assessment.

3 So by applying the criteria and the
4 key questions that Dr. Trikalinos described, we
5 came up with an evidence base of almost 10,000
6 citations. At the end of the day after
7 applying our inclusion and exclusion criteria,
8 we came up with a sample of 94 studies. Of
9 those, 70 were subgroup analyses that were
10 either comparative in nature or
11 non-comparative, and another 24 studies that
12 gave us evidence of prediction studies and
13 predictive models, and weight loss after
14 bariatric surgery based on different
15 predictors.

16 So, this slide describes very, from a
17 few thousand feet up about what, how the
18 evidence looked like, the evidence base. We
19 did not identify any randomized studies where
20 other procedures are compared with bariatric

21 surgeries or bariatric procedures. And among
22 the 70 studies, non-randomized studies, we
23 found 13 were comparative, or at least were
24 doing comparisons based on modeling or design
25 and the majority of the 70, 57 of them were not

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1 comparative in nature, which means that they
2 did not take any efforts, any approach to
3 minimize bias. And this, the majority of them
4 were speculative (unintelligible) and the
5 reports (unintelligible) pre-post design.

6 Of interest is also that we've not
7 identified any studies in the Medicare
8 population that pertained to endoscopic
9 procedures, so all the results that we're going
10 to discuss today are about surgical
11 interventions. And the majority of the studies
12 that were identified as eligible were published
13 after 2010, which actually means that our
14 timing criteria, to include studies after 2000,
15 did not cure this at all.

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16 Of the 70 studies that we had, of the
17 70 observational studies, seven were found to
18 use the actual data from Medicare
19 beneficiaries, these are different types of
20 claims data that Medicare makes available. And
21 of the remaining 63 studies, three were in
22 patients who have end-stage renal disease,
23 three were in patients who have some type of
24 disability as was described by the
25 investigator, and the majority were on patients

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1 who met the age criteria that we set of 55
2 years old or older.
3 This table shows how, what type of
4 bariatric surgeries were identified in the
5 Medicare population, how these studies are
6 performed, whether they're open or laparoscopic
7 and when, these are numbers about the cohorts
8 in different studies.
9 So we identified studies on adjustable
10 gastric banding, mini-gastric bypass, Roux-en-Y
11 gastric bypass, single anastomosis with

12 duodenal switch, sleeve gastrectomy, vertical
13 band gastroplasty, and biliopancreatic
14 diversion with a duodenal switch. And as you
15 can see, the majority of them were conducted
16 laparoscopically even though the procedures
17 were relatively new.

18 The next table shows how these
19 procedures are distributed in the literature
20 based on different types of outcome categories,
21 so we show here adverse events, weight and
22 BMI-related outcomes, and other health outcomes
23 based on the different interventions and the
24 different way that these interventions were
25 performed. Again, you can see that most of

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1 them pertained to laparoscopically performed
2 surgeries.

3 This is a graph that we created in
4 order to try to show, to generate the evidence
5 map, this was an iteration of the evidence map,
6 and on the vertical axis we show the different

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7 types of interventions, or (unintelligible)
8 where identified, and the vertical axis shows
9 weight loss outcomes and how they were divided
10 in the literature. Each cell shows circles
11 that represents one cohort of patients who
12 received this type of procedure and how, their
13 respective outcome measures, and the number on
14 the corner here shows the actual number of
15 cohorts.

16 So you can see that for some
17 interventions like mini-gastric bypass, there's
18 probably very sparse evidence, only one cohort
19 of patients who have received this intervention
20 and have measured the outcome of percent excess
21 weight loss, while on the other side there is,
22 there are many studies about, or many cohorts
23 of patients who have received Roux-Y gastric
24 bypass and have measured, in those patients,
25 many different outcomes have been measured.

1 The next slide you see
2 (unintelligible) weight loss outcomes, we're

3 showing different types of postoperative
4 complications that take place within 90 days
5 after surgery, and we can see that for some
6 specific outcomes or outcomes that are
7 particularly important in patients like
8 thromboembolism or acute cholecystitis, these
9 outcomes are not very often reported in the
10 literature.

11 So this type of graph, like also the
12 one that we have included later about health
13 outcomes, can give us a very good idea of how
14 the evidence base looks like, and can help us
15 quickly identify where the evidence does exist
16 in regards to interventions and outcomes.

17 So, I'll switch now to our next key
18 question, which was about describing the
19 effects on interventional weight loss outcomes,
20 and I will start with comparative studies that
21 bear on this question. We actually identified
22 only three such studies that compared either
23 Roux-en-Y versus sleeve gastrectomy or
24 laparoscopic adjustable gastric banding, or
25 sleeve gastrectomy versus laparoscopic

1 adjustable gastric banding. We also identified
2 a fourth study which compared laparoscopic
3 sleeve gastrectomy against conventional medical
4 treatment.

5 So this last study included two groups
6 of patients. Each of them was, it had 30
7 participants, and we saw that on average,
8 laparoscopic sleeve gastrectomy was associated
9 with statistically significant improvement of
10 BMI and body weight outcomes.

11 This is a separate study that compared
12 BMI and weight loss between the laparoscopic
13 adjustable gastric band, Roux-en-Y gastric
14 bypass and sleeve gastrectomy in three
15 different cohorts of patients, and you can see
16 that at six months each graph shows the
17 percentage, the values of the outcomes for
18 excess weight loss, percentage of weight loss,
19 BMI reduction, and weight loss in these
20 patients, and you can see for all three
21 outcomes, Roux-en-Y gastric bypass outperforms

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22 both sleeve gastrectomy, which is the green

23 bar, and LAGB.

24 And same patterns seem to exist in 12

25 months where again, Roux-en-Y gastric bypass

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1 seemed to have better outcomes in terms of

2 weight loss, BMI loss, both for, compared to

3 both LAGB and sleeve gastrectomy.

4 This slide had to be put together, we

5 took the previous graphs and we saw easily how

6 the results looked like at six and 12 months.

7 And the main finding on this graph is that

8 there's the same effect for all three bariatric

9 surgeries at six and 12 months and if anything,

10 the effect seems largely, a bit higher from six

11 to 12 months.

12 So, the second type of studies that

13 were identified went to weight loss outcomes,

14 they were non-comparative studies, and these

15 represent the majority of the evidence base.

16 And as I mentioned before, these are described

17 weight loss outcomes before versus after

18 bariatric surgery. And the main limitation of
19 those studies is they did not have a control
20 group so they did not allow us to make further
21 comparisons between different interventions.

22 We did a little bit of a review slide
23 attempting to describe the findings. What we
24 saw here are different data points, each of
25 them representing the value of the outcome

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1 before versus after bariatric surgery, so the
2 percent excess BMI loss, percent excess weight
3 loss, percent of total body weight loss, BMI
4 loss as an absolute outcome, and weight loss.

5 And we have presented the various
6 different types of interventions, gastric
7 banding which are the blue circles, Roux-en-Y
8 gastric bypass which is the red triangles, and
9 sleeve gastrectomy which are the green crosses.
10 So, this graph shows that for all those three
11 procedures there seems to be an effect on
12 different weight loss outcomes, which is highly

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13 variable, and the distribution is quite
14 substantial for these three procedures, but I'd
15 like to draw your attention here to avoid
16 making any comparisons between the
17 interventions, which one may be attaining
18 better outcomes, because these are different
19 cohorts of patients and these interventions are
20 not directly compared to each other, so this is
21 more of a discrete approach to see how effects
22 are distributed in Medicare patients.

23 The next slide, the intervention was
24 identified as mini-gastric bypass. We only had
25 one study that gave us a representative graph

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1 of how weight loss changes over time, so you
2 can see here that patients who received
3 mini-gastric bypass have increased actual
4 weight loss at the first year, and this weight
5 loss was sustainable up to five years after
6 surgery. Among all those people who received
7 bariatric surgery with mini-gastric bypass, 95
8 percent were followed up at one month but only

9 72 percent of them had data available at five
10 months, so there was some attrition going on
11 over time.

12 A similar graph, this is for single
13 anastomosis duodenal switch, where we saw
14 excess BMI loss and percent excess weight loss
15 changed over time for patients who received
16 duodenal switch, and you can see again that
17 from baseline out to 18 months, the effect of
18 this intervention seems to increase.

19 This table is something that we have
20 in our technology assessment, and I'm not going
21 to go through the details of it here, but I
22 would like to draw your attention to the last
23 column which holds the overall strength of
24 evidence for different procedures and different
25 outcomes. So based on the evidence that we

1 found we determined that most of the studies
2 are non-comparative studies and nonrandomized
3 studies. We have a low to moderate strength of

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4 evidence that different bariatric surgeries
5 (unintelligible).

6 The next key question that we
7 addressed was about the effect of bariatric
8 surgery, different procedures on non-weight
9 outcomes, and here we identified 27 studies
10 that actually tried to compare bariatric
11 procedures to each other or other
12 interventions, but only 12 of those were
13 admissible based on the criteria that
14 Dr. Trikalinos described in regards to giving
15 us unbiased data on the treatment effects.

16 So, the big picture here is that most
17 studies, they just present or provide
18 statistically significant changes when it comes
19 to intermediate endpoints or what we call soft
20 outcomes, like lipids or metabolism biomarkers,
21 but very few studies actually saw that there is
22 a type of health outcome like diabetes or
23 cardiovascular disease.

24 This is an example, this is a forest
25 plot showing the pooling approach of different

1 types of sources, how bariatric surgery
2 compares to, different types of bariatric
3 surgeries compare to either no surgery or
4 orthopedic surgery in regards to mortalities.
5 And you can see that for some of these studies,
6 there seems to be an effect when it comes to
7 mortality, but for some of them when it comes
8 to comorbidity, mortality like cardiovascular or
9 cancer mortality, the effects seem to be not
10 clinically significant.

11 The next figure shows the results of
12 one study that provided, compared different
13 types of bariatric surgeries, (unintelligible) a
14 note identifies specific procedures that these
15 patients have received, so there is a lamp or,
16 a group that, I'll call it a group that
17 received any bariatric surgery, and you can see
18 that compared to either gastrointestinal or
19 orthopedic surgery, these patients who received
20 bariatric procedures are doing better in terms
21 of myocardial infarction but there seems to be
22 hardly an effect when it comes to stroke.

23 These is a similar slide, a slide that

24 compares, one type, sleeve gastrectomy, in
25 regards to various complications between zero

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1 to 90 days after surgery, and there is, as the
2 previous presenter described, all the effects
3 are very close to the null line of low effect,
4 so this study means that bariatric surgery is
5 not associated with any significant
6 complications.

7 The next outcome that I'm going to
8 present some evidence on is diabetes and
9 metabolic outcomes where we identified four
10 studies. One, the best one of them is the same
11 as before, where sleeve gastrectomy was
12 compared to conventional weight loss treatment,
13 and there seems to be a favorable
14 (unintelligible) for sleeve gastrectomy
15 compared to medical treatment when it comes to
16 lipids, triglycerides and these other
17 modalities. However, there seems to be no
18 effect on LDL cholesterol in these patients.

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19 Another study looked at successful
20 cease of insulin in type 2 diabetic patients
21 with Roux-en-Y versus laparoscopic adjustable
22 gastric banding, and both measured the outcome
23 of clinical remission of type 2 diabetes, and
24 Roux-en-Y gastric bypass always fared better
25 compared to LAGB. However, in a separate study

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1 that compared bariatric surgery with no surgery
2 at all, there was no evidence that type 2
3 diabetes improved.

4 This is a similar graph from the
5 studies identified before where laparoscopic
6 adjustable gastric banding, Roux-en-Y gastric
7 bypass and sleeve gastrectomy were compared to
8 each other, and now this is being tied to
9 glucose level, HDL, HbA1c, LDL, total
10 (unintelligible) and at six months, as well as
11 12 months after surgery, there seemed to be no
12 statistical difference between these three
13 procedures.

14 One study compared, or produced

15 evidence in regards to polypharmacy, how many
16 different drugs people received and whether
17 there's a reduction after bariatric surgery, so
18 there seems to be a great reduction in the
19 number of medications that people use after
20 Roux-en-Y gastric bypass when compared to
21 sleeve gastrectomy or gastric banding, but
22 sleeve gastrectomy and LAGB gastric banding do
23 not perform differently to each other.

24 However, this effect was also, this
25 type of effect was also observable at 18

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1 months, where the number, the mean number of
2 medications, of antihypertensive medications
3 used was reduced from 1.5 to .83 pills per day.

4 The next outcome that we will present
5 here today is respiratory outcomes, and
6 unfortunately for this, we identified only one
7 study, which showed that there is some
8 improvement in sleep apnea with bariatric
9 surgery at six months, but there's no longer

10 August 30th MEDCAC Meeting Panel Proceedings JS and LA
effect at one or two years.

11 When it comes to musculoskeletal
12 outcomes, we identified one study that actually
13 did not take, there is no comparison with
14 regard to the variables that they include in
15 their analysis, but we're showing here the
16 results, or the indication that Roux-en-Y
17 versus a control group in post-menopausal women
18 seemed to have no difference in regards to TSH,
19 alkaline phosphatase or other biomarkers of
20 bone metabolism.

21 I'm going to talk at the very end
22 about the population of Medicare beneficiaries.
23 There's no evidence about, no studies at all
24 that provides comparative evidence about
25 health-related quality of life outcomes. There

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1 seems, there are some studies that report
2 changes in different scales of measures of
3 quality of life after bariatric surgery, but it
4 is evident that there's lots of heterogeneity
5 in how these outcomes are measured, and the two

6 most common scales that were identified were
7 SF-36 and the Disability Rating Index.

8 So for most outcomes that are of
9 interest to the Medicare population, and we
10 tried to identify them here, we actually found
11 very limited or no evidence at all when it
12 comes to quality of life, cancer, nutritional
13 deficiencies, renal function, and other patient
14 relevant outcomes.

15 Again, a very busy table here that
16 tries to summarize the strength of evidence in
17 regards to the effects of bariatric surgeries
18 on non-weight loss outcomes, and as was the
19 case for weight loss outcomes, again, for most
20 of these comparative outcomes, the overall
21 strength of evidence seems to be low or
22 moderate.

23 The final topic that I am going to
24 discuss pertains to prediction models, for us
25 to predict outcomes of bariatric surgery in

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1 patients that meet the Medicare criteria. So,
2 one thing which I've identified here were
3 models that explicitly defined an outcome of
4 minimum weight loss, but actually there was no
5 such study that gave an explicit definition,
6 and instead there were different types of
7 models that investigators used in regards to
8 how they defined success or failure in
9 bariatric surgery.

10 The most interesting thing from our
11 appraisal of the different predictive models
12 that exist in the literature right now is that
13 none of these models were internally validated
14 or, even more importantly, externally
15 validated, and these two procedures or two
16 processes are very important when we evaluate a
17 model for predictions because if the model
18 isn't internally or, even better, externally
19 validated, there's more problems that it can be
20 generalized in populations other than those
21 where the study was conducted.

22 Here is a table that tries to
23 summarize the different predictors that were
24 included in the 14 models that we identified.

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25 I will not describe one by one, but we have

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1 detailed explanations and effect sizes for
2 these different predictors in our report in the
3 technology assessment. But I would say that
4 some of the more strongly predictors that have
5 been included in models are age, gender,
6 (unintelligible) medications, and also some of
7 them included the specific type of bariatric
8 surgery that patients received.

9 So, summarizing what we found in
10 regards to the evidence base of bariatric
11 surgery in the Medicare population, we did not
12 find any studies on endoscopic procedures. We
13 found no randomized evidence for surgically
14 performed bariatric interventions and, most
15 importantly, we found very few nonrandomized
16 comparative studies, because the majority of
17 the studies were pre-post studies that did not
18 have any comparative group.

19 So to the strength of evidence as I
20 described both for weight outcomes and

21 non-weight-related outcomes, it is low to
22 moderate, and the main concern that we have
23 here that we noted across the papers, is that
24 it's a little confounding that their treatment
25 studies do not fully take into account, but

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1 based on whatever information we can infer from
2 pre versus post interventions with pre-post
3 studies, we can say that there seems to be a
4 sustained effect of bariatric surgery in the
5 Medicare population. But again, we are not
6 making full representation that this is a
7 causal treatment effect.

8 As to conditions that Dr. DeMaria
9 mentioned, there seems to be extensive evidence
10 that bariatric surgery improves outcomes in
11 general populations, but for us to make a
12 formal statistical inference about how this
13 evidence translates into the Medicare group
14 selection, this would go beyond the scope of
15 this report, and that's why all our interest is

16 August 30th MEDCAC Meeting Panel Proceedings JS and LA
primarily based on patients above 55 years.

17 So, we also tried to identify what
18 evidence, what gaps exist in the evidence base
19 based on the extensive search that we did. So
20 the major gap that we see is that there are
21 practically no randomized studies that can give
22 us an unbiased statement of total treatment
23 effects.

24 There is also not many well-designed
25 or well-executed nonrandomized studies that

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1 would allow us to make inferences about
2 treatment effects.

3 And when it comes to prediction
4 models, there's also a lack of validated models
5 that we can reliably use to change our
6 practice.

7 Also, there is no large
8 (unintelligible) analysis which would allow us
9 to tell what effects of bariatric surgery is
10 direct or non-weight loss outcome, and what may
11 be mediated or indirect to its effect on weight

12 loss outcomes.

13 What could be done given these
14 variations? So, we believe that there is now a
15 wealth of routinely-collected health data, many
16 of them were presented earlier, and I believe
17 there are other presenters who are discussing
18 these data in detail. So it is now possible to
19 design nonrandomized comparative studies using
20 routinely-collected field data in a way that
21 tries to imitate a randomized trial. And there
22 are also methods that try to calibrate what
23 treatment effects we see from (unintelligible)
24 patients in an RCT to a viable collection by
25 combining different study designs. And of

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1 course, these small pieces of factual data can
2 be used for us to validate, or for the
3 community to validate models that can allow us
4 to predict outcomes from bariatric surgery.

5 Some examples for these type of data
6 sources include Medicare claims, which are

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7 actually directly applicable to Medicare
8 patients, the Medicare population. Also,
9 electronic health records and (unintelligible)
10 registries and the MBSAQIP.

11 And with that, I would like to thank
12 our team, and two of the members that are in
13 the audience today.

14 (Applause.)

15 DR. CUYJET: Thank you very much. Our
16 next presenter is Joe Nadglowski, president and
17 CEO of the Obesity Action Coalition.

18 MR. NADGLOWSKI: Thank you,
19 Mr. Chairman. My name's Joe Nadglowski, I'm
20 president and CEO of the Obesity Action
21 Coalition, which is a 501(c)(3) nonprofit
22 organization made up primarily of people with
23 obesity. We have about 60,000 members and 90
24 percent of them have self-identified themselves
25 as having obesity. The other ten percent,

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1 though, are healthcare professionals, and we do
2 have a few corporate members as well, so I'd

3 add that as part of my disclosure slide here.

4 I serve on lots of other activities related to
5 bariatric surgery that I want to disclose.

6 I've been part of the data access
7 committees for both the old Surgical Review
8 Corporation's database, the BOLD database, as
9 well as a member of the data access committee
10 as a patient representative for ASMBS. You're
11 going to hear about some PCORI work next and
12 I'm actively involved in those projects,
13 including sitting on the board of one of the
14 data registries, and I participate in all kinds
15 of other panels that are listed here just as
16 full disclosure. I am also a reviewer on the
17 document that was, or the data that was just
18 presented as well.

19 I will say for all those projects I
20 listed as mine, but I received no personal
21 compensation, I have no financial ties to
22 industry. All those monies that are paid go to
23 OAC and not to me personally.

24 So I'm supposed to give you a patient
25 view of this conversation today, I'm going to

1 take it in a little bit of a different
2 direction and then we'll hit a couple of the
3 points that folks have brought up already. So,
4 I think this paper has been referenced already
5 but I think it's very important that we
6 understand that obesity is a chronic disease
7 and we have a limited understanding of its
8 pathogenesis. I think there is a bias in
9 society that people understand, that we know
10 what causes obesity, people eat less, or eat
11 more and exercise less than they should, but it
12 is much more complicated than that. And for
13 any of you who haven't read, it is worth
14 reading the Endocrine paper, and Dr. DeMaria
15 mentioned that as well.

16 Obesity is awfully widespread and I
17 think one of the things that gets lost in this,
18 and oftentimes is criticizing some of the
19 bariatric surgery studies is that wow, they're
20 all women in these studies, right, where are
21 the men? But the reality is the data shows us

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22 that actually twice as many women have severe
23 obesity as men, and so therefore that is the
24 population who struggles with obesity and are
25 most likely to use these procedures.

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1 So just a couple things for your
2 consideration from my perspective is, you know,
3 people with obesity vary, as do their responses
4 to obesity interventions. I'm going to make a
5 bold statement here when I say we don't have
6 one therapy that works for everyone. So I know
7 we engage in these efforts where we try to
8 compare therapies, but I will tell you I don't
9 think we're there yet, right, because we don't
10 have a therapy, we don't have a standard
11 therapy that if we give it to someone we know
12 it's going to work. The reality is we have
13 varying responses to these therapies.

14 And frankly, success looks very
15 different from a patient perspective. You
16 know, to some people weight loss is important,
17 but others, comorbidity resolution or quality

18 of life improvements or functional status. And
19 so I think as we challenge and we look forward
20 at this data today, I know quality of life made
21 the bottom of the list there, but I think we
22 should add other of those items too that
23 actually really look at the patient experience.
24 You know, many of us who struggle with
25 obesity, myself included, what's important to

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1 us is not the pounds on the scale, and for some
2 of us it's not actually the comorbidity
3 resolution, it really is how we can function in
4 our life, and I think that's important to
5 understand.

6 And I will tell you, I think our
7 biggest problem is that we treat obesity as an
8 acute illness and not a chronic disease, but
9 the reality is that, you know, we're here today
10 evaluating bariatric surgery outcomes, right?
11 But bariatric surgery is only one small part of
12 the continuum of care for obesity. Once you

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13 have obesity, you always have obesity, and yes,
14 I can see a dietician or I can use medication
15 or I can have bariatric surgery, but your
16 obesity does not go away after that, right?
17 This is something you struggle with for the
18 rest of your life, and I think comprehensive
19 care is not the norm, and so we have to be
20 careful as we pigeonhole these procedures and
21 looking at them as a one-off instead of a
22 comprehensive treatment model. Of course, I
23 realize that requires us to break the system,
24 right, that's how we pay for procedures these
25 days, but it is a real challenge.

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1 The other aspect of living with
2 obesity is the societal stigma associated with
3 it. For those of you who know me know I speak
4 about two topics, I speak about access to care
5 and I most often speak about weight bias, and
6 really this is the attitude people have towards
7 people with obesity. If you've never
8 experienced living with obesity, I would ask

9 you to find someone who does and actually have
10 a conversation with them about what their life
11 is like. The reality is that the social burden
12 that society puts on people is horrendous, and
13 people internalize that shame and blame, and it
14 makes it even worse. And the reality is, we
15 know that people who are victims of stigma
16 actually eat more, so therefore they gain
17 weight. So this idea that I'm going to
18 motivate somebody by making fun of them because
19 of their weight actually is not true, the
20 data's very clear that it causes people
21 actually to gain weight.

22 I think the other area of stigma that
23 doesn't get talked about as much is the stigma
24 of having bariatric surgery. The reality is
25 when we look at studies, there is just as much

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1 of a stigma of needing help for your obesity as
2 obesity itself, and the studies show that
3 people who have had bariatric surgery do not

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4 see the same reduction in stigma that people
5 who have lost weight through other means do.
6 Primarily that would be through diet and
7 exercise, I don't think we've studied the
8 endoscopic devices or drug therapies in that
9 situation.

10 So I challenge you as the committee
11 today, realizing there's a stigma around
12 bariatric surgery, realizing there's a stigma
13 around obesity, that you don't let those
14 attitudes influence your decisions today. I
15 would challenge you if you're reviewing a
16 question to think in your mind and say hey,
17 what if we were talking about diabetes and it
18 was a different procedure, would I ask the same
19 question, or would I question the evidence in
20 the same way. Because the reality is that what
21 we see so far is that society has a very
22 different attitude about bariatric surgery than
23 what I think it should.

24 The same challenge goes to the Agency
25 on how you use the data that you come up with

1 today. You know, the reality is, were the
2 questions asked based on bias in the first
3 place, or were they based in truly trying to
4 understand science, and that's a question only
5 the Agency itself can answer.

6 So, what do we know about seniors and
7 obesity? We sponsored a study called the
8 Action Study, and we've published a few
9 abstracts, the primary papers come out here
10 soon, but actually we find that seniors with
11 obesity actually have pretty similar views to
12 the general public. The study actually asked
13 3,000 people with obesity, and 900 plus, 30
14 percent were seniors, and so they have matching
15 views about obesity as a disease even if their
16 numbers are a little bit different than
17 Dr. DeMaria's.

18 We actually asked the follow-up
19 question around this, is that, okay, 66 percent
20 of seniors believe obesity is a disease, but
21 what percentage think that obesity is all your
22 own fault, and that number is in the 90s, so
23 obviously there's a little bit of a translation

24 of what a disease means versus blame.

25 They have significantly higher

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1 comorbidities, this matches what we saw in
2 Dr. DeMaria's data, and we see that actually
3 it's specific medical events that drive their
4 desire for obesity care. We sometimes see this
5 in the younger population but it's definitely
6 more evident in our seniors.

7 And then they have what I think is a
8 good thing, which is the right goals, right?
9 The goals around improving health, right, your
10 quality of health and your quality of life,
11 they seem to be the more appropriate goals than
12 we sometimes see with younger populations.

13 Curiously, we also see that seniors
14 are less likely to actually see their
15 healthcare provider about obesity, and whether
16 that directly impacts what we're working on
17 today or impacts other coverage decisions that
18 Medicare has around counseling, it is, this is

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19 important information.

20 And they're also less likely to have a
21 formal diagnosis of obesity, again, probably
22 more applicable to the screening and intensive
23 counseling area, but it is important to know.

24 And though, you know, seniors are
25 similar to those under age 65, there are some

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1 differences that I think we can learn from
2 moving forward.

3 So what are the realities of
4 collecting data on bariatric surgery? I think
5 we've heard a lot of what's there and what's
6 not there so far, but I wanted to actually as a
7 patient advocate tell you what the limitations
8 are. So the first one is that only a handful
9 of the RCTs we've talked about today actually
10 included the cost of these procedures; in most
11 cases the patient needs either their insurer,
12 Medicare, or their own pocketbook to pay for
13 these procedures, and bariatric surgery
14 coverage is not universal. I would say you see

15 it commonly covered in Medicare and Medicaid,
16 you see it commonly covered for state
17 employees, federal employees, if you work for a
18 large company it's likely covered, but only in
19 23 of 50 states is it considered essential
20 under the Affordable Care Act, and so you see
21 widespread coverage there.

22 I will also say that the data that's
23 going in and that we're actually able to look
24 at is biased in some way by the payers
25 themselves because they limit who can have

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1 bariatric surgery, and sometimes these limits
2 don't make any sense. And in fact, the most
3 common call we receive at Obesity Action
4 Coalition when a patients calls and says well,
5 my payer is making me, my payer or insurance is
6 making me do this or do that to be able to have
7 bariatric surgery.

8 I pulled an example from the coverage
9 database here, so they were talking about

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10 cardiovascular outcomes, and wanted to look at
11 hypertension in the Medicare population. Well,
12 one of your contractors told you you have to be
13 on one drug. The other one says you have to
14 have resistant hypertension on three drugs to
15 be able to have bariatric surgery. That
16 inconsistency has been crazy, inconsistency in
17 the data, and therefore, may ultimately not
18 produce the right outcomes.

19 RCTs can be challenging as well. I
20 will not repeat the first line because our
21 friends at AHRQ shared that already, but I will
22 tell you that randomization is tough from a
23 patient's perspective, especially when it comes
24 to obesity and severe obesity. I will tell you
25 most of us who struggle have been through

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1 dozens of programs before, and if you're going
2 to randomize me to something that is not, you
3 know, something that I've done before and
4 unsuccessful, I am not going to participate in
5 your trial. There are very few patients who

6 will be completely open to saying I will accept
7 any randomization you move me forward to. So I
8 think we -- I understand the RCT is the gold
9 standard, but I think we need to be very very
10 careful with what we're doing.

11 I will also tell you there are many
12 patients who are not open to a surgical or a
13 device intervention, okay? We talk to them
14 every day. And there are other therapies
15 available, only counseling under Medicare,
16 there are therapies that are not covered by
17 Medicare. That is a conversation for another
18 day.

19 I happen to participate in a lot of
20 these large registries and database projects
21 and so I wanted to comment on those a little
22 bit as well. You know, I think that these
23 databases have the ability to answer the
24 questions that you've asked, but I think
25 there's some challenges with that, you know.

1 It was just a couple years ago that Medicare
2 decided they weren't going to require
3 accreditation anymore, and so if we want the
4 data and we don't require people to
5 participate, to me there's a disconnect there.

6 I will also say, you know, with the
7 MBSAQIP database, when the old bold database
8 existed, I was the most common requester of
9 data from that database and I'll be honest with
10 you, I didn't use it for research purposes, I
11 used it for access and advocacy purposes. So
12 with that being said, we don't have that same
13 level of access to the MBSAQIP data, and this
14 is something that my friends at MBSA have heard
15 me say many times, we haven't yet convinced the
16 College of Surgeons to give us public access to
17 that database to answer some of these important
18 questions.

19 My friends from PCORI are up next and
20 they have this wonderful network that I think
21 has the ability to answer some of the
22 questions, you know, all this data they've
23 collected across the country and the Clinical
24 Data Research Networks and the work that

August 30th MEDCAC Meeting Panel Proceedings JS and LA
25 Dr. Arterburn is doing to actually study

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1 bariatric surgery through that data is
2 important, and I think it will help you with
3 some of the questions moving forward. We're
4 about six months too early, if we had this
5 hearing six months later you'd see some of that
6 data.

7 But with that being said, I do want to
8 point out some challenges with that data. I
9 will tell you that the Clinical Data Research
10 Networks, because I sit on the board of one of
11 them, is made up of the largest providers in
12 the state, and oftentimes the kind of places
13 that perform bariatric procedures, especially
14 the endoscopic procedures, these surgical
15 centers are not part of those networks. So we
16 have to understand that it may not give us all
17 the data we want moving forward, so there isn't
18 a perfect solution in my mind with the data.

19 So, I mentioned this earlier, I think
20 it's worth repeating, that obesity care is

21 provided as acute care and not chronic care,
22 and I will tell you that, I think most of you
23 know this, but when a payer pays for bariatric
24 surgery or one of these endoscopic procedures,
25 it's paying for the procedure, it's not paying

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1 for the post care or anything along those
2 lines, and oftentimes that post care is not
3 covered by insurance, and many of them actually
4 allow only one procedure per lifetime.

5 Now think about that again. That's
6 thinking of obesity as an acute thing, and
7 right, we have a perfect solution. We would
8 never tell a cancer patient that they're only
9 allowed one treatment per lifetime. You know,
10 we, most of us would say we're going to
11 progress from the least invasive to the most
12 invasive until we find the solution, right?
13 But in obesity we aren't there, and actually
14 the data reflects that as you see some of these
15 studies and you see how we're being

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16 shortsighted in the way we allow people to have

17 these procedures done.

18 I will tell you I think the thing that
19 concerns me the most about bariatric surgery is
20 the long-term follow-up and I think there's a
21 real opportunity to fix long-term follow-up by
22 actually providing reimbursement for that care.

23 I mean, people see dietitians, they see
24 exercise physiologists, they go to support
25 groups, and they are required to take vitamins

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1 for the rest of their lives in many of these
2 procedures. And the reality is that at times
3 these services aren't provided, because
4 Medicare and other agencies don't provide the
5 reimbursement for it.

6 You also see a wide problem when
7 people move. Again, it was the initial act of
8 surgery that ended up paying for the lifetime
9 of care for this patient. Where are they going
10 to get this care right now? Oftentimes they're
11 charged prohibitive fees to be able to be part

12 of that which aren't covered by their
13 insurance.

14 And then finally, a topic that's very
15 important to me. I truly believe in the value
16 of the support group system, and we have great
17 evidence in the behavioral weight management
18 programs that support groups provide great
19 assistance to people moving forward, but again,
20 in our current reimbursement system, and our
21 current accreditation system, there's little
22 incentive to conduct these in bariatric
23 practices.

24 So what does this mean? I think
25 really, the reimbursement system discourages

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1 long-term care and easier data collection. I
2 know I'm throwing out probably an impossible
3 request, but that said, we need to break the
4 system and come up with a better system to
5 reimburse these services, but I do think it
6 really harms people. You see people and I

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7 think, we didn't see the data in the studies,
8 but I would imagine issues around malnutrition
9 and things like that long term aren't being
10 collected, and this important data that we need
11 to be able to bring forward to people who are
12 considering these procedures or have had them
13 already. And I think that really does explain
14 the low follow-up rate you see on many of these
15 post-bariatric surgery studies, you know.

16 And I will tell you that this has
17 created a cottage industry. Many of these
18 people come to me at OAC or through our
19 organization at OAC looking for this
20 information and we try to provide it as best we
21 can, but it's also popped up all over the,
22 information on the Internet which there are
23 some studies of as well, showing how poor
24 quality -- some are high quality, some are very
25 poor quality, where people are basically

1 getting medical advice from their fellow
2 patients and that is something that, you know,

3 is a tragedy in my opinion.

4 All right. So let's talk about what I
5 think are important to patients. I will again,
6 because of the wide variety of patients and
7 they're very different, we don't have one thing
8 that's important to everyone. But with that
9 being said, I do think we have to move beyond
10 weight loss and physical comorbidities towards
11 quality of life, functional status and
12 patient-reported outcomes. I know it didn't
13 make the AHRQ report because of timing but I
14 would encourage you to look at the Kolotkin
15 piece that reviews quality of life
16 post-bariatric surgery, out to 12 years data,
17 and included some in-depth discussions on
18 potential improvement of future studies in this
19 area, and I think he's going to present a
20 little bit in the public comment section today.

21 But I also think the ongoing PCORI
22 LOBSTER project which is Long-Term Outcomes of
23 Bariatric Surgery Techniques and their Effect
24 on Related Patient-Reported Outcome Measures,
25 studied by Dr. Hutter and his colleagues,

1 should give us a greater collection of that
2 patient-reported outcomes data and the
3 functional status data moving forward. Again,
4 I would encourage the MBSAQIP and the ACS to
5 fully adopt that program and implement it as
6 part of their accreditation process.

7 So in conclusion, I'll just say that I
8 think bias impacts people with obesity as well
9 as people's perceptions about obesity
10 treatment. Please, please don't let bias enter
11 your conversations today. Obesity is a chronic
12 disease and we don't have solutions for
13 everyone yet, and that's why the work that's
14 been done here and the future work that's being
15 done is so very very important.

16 But you have to acknowledge that
17 responses and treatment goals vary between
18 patients. I know you might say well, we want a
19 weight loss of X percent but the average
20 patient, that may not be their goal, they might
21 want to be able to play with their

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22 grandchildren, or get on an airplane or walk
23 down the street without being made fun of.
24 I will say seniors' views, again, this
25 is their views, not just their responses,

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1 generally match the public when it comes to
2 obesity.
3 And I will tell you that data
4 collection is hard, right, and so I think we're
5 going to have to recognize that, like some of
6 the data is missing, but the reality of why
7 it's missing is going to require a concerted
8 effort by all of us to be able to move forward.
9 And finally, I want to say patient-
10 centered outcomes are important, and I think
11 all of this should be about putting patients
12 first, and I know that slide's been up a few
13 times today, and I appreciate the folks at CMS
14 including that and doing that moving forward.
15 I will tell you that for many years I got
16 invited to do these things and be the patient
17 representative. But it's only been the last

18 couple years that I've seen the change, where
19 instead of being the token patient
20 representative, now we're a valued participant
21 in the process, so I want to thank everyone
22 who's participated in that. Thank you very
23 much.

24 (Applause.)

25 DR. CUYJET: Okay. Our next

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1 presenters are Dr. Marschhauser and
2 Dr. Arterburn, after which we will have a
3 ten-minute break.

4 DR. MARSCHHAUSER: Hello, my name is
5 Kim Marschhauser, I'm a program officer in the
6 research infrastructure at PCORI,
7 Patient-Centered Outcomes Research Institute,
8 and I have no other conflicts to disclose.

9 So today I'm going to give a brief
10 introduction to PCORI as well as an overview of
11 our investment in the development of PCORnet,
12 and then I'm going to turn it over to our PI

13 August 30th MEDCAC Meeting Panel Proceedings JS and LA
for the PCORnet bariatric study, David

14 Arterburn, to talk about this important
15 observational study.

16 At PCORI our mission really is to help
17 people make informed healthcare decisions and
18 improve healthcare delivery and outcomes by
19 producing and promoting high-integrity
20 evidence-based information that comes from
21 research guided by patients, caregivers, and
22 the broader healthcare community.

23 There's three important strategic
24 goals to help us meet this mission. So, we
25 need to increase the quantity, quality and

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1 timeliness of useful trustworthy research
2 information available to support health
3 decisions. We aim to speed the implementation
4 and use of patient-centered outcomes research
5 evidence, and we hope to influence the research
6 funded by others to be more patient-centered.

7 So at PCORI, we fund patient-centered
8 outcomes research. This is a relatively new

9 form of comparative effectiveness research that
10 considers patients' needs and preferences, and
11 the outcomes most important to them. It's
12 research that investigates what works, for
13 whom, and under what conditions. And
14 hopefully, it's research that helps patients
15 and other healthcare stakeholders make better
16 informed decisions.

17 We fund research that is patient-
18 centered and engages patients and other
19 stakeholders. So what do we mean by
20 patient-centeredness? This is research that
21 aims to answer questions or examine outcomes
22 that matter to patients within the context of
23 patient preferences. It's research that
24 reflects what is most important to patients and
25 caregivers. And what we mean by patient and

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1 stakeholder engagement is that patients are
2 partners in the research, not merely research
3 subjects. This is active and meaningful

4 August 30th MEDCAC Meeting Panel Proceedings JS and LA
engagement between scientists, patients and
5 other stakeholders throughout all phases of the
6 research process.

7 So our national clinical research
8 system is well intended but flawed, and these
9 are several challenges. So, evidence
10 generation is taking too long to put into
11 practice, research is becoming increasingly
12 expensive, and ultimately research is not
13 answering the questions that matter most to
14 people.

15 So PCORI saw these challenges as an
16 opportunity to create PCORnet, which is the
17 National Patient-Centered Clinical Research
18 Network. This is a large, highly
19 representative national network that enables
20 large-scale clinical research to be conducted
21 with enhanced quality and efficiency, and the
22 mission of PCORnet is to enable people to make
23 informed healthcare decisions by efficiently
24 conducting clinical research relevant to their
25 needs.

1 So with PCORnet, we have a robust
2 infrastructure that unites people, clinicians
3 and healthcare systems with data they gather
4 every day from patients as they have health
5 encounters. PCORnet creates infrastructure and
6 tools to support rapid clinical research, and
7 utilizes multiple data sources including EHRs,
8 claims data, and data reported directly by
9 people.

10 So at PCORnet, we're trying to change
11 the research conversation from one directed by
12 researchers to one driven by the needs of
13 patients and other healthcare stakeholders. So
14 PCORnet embodies a network of networks that
15 harnesses the power of partnership. There are
16 two types of partner networks in PCORnet, there
17 are patient-powered research networks or PPRNs,
18 and these are networks that are operating
19 governed by patients and their partners. So
20 these networks are collecting patient-reported
21 data, they are advocating for the needs of
22 their communities, and they are driving
23 clinical research.

24 So, the second kind of network is our
25 clinical data research networks, or our CDRNs.

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1 These are networks that are routinely health
2 systems such as hospitals or health plans.
3 These networks are currently collecting health
4 information during the routine course of care,
5 and we have over 13 clinical data research
6 networks that serve millions of Americans
7 across more than a hundred health systems.

8 PCORnet also has one coordinating
9 center. So the coordinating center leads the
10 network in engagement and interactions. They
11 work to partner with outside researchers and
12 really support the network's infrastructure.
13 The coordinating center is a collaboration
14 between PCORI, the Duke Clinical Research
15 Institute, the Genetic Alliance, and Harvard
16 Pilgrim Health Care Institute, and together
17 they fill out a multidisciplinary network.

18 The plan (unintelligible) data, and

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19 this data really is a collaboration and
20 partnership between patients, clinicians,
21 researchers and health systems. So with
22 PCORnet we have data on more than a hundred
23 million patients and this data comes from a
24 variety of sources, so to make it useful we had
25 to put it into a standard structure, so that's

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1 why the Common Data Model was created. So
2 shown in blue are the data domains that are
3 currently in the Common Data Model; we have
4 data domains such as claims data,
5 patient-reported outcomes, lab results,
6 demographic information, and highlighted in
7 green are ones that we are working to add in
8 the future to the Common Data Model.
9 So shown here is a schematic of how
10 the PCORnet distributed research network works.
11 So if you wanted to use PCORnet to answer a
12 research question, you would submit a question
13 to the virtual front door, the coordinating
14 center would convert that question to a query

15 and send it to the network partners. They
16 would review the query, provide a response, and
17 send it back through the front door to the
18 requester.

19 It is important to note here that this
20 entire process happens through our local
21 network site, so the data is secure and it
22 never moves.

23 You can use PCORnet for many kinds of
24 research, you can use it for pre-research for
25 feasibility queries, for observational studies

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1 such as epidemiology or comparative
2 effectiveness or safety. You can also use it
3 for interventional studies such as pragmatic or
4 cluster randomization design.

5 So, we've been testing the network's
6 functionality in multiple research settings.
7 PCORI had funded 14 demonstration studies which
8 not only answer important patient-centered
9 research questions, but are also testing the

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10 infrastructure and key functional aspects of
11 PCORnet.

12 Now I am going to turn it over to
13 David Arterburn to talk about one of our
14 observational demonstration studies.

15 DR. ARTERBURN: Good morning, thank
16 you to the committee for the invitation to
17 speak today. I'm David Arterburn, I'm a
18 general internist and researcher at Kaiser
19 Permanente Washington. I'll be speaking about
20 the PCORnet bariatric study. I'm an employee
21 of Kaiser Permanente Washington and the
22 Washington Permanent Medical Group. I've also
23 received research from PCORI and NIH in the
24 area of bariatric surgery.

25 The PCORI bariatric surgery study is

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1 unique for me in that I've been doing research
2 on electronic health records to help me
3 understand outcomes in bariatric surgery for
4 more than 15 years, including in the VA and the
5 Kaiser Permanente system, and other healthcare

6 group research networks, but this is the first
7 time where we have patient co-PIs, and so I
8 actually have two other co-PIs along with me,
9 Kathleen McTigue, University of Pittsburgh,
10 another clinician and obesity researcher; and
11 Neely Williams, a patient partner from one of
12 the clinical data research networks that was a
13 bariatric patient and a community engagement
14 organizer, who's played an invaluable role from
15 the very beginning and inception of the project
16 in terms of designing what types of questions
17 would be important to be answered in this
18 cohort, as well as contributing to interpreting
19 the results throughout the course of the study,
20 and we have other patients who are embedded
21 within the scientific team and within an
22 executive stakeholder group I'll mention in a
23 moment.

24 The PCORnet Bariatric Project is the
25 most ambitious endeavor that I've been involved

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1 in. It includes 42 healthcare systems
2 contributing data to create one database for
3 long-term follow-up of bariatric patients.
4 It's a retrospective study so we're using
5 electronic health record data that are already
6 collected and looking at the experience of
7 those patients over time, but we include 11
8 different networks, including the Chicago area;
9 the greater plains; Philadelphia, Pennsylvania;
10 University of Utah; New York City hospitals;
11 Kaiser Permanente and health partners'
12 integrated hospital systems; the Boston area
13 pediatric hospitals; California; Florida; the
14 mid-south region including Vanderbilt and
15 University of North Carolina; and REACHnet in
16 the Louisiana area, including Baylor Scott &
17 White as well in Texas there. So a large
18 geographically diverse and representative
19 sample of population being generated from this
20 type of network.

21 And we have a large coordinating team
22 to help undertake this work. In the center we
23 have the core scientific team which again,
24 includes patients, bariatric surgeons, and

August 30th MEDCAC Meeting Panel Proceedings JS and LA
25 other scientific investigators. And an

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1 executive bariatric stakeholder advisory group,
2 Joe Nadglowski has served on that particular
3 group as one of our executive stakeholders
4 helping to advise the project on every aspect
5 of the work. A group of PIs from each of the
6 clinical data research networks advising the
7 team, and they represent everyone who is in
8 those different healthcare systems and their
9 different stakeholders as well throughout the
10 executive stakeholder group. And Kim mentioned
11 the coordinating center team which helps us
12 facilitate the running of the queries, the
13 extraction of data for analysis, and then those
14 data funnel down to our different work groups
15 for analysis.

16 Our stakeholders are playing a key
17 role in the PCORnet bariatric project. Our
18 stakeholders include patients, pediatric and
19 adult bariatric surgeons, primary and specialty
20 care providers, researchers and leaders from

21 healthcare organizations for both policy level
22 and advocacy level within different
23 organizations. They work with our PBS team to
24 help us make decisions across the board. Our
25 stakeholders are involved in helping us

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1 formulate questions, collecting and reviewing
2 the data, reviewing medication listings for
3 diabetes medications, for example, reviewing
4 our bariatric procedure code, analyzing the
5 data including prioritization of heterogeneity
6 of treatment effects in the analyses that we're
7 working on, and helping us work on
8 dissemination platforms in terms of connecting
9 with other researchers and healthcare
10 organizations, professional societies to share
11 the results. They contributed also as
12 coauthors on papers as we're beginning to
13 prepare those.

14 So we have three main scientific aims
15 and a secondary aim. These were generated by

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16 the patients and also endorsed by a large
17 stakeholder group that endorsed these as the
18 most important issues to tackle in the
19 comparative effectiveness domain. We're
20 studying gastric bypass, adjustable gastric
21 banding and sleeve gastrectomy because they're
22 the three most commonly performed procedures in
23 the United States, and within these kind of
24 healthcare systems they're the type of
25 procedures we're most likely to find data on.

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1 We wanted to look at one-, three- and
2 five-year outcomes. The PCORnet system is,
3 generates the ends from 2009 for most of the
4 healthcare systems that are involved, so
5 looking beyond five years would be unfeasible.
6 We look at weight loss as one aim, the
7 second aim is to look at type 2 diabetes
8 outcomes, and the third aim is to look at the
9 frequency of major adverse events, including
10 reoperation, reintervention, conversion
11 procedures and mortality, and we're comparing

12 those three different procedures on those
13 outcomes at one, three and five years.

14 Our secondary aim is qualitative in
15 nature and trying to understand patient
16 preferences around the risks and benefits
17 regarding the choice of whether or not to
18 undergo bariatric surgery, which procedure to
19 use, and the optimal follow-up care after
20 bariatric surgery, and we're conducting focus
21 groups in both adults and children who have had
22 bariatric surgery, and those who have severe
23 obesity and are eligible for it but have not
24 had bariatric surgery, including minority
25 patients and patients of lower socioeconomic

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1 status in both groups. And we're also
2 conducting interviews with surgeons and other
3 bariatric medicine providers to help understand
4 the evidence that they need and the
5 conversations that they have with patients to
6 help inform these types of treatment decisions.

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7 This is preliminary data. Our cohort
8 paper was just accepted in the Journal of
9 Medical Informatics Research, so this is
10 in-press data that described our overall
11 cohort. 65,000 adult bariatric patients from
12 42 healthcare systems; a mean age for adult
13 patients of 45 years, and 3,335 patients over
14 the age of 65, that's 5.1 percent of our
15 population; predominantly female, Caucasian,
16 with a large proportion of African American,
17 and 24 percent reported Hispanic ethnicity.
18 Mean BMI is typically high, 49, with 37 percent
19 having a BMI greater than 50 percent; and
20 comorbidities are common as you would expect in
21 this population, with 36 percent having
22 diabetes, 59 percent hypertension, and these
23 are identified based on ICD-9 codes, so you see
24 some laboratory data and other blood pressure
25 and other information is available within the

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1 common data model of PCORnet.

2 Some key observations, again, I

3 mentioned that we have many papers and analyses
4 in the works and Joe mentioned, we're probably
5 about six to nine months from really having the
6 key results in the public domain. But key
7 observations so far is that there's been a
8 really rapid ongoing shift in procedure use.
9 Within the PCORnet sites and I think within the
10 United States, it reflects that the sleeve
11 gastrectomy is now by far the most popular
12 bariatric procedure being performed in the
13 U.S., which has rapidly overtaken the gastric
14 bypass procedure. The adjustable gastric band
15 is really just a small single digit fraction of
16 the total volume of bariatric procedures
17 performed in the United States, and so
18 currently we're doing mostly sleeve
19 gastrectomies, which was really only introduced
20 within the last seven to eight years, in terms
21 of very common use and understanding in the
22 U.S. We have very little longer-term follow-up
23 of that procedure relative to the gastric
24 bypass or even the adjustable gastric banding
25 procedure in that regard, and so studies like

1 this are critical to help inform
2 decision-making that's happening every day when
3 two-thirds of patients are getting the sleeve.
4 There's also significant variability
5 across clinical sites within these 42 different
6 healthcare systems. You've got some sites that
7 almost exclusively do gastric bypass, others
8 that almost exclusively do the sleeve, and
9 others that are doing band, none of which are
10 doing the band primarily but some are doing it
11 much more commonly than others, where some are
12 not doing the band at all, and I think that
13 heterogeneity in the way in which providers are
14 practicing reflects uncertainty in the evidence
15 base and differences in the way in which
16 clinicians are practicing and being trained in
17 the field of bariatric surgery, which
18 influences the access for patients and the
19 types of decisions that they're making. It may
20 not be driven by evidence so much as
21 clinicians' skill or their own personal

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22 preferences. So I think there's a lot to be
23 learned there about how you can share
24 decision-making around bariatric surgery in
25 this field.

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1 Our upcoming reports include our
2 cohort description paper which will be out very
3 soon. We're comparing weight loss across
4 procedures in adults and adolescents
5 separately; diabetes outcomes across procedures
6 in adults, we have too few adolescents within
7 this cohort for a separate effectiveness
8 research analysis so we'll just look at adults
9 there; we are going to look at safety outcomes
10 in both adults and adolescents; and our
11 qualitative paper on attitudes of patients and
12 providers; and we have a methods paper in which
13 we're comparing the impact of using
14 privacy-preserving methods for analysis, and we
15 don't share individual level patient data, we
16 just share aggregate data from sites to
17 estimate the treatment effects, and so we're

18 preparing a comparison between our individual
19 level use and aggregate data and that will be a
20 report forthcoming.

21 And I think one of the most impressive
22 aspects of this work is we're on track for,
23 it's a two-year project, so everything that I
24 put there is, it really goes back to what Kim
25 presented in terms of PCORI about providing

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1 more information more efficiently, and for
2 questions that are relevant to patients and
3 providers, to help meet the needs of policy
4 makers. And so while the data aren't available
5 today, the fact that we're producing all of
6 this within two years to help answer clinical
7 questions and policy questions that are at
8 issue is a testament to what kind of work can
9 be done within the PCORI system. Thank you.

10 (Applause.)

11 DR. CUYJET: So, we're going to take a
12 quick break, I'm going to ask you to please

August 30th MEDCAC Meeting Panel Proceedings JS and LA
13 return to the auditorium by 10:35. Thank you

14 very much for your attention.

15 (Recess.)

16 DR. CUYJET: All right. I'm just
17 going to ask the panel to speak close to the
18 microphones so everybody can hear in the back.

19 And we have scheduled public comments.
20 The first speaker is Sidney Rohrscheib; am I
21 pronouncing that correctly?

22 DR. ROHRSCHEIB: Rohrscheib.

23 DR. CUYJET: Just a reminder, I will
24 ask everybody to limit themselves to four
25 minutes.

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1 DR. ROHRSCHEIB: I'm Sid Rohrscheib, I
2 practice in an area that I think the panel
3 members would consider rural. I was one of the
4 gastric banding early adopters, I've placed
5 about 2,500 of these devices in central
6 Illinois patients. My only interest to
7 disclose is a consulting and investigator role
8 with Apollo.

9 The results of gastric banding have
10 been touched on earlier today. It's really
11 been in the last five years that the more
12 compelling reviews have been published that
13 attest to its meaningful and durable benefit.

14 I really want to show you that gastric
15 band may have a particular application for the
16 Medicare population, which includes patients
17 which are older, patients who are likely averse
18 to if not fearful of having surgery, and
19 patients who may have risks for surgery making
20 more invasive procedures unwise.

21 Not to repeat what's been touched on
22 earlier, but just to supplement, you know,
23 global weight loss has been demonstrated in
24 studies that are with long-term follow-up
25 enrolling large numbers of patients. Being the

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1 least invasive procedure, gastric banding
2 should have the lowest postoperative
3 complication rates. Other outcomes that have

4 August 30th MEDCAC Meeting Panel Proceedings JS and LA
5 been measured include comorbidity resolution,
6 quality of life improvements, and when you have
7 comorbidity resolution, you have health care
8 savings.

9 With regard to Medicare, the CLOUD
10 study followed patients over age 60 after
11 gastric banding and found that weight loss,
12 comorbidity resolution and quality of life
13 improvement were consistent with those same
14 measured outcomes in younger patients. When
15 surveyed, 92 percent of these older folks said
16 they'd recommend the treatment to other obese
17 patients. With zero mortality, these authors
18 concluded that banding is perhaps the most
19 appropriate bariatric procedure for this age
20 group due to safety and efficacy.

21 If I could reinforce what's been
22 hinted at earlier today, we need to pursue the
23 treatment of this disease earlier in its
24 course. Listed are four prospective
25 multicenter trials showing undeniable fit of
gastric banding with lower BMI patients.

1 Dixon's work was the basis for our FDA making
2 gastric banding the only treatment appropriate
3 for BMI less than 35. I do believe that as we
4 continue to demonstrate the safety that was
5 illustrated earlier, we're going to find that
6 sleeve gastrectomy is appropriate for this
7 group as well.

8 The graphic I've generated here is a
9 representation of what's the most recent report
10 of MBSAQIP data. In this comparison the
11 results of the three other primary operations
12 for weight loss surgery are compared with
13 gastric banding, and what's demonstrated is
14 these operations that we offer are on a
15 spectrum, they're on a spectrum of costs,
16 they're on a spectrum of efficacy, but they're
17 also on a spectrum of adverse events.

18 There's other trends that are not
19 apparent but they're implied by this graphic.
20 There's a trend for lower to higher BMI as you
21 move from the left to the right. The
22 institutional setting in which these operations
23 might find themselves being used are generally

24 from lower to higher acuity as you move from
25 left to right. And if you use my practice and

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1 others like mine around the country, those on
2 the left are favored in the rural environment,
3 the operations on the right find themselves
4 focused in larger urban centers. Medicare
5 patients being everywhere, all these options
6 have a place.

7 Patient selection is critical to
8 outcomes in bariatric surgery, as is a
9 dedication to their follow-up afterwards. In
10 my experience, patient selection is still
11 self-determined. It's a thing called patient
12 choice. The literature supports what continues
13 to be observed in my clinical practice and that
14 is, the majority of patients which are still
15 selecting gastric banding as a primary
16 treatment are opposed to and will not pursue
17 more invasive treatment even if given --

18 DR. CUYJET: Dr. Rohrscheib, pardon me

August 30th MEDCAC Meeting Panel Proceedings JS and LA
19 for interrupting, but your time is up. Let's

20 move on to the next speaker, which will be

21 Dr. Gunstad.

22 DR. GUNSTAD: All right, so good

23 morning, everyone. I'm John Gunstad, I'm a

24 clinical neuropsychologist from Kent State, and

25 I'll have a chance to go over in the next

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1 couple of minutes to talk a little bit about

2 the potential cognitive benefits of bariatric

3 surgery. Just a little bit of information

4 about disclosures.

5 To provide a little bit of context for

6 why a neuropsychologist would be interested in

7 looking at obesity and particularly severe

8 obesity and bariatric surgery, here is some

9 background. So, we know that midlife obesity

10 is very strongly associated with stroke,

11 Alzheimer's disease, vascular dementia,

12 Parkinson's disease, these diseases all have

13 most significant adverse brain outcomes in

14 older adults.

15 Even in these victims who don't have
16 all these conditions, we know that obesity is
17 associated with accelerated cognitive decline
18 and abnormalities on brain functioning. So
19 it's kind of a rough hurdle to overcome with
20 something like this, is that as individuals
21 age, their casual obesity really seems to
22 increase brain aging by about eight to ten
23 years. We tend to think that severe obesity
24 might actually confer even greater effects.
25 So here's some work showing there's a

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1 significant interaction between age and
2 severity of obesity. So as we can see from the
3 dotted line down at the bottom, the individuals
4 with advancing age with more severe obesity
5 show greater cognitive impairment.

6 A more striking example is found in
7 this slide where we had the chance to look at
8 170 individuals with severe obesity, and what
9 we're seeing here are the prevalent finding

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10 that individuals who meet the diagnostic
11 criteria for MCI, or mild cognitive impairment,
12 which is a commonly-used rubric for identifying
13 those individuals with clinical demands or
14 clinical requirements for a memory disorder or
15 other brain-based disorder.

16 So as you can see, the rates, the
17 prevalent rates are very very high and again,
18 for the overall sample it's more than 50
19 percent, but we have to put this number in
20 context. You see the small dotted line way
21 down at the bottom; that's the rate of MCI
22 individuals over age 54 in the general
23 community, and the dotted line up above at
24 about 20 percent is the rate of MCI in
25 individuals in the community who are age 68.

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1 So what's significant in this case is it's
2 associated with, again, a more than two-time
3 increase in the rate of MCI which may
4 ultimately progress to things like Alzheimer's
5 disease and other cognitive disorders.

6 So in taking a look at all this, and
7 again, for an individual who's kind of
8 permanently less so because they're always
9 optimistic, the general thought of this gaining
10 weight or increasing weight actually harms the
11 brain, and potentially losing weight might be
12 able to heal the brain in some sort of way.

13 And we had the chance to do this
14 through the LABS ancillary study where we had
15 the chance to test cognitive function before
16 surgery and several time points later.

17 So the first, and maybe the most
18 important part of all of this, we found that
19 there was no significant deleterious effect on
20 cognitive function for individuals who went
21 through an uncomplicated surgery, and showed no
22 difference from control in time points before
23 surgery to 12 weeks later, again, kind of an
24 argument that it's safe for the brain.

25 Much more exciting is the possibility

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1 of postoperative improvement, so following
2 these individuals over time, what we found is
3 that cognitive functioning improved and
4 improved rapidly. So even by 12 weeks postop,
5 individuals showed significant improvement in
6 memory and executive functioning, so that
7 includes things like problem solving, planning,
8 organizing, relative to severely obese
9 controls.

10 In looking at this, we say that these
11 gains continued up to about one year and then
12 persisted over time, so we can argue that going
13 through this weight loss procedure, for many
14 individuals it led to improved memory and
15 ultimately, hopefully, made improvements in
16 their brain functioning. These are relevant
17 today and pertinent to the Medicaid eligible
18 individuals, and we find that the same benefit
19 actually occurred in both above and below 55
20 years of age. So when we look at this rate,
21 again, there's some potential concern that
22 obesity over the course of time could actually
23 harm the brain in ways that would be
24 irreversible and we found no evidence for that.

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25 So older adults, in this case being 55 plus,

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1 who went through bariatric surgery procedures,
2 showed the same rate of improvement in memory
3 and executive functioning as did young adults
4 going through these procedures.

5 And again, why this is particularly
6 noteworthy is we know that this type of
7 cognitive impairment is associated with other
8 bad outcomes in other populations, so persons
9 with cardiovascular disease or diabetes who
10 have cognitive impairment are more likely to be
11 hospitalized, more likely to be less adherent,
12 and actually have premature (unintelligible).
13 Thank you very much for your time.

14 DR. CUYJET: Thank you. Next is
15 Dr. English.

16 DR. ENGLISH: I thank you for the
17 opportunity for me to speak to you today. My
18 name is Wayne English, I'm a professor of
19 surgery at Vanderbilt University and cochair of
20 the standards and verification committee for

21 the Society for Metabolic and Bariatric
22 Surgery. I've also participated in several
23 clinical trials evaluating gastric balloons.
24 Here are my disclosures.
25 Today I'm going to be speaking to you

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1 on the importance of MBSAQIP accreditation and
2 then briefly discuss gastric balloons. The
3 MBSAQIP standards are predicated on creating a
4 common theme for any metabolic or bariatric
5 surgery practice in an effort to reduce
6 practice variation and improve overall quality
7 of care. Site inspections are conducted every
8 three years to ensure centers are maintaining
9 high quality structured process and outcome
10 measures. Real-time comments are adjusted and
11 semiannual risk-adjusted reports are provided
12 to assist with quality improvement efforts.

13 The history of the development of
14 MBSAQIP, I'm not going to go into any major
15 details other than, this is a relatively new

16 August 30th MEDCAC Meeting Panel Proceedings JS and LA
program with much more robust data checks than
17 previous programs that existed. There are
18 currently over 800 centers in the United
19 States, and a review of the most current
20 nationwide intake and sample data available to
21 us demonstrated that 92 percent of the centers
22 performing metabolic and bariatric surgery in
23 the United States are accredited centers.
24 Therefore, we are capturing the lion's share of
25 the metabolic and bariatric surgery data across

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1 the country.
2 When the standards were first
3 developed in 2014, there were over 1,100 public
4 comments considered before they were finalized.
5 With lessons learned the standards were
6 implemented, and subsequently revised in 2016.
7 Future editions of standards will take place
8 every three years to ensure satisfactory
9 updates with new trends or to correct issues
10 with the existing standards.
11 The core standards have a minimum

12 volume requirement of 50 cases annually to gain
13 comprehensive accreditation status, but centers
14 performing lower volumes can still become
15 accredited by performing procedures on lower
16 acuity patients. The standards are verified
17 through onsite surveys and performance reviews.
18 As a result, surveys are reviewed by blinded
19 application reviewers and if there is a
20 disagreement, it is adjudicated by a special
21 committee.

22 To ensure that new procedures are
23 being introduced safely, ASMBS developed a new
24 pathway to standardize the introduction and
25 approval of emerging technology, new procedures

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1 and various new and existing techniques.
2 MBSAQIP requires data entry for all procedures,
3 and centers can readily perform procedures if
4 it's listed as an approved procedure. However,
5 IRDO decides if required, if a procedure is not
6 approved.

August 30th MEDCAC Meeting Panel Proceedings JS and LA
7 An important change in the standards
8 was made to capture all data, emerging
9 technology, new procedures and variations of
10 existing techniques, which will lead me to the
11 next topic of gastric balloons. I'm not going
12 to go into any details since this has been
13 brought up on previous discussions, other than
14 to help assist with answering question number
15 three. For the additional discussion topic
16 section, I would like to ask you to consider
17 the following: With the introduction of new
18 technology and increasing number of procedures
19 being performed in the United States, a 36
20 percent increase since 2011, it's critical to
21 monitor outcome functioning, and the MBSAQIP
22 provides a platform that currently is capturing
23 data from 92 percent of inpatient centers
24 across the country. I want to thank you for
25 your time today.

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1 DR. CUYJET: Thank you. Dr. Still is
2 the next presenter.

3 DR. STILL: Good morning, everyone,
4 it's a pleasure to be here. I'm a little bit
5 in the minority that I'm not a surgeon, I'm
6 just an internist and an obesity medicine
7 specialist, and I would like to present our
8 bariatric surgery outcomes to try to answer
9 some of your questions from Geisinger Health
10 System in central Pennsylvania. Here are my
11 disclosures. I speak for a couple
12 pharmaceutical companies, I do have an
13 investigator initiated grant, we consult on
14 surgery, and I'm an employed physician at
15 Geisinger.

16 So, our bariatric surgery cohort is
17 pretty typical of what we've heard, about 80
18 percent female, 20 percent male. A little
19 difference is we have longer follow-up, we have
20 about 70 percent follow-up at eight years, and
21 our BMI is a little higher, the average BMI
22 that we operate on is 51.

23 In answering some of the questions
24 with regard to Medicare population with weight
25 loss, I've split it up between over 65 and

1 under 65, and you can see the percent weight
2 loss after five years. Of note, the patients
3 under 65 were 678 Medicare patients, and over
4 65, about 150, and this is pretty typical of
5 what we see in our general population with
6 regards to weight loss, it's very durable over
7 the long term.

8 With regard to diabetes remission I
9 also broke it up not only between under and
10 over 65, but patients that were on insulin
11 preoperatively, and you can see the remission
12 rates between the two groups.

13 One thing I think is important from an
14 internist in treating diabetes, it's great that
15 we look at remission rates, but a lot of
16 improvement is on getting off of insulin,
17 getting their lipids under control, all these
18 bundles that were so important to us with
19 regards to patient care significantly improved,
20 whether they remit their type 2 diabetes or
21 not.

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22 With regard to the Medicare population
23 change of quality of life, you can hear a
24 significant improvement in quality of life
25 before and after surgery both on the Medicare

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1 population younger than 65 and older than 65.
2 Switching gears to all patient
3 populations within Geisinger, not just the
4 Medicare but looking at all-cause mortality, so
5 these were age and matched controls of
6 individuals within our integrated health system
7 versus individuals who underwent bariatric
8 surgery, and you can see that there's a
9 significant improvement in all-cause mortality
10 over ten years, or at ten years.
11 With regard to MI, stroke and heart
12 failure, also with regard to cardiovascular
13 events, to answer your questions about that, a
14 significant improvement. And just to split
15 these up a little bit with what Dr. DeMaria
16 said today, what was really significant was the
17 improvement in congestive heart failure as well

18 as outlined today, it was very very important,
19 very costly, and very high morbidity and
20 mortality for the patients.

21 Switching gears with regards to
22 musculoskeletal, which I think is a barrier to
23 care, is the SWIFT trial that I serve as a PI,
24 a multicenter looking at surgical weight loss
25 improvement of functional status trajectories

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1 following total replacement. We know that
2 degenerative disease is much higher in patients
3 with obesity, and actually patients with
4 obesity require arthroplasty about five or ten
5 years earlier. There's been really no
6 randomized trials and we know that the 30-day
7 postoperative complication following knee
8 replacement is much higher in individuals with
9 a BMI of 40.

10 So this is, the SWIFT trial is to look
11 at those bariatric surgeries before total knee
12 replacement, improvement of perioperative and

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13 long-term outcomes in extremely obese patients,

14 and does bariatric surgery before TKA actually
15 delay and negate the need for the arthroplasty.

16 And so this is, the top rung here is
17 individuals that are both in the control arm
18 and individuals that will have bariatric
19 surgery, and we will see afterwards how they
20 do. Thank you very much for your time.

21 DR. CUYJET: Dr. Jirapinyo, if I'm
22 pronouncing that correctly.

23 DR. JIRAPINYO: Thank you very much.
24 I'm Sigh Pichamol Jirapinyo, I'm a bariatric
25 endoscopy fellow from the Brigham & Women's

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1 Hospital. GI paid for my trip today;
2 otherwise, no other financial relationships.

3 Obesity is associated with multiple
4 comorbidities, including cardiovascular
5 disease, fatty liver, and type 2 diabetes. As
6 the number of obesity cases increases, the
7 number of patients affected by these
8 comorbidities continues to rise. In 2015, 30

9 million Americans, or approximately ten percent
10 of the U.S. population had diabetes. This
11 translates to approximately 245 billion U.S.
12 dollars spent caring for this patient
13 population.

14 Traditionally, diabetes is treated
15 with oral and injectable medications such as
16 insulin. However, for some patients, their
17 glycemic control remains inadequate despite
18 optimal maximal medications and also a
19 combination of medical therapies.

20 On the other hand, worldwide bariatric
21 surgery has been shown in multiple studies to
22 be effective at treating diabetes. In fact,
23 recently the international diabetes
24 organizations have released a joint statement
25 suggesting that worldwide gastric bypass be a

1 recommended therapy for diabetes in patients
2 with BMI of higher than 40. It should also be
3 considered in patients with BMI of higher than

4 August 30th MEDCAC Meeting Panel Proceedings JS and LA
30 whose glycemic control remains suboptimal.

5 Nevertheless, despite efficacy, only
6 one percent of patients who are eligible for
7 surgery undergo the surgery. Realizing this
8 gap in therapy, a breakstone technology was
9 recently developed to treat diabetes and
10 obesity. The device is a 67-millimeter
11 fluoropolymer screen that is endoscopically
12 placed into the (unintelligible) proximal to
13 the duodenum. It minimizes the gastric bypass
14 anatomy by preventing a contact between food
15 and the proximal small intestine.

16 Additionally, it accelerates food
17 progression and allows it to reach the distal
18 small bowel earlier. This leads to a spike in
19 gut hormones that leads to, that are beneficial
20 for weight loss and glycemic control. A recent
21 meta-analysis of 17 published studies shows
22 that this method is effective at treating
23 diabetes and obesity. At one year after device
24 implant, which is when the device is removed,
25 hemoglobin A1c decreases by 1.3 percent

1 compared to baseline. Compared to the control
2 patients who undergo a sham procedure or
3 lifestyle modification alone, the
4 (unintelligible) had a greater decrease in
5 hemoglobin A1c of 0.9 percent. This metabolic
6 effect appears to last up to at least six
7 months post-explant.

8 From a weight loss standpoint at the
9 time of explant, patients lose approximately
10 11.3 kilograms, with corresponding decrease in
11 BMI of 4.1, percent total weight loss of 19,
12 and percent excess weight loss of 39. This
13 effect on weight loss appears to be significant
14 at at least one year post-explant.

15 Similar to Roux-en-Y gastric bypass,
16 the (unintelligible) was shown to be associated
17 with an increase in gut hormones
18 (unintelligible) as well as an increase in GIP.
19 This suggests that the (unintelligible) liner
20 is similar to the use of the Roux-en-Y gastric
21 bypass, and we know (unintelligible) for
22 diabetes.

23 Given its minimally invasive nature,

24 this liner makes it easier to increase the
25 number of patients who are receiving effective

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1 therapy for diabetes in the near future.

2 Additionally, this would allow us to reduce
3 complications of diabetes such as many
4 cardiovascular diseases, end-stage kidney
5 diseases, and death. Thank you very much.

6 (Applause.)

7 DR. CUYJET: Leslie Narramore is our
8 next speaker.

9 MS. NARRAMORE: Hi. My name is Leslie
10 Narramore and I am the director of
11 reimbursement at the American
12 Gastroenterological Association. I have no
13 conflicts.

14 So, as internists, specialists in
15 digestive disorders, and endoscopists,
16 gastroenterologists are uniquely positioned to
17 play an important role in the multidisciplinary
18 treatment of obesity. The AGA is leading a

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19 multidisciplinary initiative to guide
20 gastroenterologists in the comprehensive care
21 of patients with obesity. Our Practice Guide
22 on Obesity and Weight Management, Education and
23 Resource, known as POWER, provides physicians
24 with an evidence-based comprehensive
25 multidisciplinary process to guide and

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1 personalize innovative obesity care for safe
2 and effective weight management.
3 It's vital to understand the
4 importance of embracing obesity as a chronic
5 relapsing disease that requires a long-term
6 multidisciplinary approach to management.
7 Patients who are overweight or obese present to
8 gastroenterology clinics daily with
9 obesity-related gastroesophageal reflux disease
10 and its associated risks of Barrett's esophagus
11 and esophageal cancer, nonalcoholic fatty
12 liver disease, and an increased risk for colon
13 polyps and cancer. Since the gastrointestinal
14 disorders resulting from obesity are frequent

15 and often present sooner than type 2 diabetes
16 and cardiovascular disease, gastroenterologists
17 should be on the front line in providing
18 effective therapies.

19 There is rich evidence supporting
20 improved health outcomes after treatment with
21 nonsurgical endoscopic bariatric therapy or
22 EBT, which are provided by gastroenterologists
23 in patients which include the Medicare
24 population that other presenters have provided
25 in detail.

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1 In addition, the AGA POWER white
2 paper, an episodic framework for the management
3 of obesity, provides ample evidence that EBT
4 intervention benefits outweigh harms, and
5 highlights the necessity of using these tools
6 as part of a comprehensive support program to
7 provide long-term benefits. Instead of a
8 linear care pathway, the POWER program is more
9 circular, to present the fact that obesity is a

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10 chronic disease that requires a lifelong
11 multidisciplinary approach for effective
12 long-term therapy.

13 Given the challenges of both achieving
14 weight loss and sustained weight management,
15 approaches that combine therapies can improve
16 clinical efficacy. While bariatric surgery is
17 an option for patients who meet Medicare
18 criteria, low adoption demonstrates that
19 patients often have a psychological bias
20 against anatomy-altering surgery, its risks and
21 potential costs. To reach more Medicare
22 beneficiaries with obesity, MedCAC should
23 consider coverage of EBT for patients who are
24 unwilling to undergo life-altering surgery, who
25 might find a nonsurgical approach more

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1 acceptable, or for patients with multiple
2 comorbidities who are not good candidates for
3 bariatric surgery.

4 Additionally, the truly minimally
5 invasive approach of EBT may also allow for

6 earlier interventions at lower class levels of
7 obesity. The POWER program provides physicians
8 with a comprehensive multidisciplinary process
9 to guide and personalize obesity care that
10 incorporates concomitant use of obesity
11 therapies based on individual patient
12 comorbidities and goals.

13 EBT has proven successful when
14 supported by comprehensive obesity care and
15 support. However, there are barriers to
16 widespread adoption. Barriers to care include
17 the 1987 national coverage determination, or
18 NCD, for gastric balloon for treatment of
19 obesity, 100.11, which established non-coverage
20 of gastric balloon devices. Gastric balloons
21 in use today are both safe and effective, as
22 demonstrated in pivotal FDA trials. However,
23 the NCD has not been updated since its
24 implementation 30 years ago.

25 We ask CMS and MedCAC to consider

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1 retiring NCD 100.11. Given the crisis of the
2 obesity epidemic, the profound costs to patient
3 health and healthcare spending, EBTs are
4 effective therapies that can safely improve the
5 treatment of obesity and are important
6 advancements to existing therapy options.
7 Thank you for the opportunity to provide input.

8 (Applause.)

9 DR. CUYJET: Dr. Shelby Sullivan is
10 our next presenter.

11 DR. SULLIVAN: Thank you for inviting
12 me to talk here today. I do have some
13 disclosures. I have both had research and
14 grant support as noted here, as well as
15 consulting for a number of different devices
16 that we will be talking about today.

17 I'll start by just briefly talking
18 about weight loss in relation to cardiovascular
19 mortality, or cardiovascular outcomes. This is
20 a post hoc analysis that was done for the Look
21 AHEAD trial that included 4,406 subjects aged
22 45 to 76, the average age was greater than 55.
23 This was data that was presented earlier today
24 looking at outcomes in patients who are in the

1 population.

2 What was found in this post hoc
3 analysis is that even though the trial was not
4 looking at the differences in cardiovascular
5 outcomes in patients who were in the intensive
6 arm as compared with the control arm, patients
7 who had ten percent or more total body weight
8 loss gained reductions in cardiovascular
9 outcomes. This is important when we start
10 talking about our bariatric therapies which I
11 will get to in a minute.

12 We have a number of devices that have
13 recently been approved for use by the FDA.
14 These include the intragastric balloons which
15 are shown on this slide. I have included the
16 ReShape dual balloons and the Orbera balloons,
17 which are gold fluid filled balloons that are
18 placed endoscopically and removed
19 endoscopically, as well as the Obalon balloon
20 system, which is a three-balloon system that is

21 swallowed, that is contained in capsules and
22 are swallowed over time, and filled with a
23 nitrogen mix gas. All of these balloons are
24 removed six months after initial placement and
25 all of them are removed endoscopically.

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1 When we look at a comparison of these
2 intragastric balloons, just look at the data,
3 there is no good evidence that these balloons
4 are effective compared to the control group.
5 There is a difference between the study that
6 was done that was a randomized control compared
7 to those that were randomized to sham controls,
8 which ultimately showed Obalon being randomized
9 by sham control trials.

10 And there was a serious adverse event
11 rate that was in the 10 percent range for
12 Orbera and ReShape. However, these both were
13 driven by, the majority of the serious adverse
14 events were because of dehydration and we have
15 since become much better in being able to treat

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16 these and prevent those from happening, and the
17 serious event rates in clinical practice are
18 significantly lower.

19 The other thing to point out from this
20 is that the weight loss that we see in these
21 trials is significantly lower than the weight
22 loss that we see in clinical practice. This is
23 data from the ReShape and Orbera clinical case
24 series compared with the clinical trials, and
25 you see that there's significantly greater

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1 weight loss in the clinical case series, which
2 are in the dark blue.

3 In addition to that, there is some
4 long-term weight loss evidence with these
5 balloons as well. We have this study that came
6 out of Europe which shows that weight loss
7 maintenance in at least 23 percent of patients
8 occurred with the Orbera balloon system at five
9 years.

10 Now in addition to that, we had weight
11 loss maintenance of almost 90 percent in the

12 Obalon balloon system, the randomized sham
13 control trial in the U.S. as well.

14 Going on to our next device, we have
15 the AspireAssist system which was approved for
16 use as well, with a similar concept of a
17 percutaneous endoscopic gastrostomy tube, and
18 has a known serious adverse rate of two percent
19 in the older adult population. This includes
20 the aspiration of gastric contents 20 minutes
21 after a meal two to three times a day, and it
22 removes 25 to 30 percent of those calories.
23 However, that aspiration only accounts for
24 about 50 to 80 percent of the weight loss, and
25 the remaining weight loss is due to lifestyle

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1 changes and mealtime behaviors, which actually
2 reduced the amount of food they actually
3 consumed. Weight loss with this device is
4 approximately 14 to 21 percent at one year,
5 with a limited number of patients out to four
6 years that demonstrates about 20 percent weight

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loss out at four years.

8 So in summary, we have the balloons
9 that have 10 percent or more weight loss in
10 clinical practice at one year and has a very
11 good safety profile, and aspiration therapy had
12 14 to 21 percent as well. And we would
13 recommend that if CMS would like to get more
14 validation in these older adults that they
15 would do this in a registry program, as there
16 is now funding mechanisms to actually get this
17 data in this compilation.

18 DR. CUYJET: Thank you, Dr. Sullivan.
19 Dr. Hutter is next.

20 DR. HUTTER: I would like to thank the
21 panel for the honor of presenting today. My
22 name's Matt Hutter, I'm a bariatric surgeon,
23 I'm the director of the MGH Weight Center and
24 the director of the Codman Center for Clinical
25 Effectiveness. I do have a disclosure. I'm

1 the PI in this study funded by PCORI and I will
2 be discussing that study today.

3 As was talked about before, the
4 accreditation program has been established for
5 metabolic and bariatric surgery, combining the
6 American College of Surgeons with the ASMBS to
7 create the MBSAQIP. Dr. David Hoyt is the
8 executive director of the American College of
9 Surgeons and the American College of Surgeons
10 overlooks the cancer database, the common
11 database, and if you want to relay a message,
12 it's sent to the bariatric data collection
13 program, and what the Bariatric Society has
14 done is one of the shining examples of what can
15 be done in surgery for improving quality of
16 care.

17 So specifically with the
18 self-accreditation program, bariatric-specific
19 data points for qualified clinical data
20 registries, we're putting the patient-reported
21 outcomes over some of those details.

22 The MBSAQIP data collection has been
23 talked about before. It's a hundred percent of
24 cases. 95 percent of all bariatric cases
25 throughout the country are currently enrolled

1 in this accreditation program, and all of the
2 cases are included. This is clinically rich
3 statements. This is highly trained nurse
4 reviewers at the collection centers; we're
5 using standardized definitions, not ICD-9 codes
6 to look at each medical record to look at
7 outcomes, bariatric-specific outcomes,
8 weight-related diseases, diabetes,
9 hypertension, hypercholesterolemia, obstructive
10 sleep apnea. And not just at 30 days, it's 30
11 days, six months, one year, and annually
12 thereafter, so a very strong robust data
13 collection programming which is the
14 underpinning not only for accreditation but
15 most importantly for quality improvement, and
16 also for the opportunity when we get new
17 techniques and new technology to look at them
18 and the safety in regard to them.

19 When the sleeve gastrectomy was
20 starting to be done, there was not a CPT code.
21 We added a variable before it was done. When

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22 the FDA decided to approve these devices, we
23 actually added variables to the endoscopic
24 bariatric procedures, and we mandated that they
25 cover all of the information. So very robust

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1 data that we've kept importing information
2 from, compared across 95 percent of all the
3 hospitals in the country and in the future with
4 new devices. High quality data prospectively
5 gathered. Each site trained, audited.

6 The data collectors are not involved
7 in patient care, so if you're the nurse or the
8 surgeon in patient care, you can't enter the
9 data on that patient, it has to be objective.
10 The standard definitions are audited, with site
11 reviews of the data as well.

12 We also applied and work with CMS in
13 order to become a qualified clinical data
14 registry, the only program in the American
15 College of Surgeons that is currently a QCDR,
16 the bariatric program is, again, a shining
17 example of what we can do. So working with CMS

18 with the knowledge that this is a qualified
19 clinical data registry, and we've come up with
20 additional methods to produce the nine
21 different methods that are currently available
22 through QCDR, we update these yearly, and
23 surgeons are currently participating in this
24 program.

25 We're also developing patient-reported

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1 outcomes, so as has been talked about before,
2 patient-reported outcomes are what matters most
3 to the patients, so we've recently been funded
4 by PCORI, a four-year grant, the long-term
5 outcomes of bariatric surgical techniques,
6 working with the American College of Surgeons,
7 with Mass General Hospital, and with the
8 MBSAQIP to bring patient-reported outcomes to
9 the actual data collection programs.

10 We've gone through an alpha pilot, we
11 have data collection programs, and we're
12 currently in a beta pilot to roll this out, and

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13 we're looking forward to voluntary national
14 implementation as soon as July, or January of
15 this upcoming year, so this is right in the
16 works.

17 The PCORI grant conducts focus groups
18 to get alpha pilots to look at the data
19 collection programs, to look at this, and we're
20 using validated metrics. So what was added was
21 20 different focus groups in order to identify
22 the metrics that made the biggest difference to
23 patients in order to collect that information.

24 But most importantly, we want to
25 report this back, so this is The Right

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1 Operation for the Right Patient Tool, this
2 robust data collecting program, and we get it
3 back to the patient level with this tool, so
4 patient-reported outcomes can be compared with
5 all other assessments. I want to thank you
6 very much for the opportunity to present today.

7 (Applause.)

8 DR. CUYJET: The next presenter is

9 Dr. Scott.

10 DR. SCOTT: Hello. My name is John
11 Scott and I'm a bariatric surgeon in
12 Greenville, South Carolina, and I'm also the
13 acting cochairman for the ASMBS. My
14 disclosures are listed here.

15 We've spent hours reviewing the ample
16 evidence to support bariatric surgery obesity
17 care in the Medicare population. I would like
18 to focus my comments on a significant barrier
19 to care that exists for many patients.

20 Sadly and unfairly, universal coverage
21 for bariatric surgical services does not yet
22 exist. In addition, many local coverage
23 decisions force Medicare-receiving patients who
24 suffer from obesity and who are interested in
25 bariatric surgery to navigate a maze of

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1 arbitrary preoperative requirements. One such
2 barrier to care is the mandatory preoperative
3 six-month medical weight management program,

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4 and these programs delay surgical care. This
5 is unique among surgical interventions for
6 chronic life-threatening disease processes.
7 Evidence demonstrates that
8 LCD-required delays have unintentionally led to
9 patient frustration, delays in specific obesity
10 care, disease progression, especially type 2
11 diabetes. These mandates unnecessarily
12 increase medical costs as medical providers
13 have up to four visits to facilitate these
14 programs. There is an absence of reasonable
15 level of medical evidence to support this
16 practice. Therefore, it is the position of the
17 ASBMS and it is my opinion that the requirement
18 for documentation of a prolonged preoperative
19 procedure prior to bariatric services being
20 performed is inappropriate and
21 counterproductive. Policies such as these
22 delay, impede and otherwise interfere with
23 live-saving and cost-effective treatment, and
24 these are unacceptable without supporting
25 evidence.

1 There is no large-scale evidence that
2 exists which indicate that LCD-mandated
3 six-month medical weight loss programs
4 significantly alter postoperative courses for
5 patients. However, there are many studies that
6 show otherwise. In fact, there's several
7 studies that support the opposite conclusion.
8 In this one study, 1,400 patients were
9 stratified payer mix and presurgical weight
10 loss requirements and matched into groups. A
11 regression analysis was performed, and no
12 significant differences were found in weight
13 loss outcomes between the mandated weight
14 management group and the comparison group at
15 one to two years.

16 Other studies indicate that two-week
17 very low calorie diets do not impact operative
18 time, intraoperative blood loss, or
19 complications. Six months of intensive
20 behavioral therapy versus standard preoperative
21 care demonstrated no difference in weight loss
22 after six to 12 months postop. And six months
23 of medical weight loss versus usual care

24 demonstrated no differences to weight loss or
25 behavioral outcomes.

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1 I recently reviewed our own internal
2 data from GHS between 2014 and 2015. We
3 obtained data on 354 patients and of these, 75
4 percent of patients were required by insurance
5 mandated preoperative management programs, and
6 25 percent of patients had no preoperative
7 insurance mandated delay. We found that
8 participation in insurance or LCD-mandated
9 weight management program for three to six
10 months prior to performance of bariatric
11 surgery was not associated with any improved
12 patient outcomes.

13 To be specific, we saw no significant
14 differences in patient rate of follow-up,
15 percentage of aggregate weight loss,
16 readmissions, reoperations at 12 months, or
17 postsurgical follow-up. To our knowledge,
18 there are no medical restrictable conflicts for

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19 these patients who were not required to
20 complete an insurance-mandated weight loss
21 program. This suggests that undergoing
22 bariatric surgery without completing an
23 insurance-mandated weight management program is
24 safe and effective in the short term.
25 In conclusion, there is no randomized

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1 control trial, no large prospective study, or
2 no meta-analysis that supports the use of
3 LCD-mandated preoperative weight management
4 programs. This practice is arbitrary,
5 capricious, unnecessary, and often delays
6 life-saving treatment, contributes to patient
7 attrition, and is most likely unethical.
8 Decisions regarding readiness of a patient for
9 bariatric surgery should be made between a
10 doctor and a patient. If future coverage
11 decisions are based on payer instructions, this
12 barrier to care should be universally
13 abandoned. Thank you for your time.
14 (Applause.)

15 DR. CUYJET: Dr. Sudan.

16 DR. SUDAN: My name is Ranjan Sudan,
17 Duke University. I serve on the executive
18 council of the ASMBS and I was previously their
19 research committee chair.

20 Obesity is a chronic disease that is
21 successfully treated by different primary
22 bariatric operations. A number of factors are
23 considered when selecting a particular
24 operation, but the initial operation is
25 indicative of inadequate weight loss or

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1 resolution of comorbid conditions. But given
2 its chronic nature, weight gain or comorbid
3 conditions may recur despite initial success.

4 The purpose of this talk is to
5 evaluate outcomes and fill a gap in knowledge
6 after reoperative bariatric surgery from a
7 large multi-institutional database of the
8 ASMBS. For the purposes of this study,
9 reoperations were divided into corrective, for

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10 instance a slipped band or a gastric fistula,
11 or corrective operations in which an operation
12 was converted to a different type of bariatric
13 operation.

14 The volume distribution in this study
15 was over 450,000 patients that were considered
16 and the vast majority of them, 94 percent, did
17 not undergo reoperation, about six percent of
18 these patients underwent reoperation, and only
19 of that, about 30 percent underwent conversion
20 operations, suggesting the robustness of the
21 primary bariatric operations.

22 The length of stay for these three
23 operations was about two days, and not that
24 much significantly higher than 1.78 days for
25 the primary bariatric operations.

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1 Weight loss after conversion to the
2 various bariatric operations is shown here, and
3 would be expected as the community of the
4 operation increased. The weight loss after the
5 conversion was also seen to be higher.

6 Comorbid conditions are listed here
7 and the first column is the time of the
8 operation compared to the reoperation in the
9 second column, and what we see is resolution of
10 comorbid conditions as measured by decrease in
11 either medication or loss of device for sleep
12 apnea was very good at one year, and quite
13 comparable.

14 Severe adverse events were measured
15 both at 30 days and at one year, and they were
16 compared to primary operations versus
17 reoperations, and again, in reoperations severe
18 adverse events at 30 days was at two percent
19 and at one year it was 2.4 percent, not that
20 much higher from the primary operations at 1.6
21 and 1.87 percent respectively.

22 Same with the mortality rates at 30
23 days and at one year, were not much higher for
24 reoperations compared to primary operations.
25 Death rate at one year was .26 percent after

1 August 30th MEDCAC Meeting Panel Proceedings JS and LA
reoperations.

2 So in summary, most bariatric patients
3 do not need reoperations. Among those who do,
4 given the chronic nature of this disease, the
5 complication rate is low and outcomes are
6 comparable to primary bariatric procedures for
7 both weight loss and resolution of comorbid
8 conditions.

9 Prior to this study, there was a great
10 amount of reluctance both on the part of
11 patients, surgeons, as well as payers, to
12 reimburse for reoperative bariatric surgery,
13 primarily because they thought the complication
14 rates were going to be too high, and the
15 benefits unknown. We have shown that both the
16 complication rates as well as the benefits are
17 certainly there, and this has helped us
18 actually obtain coverage from our local payer
19 for reoperations. I thank you for your time.

20 (Applause.)

21 DR. CUYJET: Dr. Hallowell will
22 present next.

23 DR. HALLOWELL: Thank you for the
24 opportunity to present and address the panel

August 30th MEDCAC Meeting Panel Proceedings JS and LA
25 today. I'm Dr. Peter Hallowell from the

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1 University of Virginia, and I'm the director of
2 bariatric surgery there. I have no financial
3 disclosures.

4 Long-term outcomes are difficult to
5 obtain in the United States due to many factors
6 including a mobile society, change in insurance
7 status, costs, and a lack of an integrated
8 records system. In an attempt to fill the gap,
9 we looked at our long-term results.

10 Last year we published our ten-year
11 results. We were able to obtain 60 percent
12 complete follow-up, and this procedure had good
13 maintenance of weight loss at ten years, and a
14 decrease in significant comorbid conditions
15 including diabetes, cardiac disease,
16 obstructive sleep apnea, hypertension, DJV and
17 pulmonary conditions.

18 This is a paper out of western
19 Australia, this is included because 95 percent
20 of the patients in this cohort had laparoscopic

21 adjustable banding. The mortality rate was .01
22 percent and that is in line with what we see in
23 the United States for that procedure, and in
24 this cohort only 1.4 percent of the patients
25 underwent a revision, and as you can see, the

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1 decreased hospitalization and a low long-term
2 all-cause mortality rate.
3 This paper from Sweden utilizing the
4 SOS database that Dr. DeMaria talked about
5 earlier, looked at female-specific cancers
6 including breast, endometrial and ovarian, in
7 women with obesity, the overall reduction in
8 cancer for the surgical group, and over half of
9 the cancers in this study were female-specific,
10 and again, you can see great follow-up at 18
11 years.

12 This is Ted Adams' paper out of Utah.
13 Again, good long-term follow-up, 24 years with
14 a mean of 12-and-a-half; good patient referral.
15 The cancer incidence was decreased by 24

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16 percent in the surgical group, cancers likely
17 to be obesity-related were decreased 38
18 percent, overall cancer mortality was 46
19 percent lower, and interestingly, mortality
20 from non-obesity-related cancers were also 47
21 percent lower in the surgery group.

22 Another paper from Ted Adams' group
23 out in Utah. It's a cohort study again, with
24 high numbers. In this study they broke out
25 their patients by age classification, less than

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1 35, 35 to 44, 45 to 54, and 55 to 74. The
2 follow-up was over seven years, and gastric
3 bypass provided survival benefit even in the
4 older age group and in the subgroup of 65- to
5 74-year-olds.

6 Again, we bring up the Swedish Obesity
7 Subject Study, this paper was published in
8 2007, so a little bit over ten years ago. This
9 is one of the first and longest-term follow-up
10 studies in the literature, and now out well
11 over 25 years. Patients were enrolled between

12 the ages of 37 and 60, matched one to one with
13 nonsurgical controls, and there were nearly
14 2,000 patients in each arm. Most of the
15 patients had (unintelligible) which is
16 something we don't do now. Here is the
17 survival curve.

18 So in summary, I've shown you data for
19 greater than five years. Bariatric surgery
20 produces an overall decrease in mortality
21 compared to no intervention, a decrease in
22 cancer intervention, and there are now 14
23 papers showing survival advantage of bariatric
24 surgery. Thank you.

25 DR. CUYJET: Time's up, thank you.

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1 (Applause.)

2 DR. CUYJET: Dr. LaMasters.

3 DR. LAMASTERS: Thank you for the
4 opportunity to present today about a topic that
5 I think is very important and I'm very
6 passionate about. My name is Teresa LaMasters

7 August 30th MEDCAC Meeting Panel Proceedings JS and LA
and I am a community bariatric surgeon from
8 Des Moines, Iowa, and I work with Unity Point
9 Clinic there. I do a lot of work with the
10 American College of Surgeons and with the ASMBS
11 regarding accreditation and access to care.
12 Today I'm representing ASMBS in my discussion.
13 So these are my disclosures. My only
14 personal financial disclosure is that I've been
15 a speaker for Gore & Associates, and the
16 faculty for ASMBS. The rest of the ones are
17 related to ASMBS.
18 So, you've already heard many times
19 today that obesity is a chronic progressive
20 disease and there's definitely been increased
21 awareness, not just in the medical community
22 but in the public, regarding the seriousness of
23 this disease. Recently multiple healthcare
24 providers have actually come together to
25 collaborate on the treatment of this disease.

1 ASMBS has led the way in establishing
2 collaborative partnerships with healthcare

3 professionals with development of the National
4 Obesity Collaborative Care Summit. This has
5 been going on for the past four years. This
6 includes participation by multiple specialty
7 societies to develop collaborative guidelines
8 to improve the care of patients with obesity.
9 The goals of this summit are educational,
10 advocacy, and to develop collaborative
11 guidelines and position statements. Many
12 specialties are involved.

13 Surgeons are involved through the
14 American College of Surgeons and the ASMBS, the
15 AMA, the American Heart Association, the
16 Academy of Nutrition and Dietetics,
17 endocrinology, oncology, OB/GYN, orthopedics,
18 anesthesiology, and many others.

19 The healthcare environment really has
20 shifted. There's a much higher emphasis on
21 quality outcomes with excellent patient
22 satisfaction and all at appropriate cost
23 levels. To be successful in this model of
24 care, we must have a collaborative approach to
25 our treatment of patients.

1 So we know an important first step in
2 the treatment of patients' obesity is just to
3 start the conversation, but many medical
4 providers actually shy away from this
5 conversation. There can actually be many
6 barriers for this position; this can include
7 being staffed with inadequate training, their
8 own bias or pessimism that people can actually
9 make these changes, and just simply inadequate
10 time, especially in our EHR heavy world.

11 So to facilitate that conversation, we
12 feel that we need to better understand the
13 public's perception of this disease of obesity,
14 so to that end ASMBS commissioned a study with
15 the NORC, or the National Opinion Research
16 Center, out of Chicago. And the results of
17 that study show that the population understands
18 that obesity is a very serious disease, even
19 more serious than cancer, but there's a
20 disconnect on how it affects them individually
21 and about the effectiveness of treatment

22 August 30th MEDCAC Meeting Panel Proceedings JS and LA
options.

23 Four in ten Americans who meet the BMI
24 criteria for obesity have never even talked
25 with their doctor about their weight.

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1 Three-quarters of the respondents said yes, I
2 tried to lose weight on my own before, and more
3 than 60 percent said they believe that
4 healthcare insurance should help pay for the
5 treatment of obesity, including bariatric
6 surgery.

7 So I'll tell you, bariatric surgery
8 has just begun to scratch the surface in the
9 treatment of this complex disease. Bariatric
10 surgery is a safe, effective and important
11 piece of a comprehensive treatment strategy for
12 this complex disease. This is a
13 life-threatening disease that affects a large
14 portion of our population. Thank you for your
15 time and attention.

16 (Applause.)

17 DR. CUYJET: Dr. Leslie.

18 DR. LESLIE: Well, thank you very much
19 to the chair and to the panel for the
20 opportunity to present. I'm Dan Leslie at the
21 University of Minnesota, I'm the medical
22 director for now our more comprehensive weight
23 management center. The University of Minnesota
24 performed the first two bariatric procedures
25 back in 1954 at the VA Medical Center, so a

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1 long history.

2 So for the disclosures, Medtronic has
3 paid for my travel to come here to present, and
4 we worked with their health economics group to
5 produce a variety of data about the Medicare
6 population, and this is really a summary of our
7 findings.

8 Number one, we found that about
9 two-thirds of Medicare beneficiaries undergoing
10 bariatric surgery are actually under 65 years
11 of age, and so to look at just that older
12 population, it doesn't provide the full

13 August 30th MEDCAC Meeting Panel Proceedings JS and LA
14 picture. The average age of Medicare
15 beneficiaries having bariatric surgery is
16 actually about 46 years of age, while that in
17 the commercial population is 43 years.

18 And so of the 70 studies in the AHRQ
19 review, 57 studies were on patient populations
20 with a mean age of 55 years and older, and
21 excluded a lot of patients, certainly, who are
22 inside the Medicare population.

23 In addition, the conclusion of the
24 AHRQ review that the strength of evidence is
25 low to moderate excludes at least 25 randomized
clinical trials, a technology assessment by the

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1 Southern California Technology Group and the
2 State of Washington healthcare advocacy groups,
3 and numerous prospective and retrospective
4 trials directly relatable to the majority of
5 Medicare beneficiaries who undergo bariatric
6 surgery. So, the published body of evidence
7 clearly supports safety and efficacy of
8 bariatric surgery for treating obesity and

9 related comorbidities.

10 So very briefly, so the average age of
11 Medicare bariatric patients is 46. Two-thirds
12 were disabled, two-thirds were less than 65
13 years of age, and that chart outlines this.

14 This has been relatively stable over
15 time, you can see the difference between 2011
16 and now 2015, and the numbers were stable, and
17 with end-stage renal disease represent over 70
18 percent.

19 And then a higher proportion of women
20 and minorities are having bariatric surgery
21 inside the Medicare database. 76 percent of
22 the disabled are female and 67 percent of
23 elderly are female as well. And then the
24 percent of Medicare bariatric surgery from the
25 nonwhite population, I think you can see at the

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1 bottom right there, disabled 28 percent,
2 elderly nine percent.

3 I'm not going to run through the rest

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4 of the slides because a lot of them -- I think
5 a main focus, too, on the AHRQ review was the
6 concept of minimal weight loss requirement. In
7 the Look AHEAD study targeting a weight loss of
8 ten percent, at four years 23 percent of the
9 intensive lifestyle intervention achieved that
10 amount of weight loss. In bariatric surgery,
11 at least one study, and we don't typically cast
12 our data in terms of minimal weight loss,
13 patients don't want to hear that, they want to
14 hear how much weight they can lose, the number
15 is 99 percent with at least 10 percent at two
16 years, and 96 percent at six years.

17 You've seen a lot of other data on
18 durability, and I think the bariatric surgery
19 certainly offers good outcomes for our
20 patients. Thank you.

21 (Applause.)

22 DR. CUYJET: And the last of our
23 scheduled speakers is Dr. Petrick.

24 DR. PETRICK: So I'm Tony Petrick, I'm
25 from Geisinger Medical Center, if we can get

1 the slides up there, and I'm going to talk to
2 you really about two key points.

3 First, I'd like to reiterate what
4 Dr. Leslie just said. When you look at the
5 demographics of the Medicare population
6 undergoing bariatric surgery, they do not look
7 like the demographics of patients in the United
8 States undergoing elective surgery. They in
9 fact look very much like the demographics of
10 the studies you've heard cited and quoted
11 today. Only Dr. Finkelstein wrote in Health
12 Affairs and said that only about 25 percent of
13 the bariatric surgical patients were over the
14 age of 65.

15 The two key points I really want to
16 talk about are the critical importance of our
17 Medicare patients having their surgery in
18 institutions that are accredited, and there are
19 really two reasons for this. You've seen most
20 of my slides before. One is safety and the
21 other is that if we look at the agenda and the
22 implication that there are care gaps that need
23 to be bridged, the absolute best way to do this

24 is under the umbrella of accreditation.

25 So these are slides you've seen

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1 before, we're going back to data that we
2 reviewed in the late 1990s, and this shows an
3 unacceptably high one-year mortality of 4.6
4 percent for bariatric surgery. This under the
5 umbrella of accreditation was dramatically
6 reduced between 2002 and 2009 and we took a
7 look at this, Dr. Morton took a look at this in
8 accredited and nonaccredited centers, and found
9 that in this large study, not only was it less
10 costly to have bariatric surgery in an
11 accredited center, but also the mortality was
12 significantly lower, and we look at that bottom
13 row, the failure to rescue, it becomes an
14 important concept. What we found that might be
15 a mechanism here, that in unaccredited centers,
16 the rates of death from failure to rescue were
17 significantly higher than in accredited
18 centers.

19 So looking at that, and again, you've
20 seen this before, the number of studies
21 published, 13, including over 1.5 million
22 patients, we find that six of eight find that
23 mortality is better in accredited studies, and
24 we have a preponderance of evidence to show
25 that risk-adjusted outcomes are better in

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1 accredited bariatric surgical centers. Towards
2 this end, some of the largest payers in our
3 country require accreditation to participate in
4 their bariatric center of excellence programs.
5 And here is the data, both current data from
6 MBSAQIP for calendar year 2016, showing that
7 the overall mortality is 0.11 percent for all
8 comers in bariatric surgery.

9 The second and just as important is,
10 this is really the best way that we can address
11 a bridge care gap. A part of, the pillar of
12 the accreditation program is continuous quality
13 improvement, not only data collection as you
14 heard from Dr. Hutter, but all centers are

15 mandated to use that data to develop continuous
16 quality improvement projects. This also allows
17 us to develop broader quality improvement
18 projects across the country.

19 The current one we call ENERGY is a
20 project looking at enhanced recovery for
21 bariatric surgery. This encompasses
22 preoperative, intraoperative and postoperative
23 care, and a very important area that we're
24 focusing on in this enhanced recovery program
25 is what we call multimodality narcotic changes.

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1 We are trying to completely eliminate or
2 significantly reduce narcotic use both
3 intraoperatively and postoperatively in our
4 bariatric patients. In a program that we
5 piloted at Geisinger, we were able to
6 accomplish that in almost 40 percent of our
7 patients.

8 As we all know, this is very costly.
9 About 25 percent of the costs of readmissions

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10 have come from surgical patients, and our first
11 quality improvement project that we established
12 nationally is the DROP that you heard alluded
13 to before. You've seen the outcomes in DROP
14 that showed that about -- that there's an
15 overall reduction of readmissions of about 10
16 percent, but most importantly, we measure
17 adherence to protocol, and the graph shows that
18 about 55 percent of patients in this country do
19 not get the intended care, and in this way we
20 make sure that 90 percent of our patients get
21 that care. Thank you.

22 (Applause.)

23 DR. CUYJET: All right. We have three
24 nonscheduled speakers. I want to remind
25 everyone, you have one minute to deliver your

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1 comments. The first is from Ted Kyle.

2 DR. KYLE: Thank you very much for the
3 opportunity to speak. My name is Ted Kyle, I'm
4 a pharmacist from Pittsburgh, founder of
5 ConscienHealth, a member of the board of

6 directors at the Obesity Action Coalition,
7 advocacy advisor to the Obesity Society.

8 We are in the midst of an epidemic of
9 chronic diseases which result from untreated
10 obesity. We have a limited range of tools for
11 managing this disease, and different people
12 respond very differently and have very
13 different needs in dealing with this condition.
14 People need options for dealing with obesity.
15 Otherwise, the disease progresses and results
16 in catastrophic effects on a person's health
17 over a lifetime. Thank you very much.

18 (Applause.)

19 DR. CUYJET: Thank you for your
20 comments. The second speak is Michael
21 Rothkopf.

22 DR. ROTHKOPF: Thank you for the
23 opportunity to comment on today's proceedings.
24 I am Dr. Michael Rothkopf, I'm a metabolic
25 internist from Morristown, New Jersey. I'm

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1 also the president of the National Board of
2 Physician Nutrition Specialists, which is a
3 group of about 600 physicians who are
4 nutritionally oriented. I do have a
5 disclosure. I have a patent on the
6 pharmaceutical enhancement of diabetes
7 resolution using increasing pharmacotherapy in
8 combination with gastric restriction.

9 My comment to the group today is
10 simply to highlight the importance of the
11 involvement of nutritionally oriented
12 physicians, internists, family medicine doctors
13 in the management of bariatric patients. This
14 involves preoperative management, postoperative
15 complications, and especially the enhancement
16 of outcomes using a combination therapy with
17 pharmacotherapy along with surgery, and
18 adjustment in medications after bariatric
19 surgery. Thank you.

20 (Applause.)

21 DR. CUYJET: Thank you. And last is
22 Robin Blackstone.

23 DR. BLACKSTONE: Thank you for
24 allowing me to speak. My name is Robin

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25 Blackstone, a professor of surgery at the

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1 University of Arizona, and I wanted to talk
2 with you about two things.

3 When I moved my practice to the
4 downtown inner city hospital in Phoenix, I saw
5 people who have failed to be treated for this
6 disease for a very long time. Obesity is a
7 disease of physiology, not choice, and this
8 disease becomes metabolically inflexible. And
9 the group of people who gain weight very fast
10 at that point, they gain weight very fast.

11 Surgery is not the only treatment for
12 this disease. Education of our young people at
13 the university setting is crucial, but I want
14 to stress that without the support of a benefit
15 for bariatric surgery and for other forms of
16 therapy, we're leaving this group of people who
17 is a very substantial group of people in our
18 society bereft of any type of treatment.

19 It's important that Medicare realizes
20 what benefit that Medicare provides means in

21 this country, because without it, no other
22 insurance company will cover it.

23 DR. CUYJET: Pardon the interruption.

24 Thank you for your comments.

25 (Applause.)

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1 DR. CUYJET: Okay, we're going to
2 resume the rest of the program an hour from
3 now, 12:45. Thank you.

4 (Recess.)

5 DR. CUYJET: Good afternoon, everyone,
6 we're going now to the next session, questions
7 to presenters, and the presenters not up front
8 in the first two rows, if you haven't
9 congregated up there, I would ask you to grab a
10 seat.

11 I'm going to exercise the chair's
12 prerogative and start the questioning, and this
13 is kind of a general question, so whoever feels
14 most compelled to answer can please do so.

15 I've heard a description in the Asian

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16 population, there was a study from Shanghai
17 Hospital, and pan-ethnic designations from our
18 point of view can be very dangerous, they can
19 skew the information, the results from a study.
20 So we have the Swedish, Scandinavian SOS study,
21 the Asian study, the predominance of obesity in
22 the female population, but I haven't seen among
23 any of the presentations data that makes it a
24 little more granular and drills down, so
25 something -- if you're in Mexico and you have a

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1 corn-based diet, if you're in Dominica or Cuba
2 you've got a rice-based diet, I don't know how
3 those variables or potential confounders play
4 into the data that was presented.
5 So if someone has some information
6 that they can dice and slice and give me a
7 better insight into which populations are
8 likely to benefit, aside from the one with
9 disabilities that we've seen, I'd much
10 appreciate it. And then we're going to go down
11 the line in sequence. Anybody want to field

12 that one?

13 MS. ELLIS: And anyone speaking, would
14 you please state your name for the record.

15 DR. SUDAN: Ranjan Sudan, Duke
16 University, thank you very much for the
17 question. Looking at the same database from
18 the Bariatric Society, we looked at ethnicity
19 and relationship ethnicity was with regards to
20 how many people from various ethnic groups were
21 getting the bariatric operation. We also
22 looked at what the benefit was in terms of
23 comorbidity resolution, weight loss, and then
24 this study that looked at preoperation also
25 looked at ethnicity.

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1 So what we found was that pretty much
2 all ethnic groups get benefits. African
3 Americans tend to have a little worse
4 resolution of comorbidity compared to
5 Caucasians when it comes to hypertension as
6 well as weight loss. The number of African

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7 Americans who are getting reoperations also
8 tends to be higher than the number of folks who
9 are getting primary operations, it goes up from
10 about 12 percent to 15 percent, so 12 percent
11 are getting primary operations and 15 percent
12 are getting reoperations.

13 The ethnic group that seems to do the
14 best is actually the Hispanics, because they
15 have about six percent of the folks who are
16 getting operations. They get good weight loss,
17 good resolution of comorbidity, and their
18 reoperation rate is correspondingly, in the
19 second study actually tends to be lower. I
20 don't know if that answers your question.

21 DR. CUYJET: No, that helps. And
22 we're going to go on down the line as I said
23 before, and please reintroduce yourself.

24 DR. ALBRIGHT: I'm Karen Albright and
25 I'm from University of Alabama at Birmingham.

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1 I had a couple of things so I'll start with the
2 first one.

3 My understanding based on the
4 presentations and the recommended reading is
5 that one of the I guess cornerstone studies for
6 longer-term data is the SOS study, and my read
7 of that is that 89 percent of those operations
8 were open, and I was wondering if someone could
9 speak to what's going on in the United States
10 now compared to that.

11 Also, my understanding is that the
12 most common, or one of the most common
13 procedures is one that's not done here anymore,
14 the vertical banded gastroplasty, and I was
15 wondering if someone could help me equate that
16 to what's happening here in current practice.

17 DR. DEMARIA: Thank you, Eric DeMaria
18 from Richmond. I'll try to address that for
19 you.

20 There's been a tremendous shift in the
21 access techniques used for bariatric surgery in
22 the United States and in fact around the world.
23 You're correct from your observations of the
24 data that the SOS trial was mostly open
25 surgery; of course, the procedures were

1 performed in an era where we didn't have really
2 advanced laparoscopic surgery. The incidence
3 of laparoscopic surgery in the United States
4 today is the predominant technique, it's well
5 over 90 percent of all procedures.

6 And then specifically the procedure
7 that is in fact no longer done, the vertical
8 banded gastroplasty, which did comprise a large
9 portion of the SOS study population, that
10 procedure has fallen by the wayside for several
11 factors. One is that some long-term follow-up
12 studies suggested it wasn't as durable in terms
13 of weight loss; another was the advent of the
14 adjustable gastric band, which is a, I'll use
15 the terminology I discredited a little bit,
16 restrictive procedure. Both are restrictive
17 procedures, and the lap, the adjustable gastric
18 band could be reliably placed laparoscopically.
19 So there was an evolution, I think, away from
20 the vertical banded gastroplasty because of
21 those factors.

22 DR. ALBRIGHT: So, would it be a
23 stretch to say that what you're describing as
24 progress, that it might result in lower adverse
25 event rates or lower complication rates?

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1 DR. DEMARIA: There have been
2 head-to-head comparisons of laparoscopic to
3 open surgery, and there is no doubt that
4 laparoscopic provides lower adverse event
5 rates, particularly in the area of
6 wound-related problems. The population that we
7 operate on is prone to having wound infections
8 and hernias develop with large wounds, and
9 laparoscopic surgery really minimizes that
10 risk.

11 DR. ALBRIGHT: Okay. And then, I just
12 had one more thing, and probably more of a
13 comment than anything. SOS to my understanding
14 was a prospective intervention but there was no
15 randomization, so that goes to your point about
16 confounders.

17 DR. DEMARIA: And I'd appreciate the

18 opportunity to comment on that, because the
19 idea of randomization was very fully discussed
20 and investigated at the time, and I think this
21 points out to the greater issue of
22 randomization to surgical procedure versus no
23 surgical procedure. It was actually felt to be
24 unethical to randomize patients to an invasive
25 procedure in that era, and we've obviously

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1 gotten away from that to some extent, but
2 you'll notice that most of the randomized
3 trials involved the adjustable gastric band.
4 So I think people ethically have taken this
5 very seriously, the idea, you know, is it
6 really fair to randomize people to surgery
7 versus no surgery, and that's one of the
8 reasons that we don't have many randomized
9 trials.

10 DR. ALBRIGHT: Thank you.

11 DR. CAMPOS-OUTCALT: Doug

12 Campos-Outcalt, University of Arizona College

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13 of Public Health. First of all, I have a
14 couple comments. I really want to compliment
15 the network that's really working on quality
16 improvement, I think that that's very
17 impressive and I was very happy to see that.
18 I'm also very happy to see the data that's
19 being collected and the rigorousness with which
20 that's being done. It makes me wish that I was
21 facing the questions I'm facing today five
22 years from now, because I think we would have a
23 much better data set to address them, so I just
24 wanted to make that comment.
25 Throughout the presentations, I've

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1 noticed a number of things which as an
2 evidence-based background person I didn't see
3 that I would have liked to have seen. For
4 instance, I would like to have seen absolute
5 weight reductions, not relative ones. I would
6 like to have heard more about numbers needed to
7 treat to achieve outcomes. And I would have
8 liked to have seen a lot more about loss to

9 follow-up, so that's just a comment in terms of
10 some of the quality of the evidence that I saw.

11 Now, I'm going to follow all that with
12 an attempt to upgrade the level of evidence by
13 pressing a little bit the team that did the
14 evidence report, so a series of questions will
15 be aimed at those two people, whose names I
16 can't pronounce, so I apologize for that. So
17 I'm wondering in the evidence report, did you
18 take into consideration first of all, magnitude
19 of effect, because that's one of the ways you
20 can upgrade observational studies is if there's
21 large magnitude of effect, so that's question
22 number one.

23 Question number two, did you look at
24 publication bias? It seems to me with
25 observational studies of the kind we're looking

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1 at, there's a real potential for publication
2 bias here, and I would like to have that
3 commented on.

4 And then heterogeneity, I would like
5 to know whether you assessed any of those three
6 things, and perhaps could have upgraded the
7 quality of evidence on some of the questions a
8 bit by having not very much heterogeneity,
9 having a very large magnitude of effect, and no
10 publication bias being found, so I just would
11 like comment on those questions.

12 DR. PANAGIOTOU: My name is Orestis
13 Panagiotou, from Brown University. I will
14 address your concerns about the difficulty of
15 assessment and schematics with you. The first
16 point pertains to whether we addressed
17 magnitude of effect as a criterion to upgrade
18 the evidence. So we applied all their
19 guidance, all the grades, and the output of
20 studies that are included in the AHRQ ACT
21 guides about how to evaluate effective
22 evidence, and to the extent that this was
23 available and we could apply it to studies, we
24 did so when we evaluated the strength of
25 evidence.

1 Your second question was about the
2 publication bias and heterogeneity. I think
3 these two questions fall under the umbrella of
4 efficacy, efficiency of the evidence, and
5 particularly because when we saw the studies,
6 we saw that different populations have
7 comparatively, different interventions are
8 compared. We have some, for example, that
9 compared surgery versus no surgery, surgery
10 versus orthopedic, bariatric surgery versus
11 orthopedic surgery, and bariatric surgery
12 versus GI surgeries, so these three types of
13 studies, although the outcome was similar, also
14 mortality, their clinical (unintelligible)
15 clinically to be combined into a meaningful
16 estimate. So by applying a priori our clinical
17 criteria about what would be a homogeneous or
18 extendable sample of studies that we could
19 operate on or perform a meta-analysis, we did
20 not do so, and that's why we did not measure
21 heterogeneity in the formal sense.

22 And that's also the reason that we did
23 not address publication bias to

24 (unintelligible) or other approaches. And also
25 for most of the comparisons that I saw, we were

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1 unable to do some kind of quantitative
2 synthesis. For the majority of outcomes we had
3 two or three studies, which means that the
4 publication bias would be very underpowered to
5 detect an association between effect sizes and
6 sample sizes.

7 DR. TRIKALINOS: And I am the second
8 one with an unspeakable name, and yes, so,
9 another thing that I should like to add is that
10 the way that you can shield an analysis from
11 publication bias is you try to identify to the
12 extent possible all the evidence that you can
13 identify that is unpublished but is accessible
14 through registries, prospective registries and
15 so on, and we have done an extensive search to
16 try to identify these sources of information.

17 That being said, publication bias is a
18 threat to any synthesis of the evidence, be it

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19 a systematic review, be it a narrative review
20 or anything else, and it becomes, the concerns
21 that you raised about descriptions of
22 heterogeneity and addressing publication bias
23 are in some sense tangential to a lot of the
24 conclusions that we draw, because we have very
25 few studies for specific comparisons of

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1 specific interventions. So if you have a lot
2 of different comparisons or a lot of different
3 outcomes and only two or three or at most four
4 studies that address this particular thing,
5 questions about quantifying heterogeneity and
6 questions about modeling treatment effects
7 versus study characteristics are good to think
8 about but are impractical to address, you
9 cannot really address that unless you have a
10 meta-analysis, let's say, of ten, 20 studies.
11 If this is not clear, I'm happy to continue on
12 that.

13 DR. HUTTER: Matt Hutter, I spoke
14 earlier, Mass General Hospital. I just wanted

15 to make, with regard to your comment with
16 regard to the data collection program, we're
17 very excited about the data that we're
18 collecting and the future information that we
19 will have. There was a comment before that the
20 data was not accessible; now it is. It will be
21 released for any participant to use for all the
22 data that we have captured from that
23 standpoint, so we're looking forward to getting
24 that out there.

25 With 180,000 new cases being collected

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1 every year, we have a lot of heterogeneity,
2 treatment methods you can look at and subject
3 to analysis. There's very positive data for
4 the procedures being done today, and as you can
5 see with the rapid turnover in procedures, we
6 don't do the vertical banded gastroplasty, but
7 the lap band is a good procedure that is being
8 done now. The sleeve gastrectomy wasn't even
9 being done in measurable numbers in 2007, but

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10 since we have the facility with the data

11 collection program that we have, we're able to
12 look at the new procedures and will be
13 collecting the new data going forward, so we're
14 very excited about that as well. Yes?

15 DR. ALBRIGHT: With your data
16 collection tool, do you have the ability, and
17 if so, how easy or difficult would it be to add
18 variables? One thing that strikes me is we're
19 talking about chronological age but not really
20 physiological age, and so I think all of us
21 have taken care of a 65-year-old or even
22 75-year-old who plays tennis, which is very
23 different than, say, someone else who's their
24 same age. And so it strikes me that a patient
25 like that would benefit from having something

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1 like frailty where we had, you know, something
2 that has been associated and correlated with
3 outcomes in older Americans.

4 DR. HUTTER: Great question. We
5 update the data collection program every six

6 months, we make recommendations for new data
collection points while we make obsolete ones
go away because of data burden from them.

Frailty is extremely important. The
NSQIP is the National Surgical Quality
Improvement Program and is our sister data
collection program, and what we've learned from
them right now, they are exploring frailty.
What they've learned we can easily add to the
MBSAQIP, so I think that is a key question that
we look forward to adding to that.

We do look at other things. You know,
this is quality improvement, not a research
tool first and foremost. I would love to add
a lot of other questions, but we have to focus
on -- we did find that functional status, using
walkers, canes, crutches as a surrogate
actually had a lot of explanatory follow-up
with regard to that. Thank you.

DR. ARTERBURN: Just a real quick

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1 addition to address Dr. Albright's question is
2 that we are currently undergoing a review of
3 the data collection, and payer status is highly
4 likely, we haven't finalized it, so we should
5 be able to do that analysis of CMS and other
6 payer status in the near future.

7 DR. MORA: Hi, I'm Marc Mora, from
8 Kaiser Permanente in Washington, and this
9 question is for Dr. DeMaria. I was obviously
10 impressed and you put a lot of time and effort
11 into pulling together all the information that
12 we looked at in terms of evidence tables.

13 One of the questions I have is a lot
14 of that was in the commercial population under
15 65, and I'm interested in how do you think
16 about it from a leadership or from a clinical
17 standpoint in terms of extrapolating that data
18 to the Medicare population, recognizing that we
19 did hear at least some work around a large
20 cohort I guess, or case series of Medicare
21 patients who had the operation who were
22 actually under 65. But I'm interested in sort
23 of your leadership clinical perspective about
24 extrapolating that information to the Medicare

25 August 30th MEDCAC Meeting Panel Proceedings JS and LA
population.

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1 DR. DEMARIA: Thank you. I appreciate
2 the opportunity to comment specifically on that
3 issue, and I think we heard some of the
4 statistics in various formats this morning.

5 Medicare as a payer is a minority of
6 the patients that we treat in the United States
7 today with bariatric surgery, ranging in the
8 three to five percent range, so it's a small
9 subgroup for sure. It's an illusion to believe
10 that they're elderly, because two-thirds of the
11 Medicare-insured patients are disabled younger
12 patients, and their age does not differ from
13 the typical bariatric surgery population that
14 we're very familiar with treating, but that's
15 an important population because of the
16 disability component, and sometimes they're our
17 most challenging patients, which is why looking
18 at these safety numbers that we can present to
19 you now from our clinically rich database is so
20 important, to see that in the mix we have such

21 high levels of safety and low mortality in that
22 population when it's mixed in.

23 So it is a bit of a challenge to
24 select out the Medicare population and to
25 really understand the outcomes. We've seen

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1 studies of patients of higher age groups with
2 bariatric surgery. Just to reemphasize, they
3 tend to have more comorbidities than younger
4 patients, they tend quite honestly, in my view,
5 to have somewhat less weight loss, but good
6 comorbidity improvement, which after all, at
7 least our experience is that the older age
8 group is very driven by comorbidities. It's
9 less of an issue if they can get into a nice
10 bathing suit at the age of 70, but more driven
11 by their concerns about diabetes and other
12 health problems.

13 So it is a challenge but we have a
14 very powerful tool to use in treatment of these
15 patients and, you know, we'd like to do a

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16 better job providing outcomes data on the
17 Medicare population, but CMS did make a
18 decision a few years ago to not require
19 accreditation for centers treating these
20 patients, and that has probably removed some of
21 our ability to provide information about that
22 population.

23 DR. MORA: That's helpful, thank you.
24 So a follow-up question as well, and for a
25 different expert, so thank you, sir.

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1 So in follow-up to Dr. Panagiotou and
2 Trikalinos -- see, I didn't have any trouble
3 pronouncing those names, although I don't think
4 I did it correctly. On the other hand, you
5 cautioned against extrapolating the data to the
6 commercial population. I'd really like to hear
7 a little bit more about why.

8 DR. PANAGIOTOU: Thank you for giving
9 us the opportunity to try to address this
10 subject and explain our results. We have
11 thought a lot about this when we were refining

12 the sequence for the technology assessment. We
13 went back to the literature to see what exists,
14 what other systematic reviews have already been
15 performed, what gaps we can address on how this
16 data is not captured, and we believe that there
17 is the question of the sensibility of patients
18 who are younger but not covered by Medicare and
19 patients who are younger but are covered, and
20 most of them would be, would have some kind of
21 disability that qualifies them for Medicare
22 eligibility. From our team's perspective and
23 when discussing this with our clinical experts,
24 we felt that these groups of patients are not
25 directly extendable, and we cannot really make

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1 inferences about the effectiveness or safety in
2 a younger commercial population who might be
3 relatively healthy to those who might be not
4 healthy and have disabilities or other
5 comorbidities that make them eligible for
6 Medicare, and these effects would cut, be very

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7 much different.

8 There are clinical ways to address
9 those concerns but this is not something that
10 is typically done in systematic reviews because
11 it requires having individual patient data to
12 try to generate distributions of comorbidities
13 in these different populations and try to
14 predict effect sizes, so that was our main
15 criterion or main thoughts about how these
16 populations perform.

17 I would also like to clarify here that
18 we did not exclude the younger patients. As
19 long as a study either had Medicare population
20 regardless of reasons for them being entitled
21 to Medicare benefits, they were included, but
22 these were only seven studies. And we also
23 included three studies that specifically
24 mentioned our patients have some degree of
25 disability, or some form of disability, and

1 were performed bariatric surgery. Some of them
2 actually looked at the resolution of the

3 disability before and after surgery. So we
4 captured with our search and criteria a
5 population that assembled, or resembles the
6 Medicare population as close as possible
7 without having to do further extrapolation
8 across these different groups of patients.

9 DR. MORA: Good, that's helpful.

10 DR. ALBRIGHT: I have a follow-up on
11 that, I'm sorry. I just wanted to know, is
12 that 55 age, is that a median, a mean, or a
13 minimum?

14 DR. PANAGIOTOU: That was either a
15 mean or a median depending on whether the
16 study, or what the study reported. Not all of
17 them reported both, it depends on how the age
18 was distributed and what people decide to
19 report.

20 DR. ALBRIGHT: Thank you.

21 DR. MORA: I just have one quick last
22 final question and this question is for
23 Dr. Arterburn and his team. One of the slides
24 that really struck me was the slide that showed
25 that in one region 80 percent of the time, that

1 the best surgeons in that region chose one
2 operation, and in another region 80 percent of
3 the time the best surgeons in that region chose
4 a different operation. And I'm interested in
5 understanding, what's your expert opinion or
6 view on the impact that that has in Medicare
7 members?

8 DR. ARTERBURN: David Arterburn from
9 Kaiser Permanente Washington. Thanks, Marc. I
10 think the answer to that is that it's probably
11 driven not only by some surgeon influence on
12 which procedures are being done, but there's
13 also payer influence there in terms of what
14 procedures are being covered and so what can be
15 offered to the patient at the time. And you
16 know, given I think the emerging data, some
17 data presented today that there's different
18 weight loss and comorbidity outcomes across the
19 different procedures, if a surgical group is
20 really leaning heavily towards one particular
21 procedure over another one, they are likely

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22 ignoring patient preferences around different
23 issues related to comorbidity improvement and
24 resolution, and they're having a conversation
25 that's driven perhaps more by insurance or by

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1 their own personal opinion about what should be
2 the likely best procedure, and it's not a clear
3 balance.

4 I mean, anytime you have that kind of
5 variation in care across different clinical
6 practices, it's probably not informed patient
7 choice that's driving that variation in care,
8 there's some other factor that's involved, and
9 I think what would be likely to happen is
10 you're going to have heterogeneity in outcomes
11 there too because you've got some patients
12 being poorly matched with a procedure. If they
13 had a different option available to them, if
14 they had a different set of information
15 presented to them in an unbiased way comparing
16 the different procedures, they might have made
17 a very different choice than the one that they

18 were under.

19 I wanted to comment also just briefly
20 about this idea about the AHRQ data and being
21 able to represent what's relevant, this sort
22 of, the review that was reviewed today. And I
23 think one other area to focus is we've done
24 several studies in the VA population, and I
25 think the VA cohort is a national

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1 representative cohort, where we've done some
2 analysis related to the long-term survival and
3 showing similar to the Swedish Obese Subject
4 study that bariatric surgery when compared to
5 nonsurgical treatment improves longevity,
6 reduces mortality, and then we also have shown
7 durability of weight loss in the ten years in
8 bariatric surgical subjects, mostly focused on
9 the gastric bypass population. But I think the
10 VA population represents a very similar to the
11 disabled and older population that you're
12 considering here, and those are long-term

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13 outcome studies with very good follow-up in the
14 VA population that I think represent sort of
15 some of the evidence base that we're trying to
16 circle on today.

17 DR. CUYJET: This will be the last
18 comment because I want to get back to other
19 chances to ask questions for the rest of the
20 panel.

21 DR. LAMASTERS: I'll try to make it
22 quick but I have another perspective on why you
23 can see a really heavy influence of one
24 procedure in a region, and a different in a
25 different region. So I'm in Iowa, and when I

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1 came to that community there was a lot of bias
2 against gastric bypass. There had been several
3 bad outcomes many years ago, it was in the
4 paper, lots of lawsuits, a toxic environment.
5 Nobody in that community wanted a bypass, I
6 don't care what you'd tell them. So we do a
7 lot of sleeve gastrectomies.

8 Now, obesity is like a hemologic

9 disease. Obese people have obese friends, they
10 have obese families. Those are the number one
11 source of patients, it's not a referral from
12 their primary care doctors. So I have a
13 patient who does great with the sleeve, they
14 tell their sister, they tell their friend at
15 work, they come and they want a sleeve. It
16 doesn't matter if I tell them I really think
17 you'd do better with a gastric bypass, they say
18 no, my sister had a sleeve, that's what I want.

19 And we still give them an informed
20 discussion, but I would argue that there is a
21 lot of patient-driven aspect to that
22 community-based preference in procedures.
23 People in a different community don't have that
24 same external bias of this history, so I think
25 there's some other things other than just the

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1 surgeon told them what to do, I think there is
2 opportunity for informed choice that still has
3 a community feeling.

4 DR. MORA: That's a helpful

5 perspective, thank you.

6 DR. CUYJET: And speakers, just let me

7 remind you, please identify yourself at the

8 mic.

9 DR. LAMASTERS: Teresa LaMasters, and

10 I'm a bariatric surgeon in Iowa.

11 DR. OLLENDORF: So, Dan Ollendorf,

12 with the Institute for Clinical and Economic

13 Review. I've got several questions so I may

14 ask them all now and respondents can jump up

15 and respond, but the first one is actually for

16 Ms. Fulton.

17 So, with the observational data we've

18 seen showing the rise in sleeve gastrectomy,

19 I'm wondering if you have any information on

20 how the local coverage determinations have

21 distributed among the contractors that you can

22 share with us.

23 And before you answer, let me throw my

24 other questions out there. For Dr. DeMaria or

25 any of the other surgeons, we've heard a lot in

1 the studies that focused on diabetes remission
2 and improvement in glycemic control, about
3 those measures. We didn't hear so much about
4 relapse or glycemic control, and I know in at
5 least some of these large trials, that was a
6 pretty sizable number, and I'd be interested if
7 you could comment on why you think that is.

8 And then finally for Dr. Arterburn,
9 sorry to make you get up again, I'm familiar
10 enough with the PCORnet infrastructure to not
11 be surprised and still be impressed by your
12 great retention numbers out to five years.
13 What I'm wondering is if there's any way that
14 you've found to capture whether patients are
15 actually still enrolled in their postsurgical
16 monitoring and follow-up programs, as a
17 potential effect modifier. So, those are my
18 three.

19 MS. FULTON: Sarah Fulton, CMS. I
20 don't have details about the MAC policies right
21 here in front of me, so I don't think I could
22 intelligently comment on that right now, sorry.

23 DR. LESLIE: Dan Leslie, University of

24 Minnesota Minneapolis, I'll offer a comment
25 about recidivism.

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1 You know, I think, we did a randomized
2 study, a diabetes surgery study, 60 patients
3 randomized to undergo gastric bypass with
4 diabetic management, and so if we looked at the
5 outcomes as a composite of A1c control under
6 seven percent, LDL of a hundred, and systolic
7 blood pressure under 130, which is the
8 definition that we're hearing today for
9 diabetes control, 49 percent in the gastric
10 bypass group, 19 percent in the lifestyle alone
11 group, and they both received equal lifestyle
12 medical management, achieved control of that
13 composite endpoint. But we know that the
14 patients in that study, we had to screen 1,900
15 patients to get 120 to undergo randomization in
16 two different countries, four different
17 centers. And the diabetes was challenging, it
18 was A1c above eight percent to begin with, and

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19 so that was the equipoise that our

20 endocrinologists allowed us to use, to offer a
21 gastric bypass in addition to lifestyle.

22 We now have five-year data that has
23 been accepted, not published, and the composite
24 endpoint is closer to the 20s range for the
25 gastric bypass, and only single digit for the

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1 lifestyle alone group.

2 The Swedish Obesity Subjects study
3 showed a similar diabetes recidivism rate,
4 around 67 percent in the ten-year time frame
5 from initial. Diabetes is progressive, beta
6 cell dysfunction is progressive, you can't
7 assume that the pancreas is secreting equal
8 amounts of insulin at the time of surgery as it
9 will be five, ten years down the road. So
10 anytime we've looked at diabetes control and
11 remission, there's generally going to be
12 recidivism going down the road past the
13 one-year point.

14 For food intake reductions, weight

15 loss, glucose control, we do very well the
16 first six to 12 months, but the amount of
17 control is pretty incredible compared to no
18 surgery, and you can ascribe a lot of that to
19 the weight loss and the dose effect of
20 additional amounts of weight loss above 10
21 percent of weight loss that bariatric
22 procedures offer.

23 DR. STILL: Christopher Still from
24 Geisinger. We do have some information on
25 relapse, so these individuals, and I just

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1 checked this, was asked this question
2 yesterday, so it's very timely. We looked at
3 relapse after diabetes remission, and the
4 definition of diabetes remission was one year
5 without elevated labs medication, so hemoglobin
6 A1c under 6.5 for one year, and found the rate
7 about 25 percent at four years after remission,
8 so 25 percent at four years after remission.
9 The rate was higher in preop insulin users and

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10 lower in non-insulin users, and higher in those
11 with late remissions, and a little lower in
12 those with remission occurring immediately
13 after surgery.

14 DR. ARTERBURN: David Arterburn,
15 Kaiser Permanente Washington. I'll actually
16 touch on the relapse thing first because we've
17 done a fair bit of work on that as well. We
18 showed in the Kaiser population that 35 percent
19 of patients redevelop diabetes within five
20 years after their initial remission, but we
21 also went on to study the microvascular
22 outcomes of that patient population and look at
23 patients who had remitted and then subsequently
24 relapsed, and looked at their health outcomes
25 compared to patients who had never remitted

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1 their diabetes, and found that even patients
2 who remitted and then subsequently relapsed had
3 a lower risk of incident microvascular disease
4 complications than patients who had never
5 achieved a diabetes remission. For each year

6 of time they spent in remission, they had a 19
7 percent relative risk reduction in their risk
8 of incident microvascular disease.

9 In that population, we know that the
10 predictors of who's going to relapse are people
11 who have later-stage diabetes, so longer
12 duration diabetes, if they're on insulin, if
13 they have poor hemoglobin A1c control at the
14 time of surgery. It suggests that patients
15 with earlier-stage diabetes are actually likely
16 to do better, have longer duration remission
17 and less microvascular disease outcomes, and
18 even those patients who do have a short period
19 of remission, even as short as one-and-a-half
20 to two years, seem to be sort of the threshold
21 within our study of when it became
22 statistically significant within our cohort.
23 Those patients had lower microvascular disease
24 risk than the patients who didn't go into
25 remission.

1 On the postsurgical monitoring piece,
2 the PCORnet study is not something we've looked
3 at currently. We have the ability to look at
4 individual encounters and go back and see if
5 the patients were seen with bariatric surgery,
6 how much of that follow-up time was with the
7 bariatric surgeon.

8 But I think a big advantage of the
9 PCORnet use of electronic health records is
10 that we're capturing all weight measures and
11 all outcomes captured in the entire healthcare
12 system. So I think one advantage is that many
13 patients don't follow up, but they do follow up
14 with someone else, they see another specialist
15 or primary care provider that does manage those
16 conditions and we can get some information
17 about it, so we can also address a piece of
18 this question to the extent that it's coded.

19 DR. SALIVE: Marcel Salive, I have
20 several questions. I want to bring them about,
21 first, just commenting on the TA that there was
22 I guess, you know, trials being done on
23 bariatric procedures; however, none met the
24 criteria for the TA, meaning that they did not

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25 have either the time period or the mean age of

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1 55, I guess, and I believe this is because --
2 and so this gives us evidence that's really not
3 applicable to the Medicare older population
4 which, as was also pointed out by the TA, like
5 around six million people with a BMI over 35,
6 so that's a lot of people without any
7 applicable evidence, so why is that?

8 It seems, I looked at some of the
9 trials being done of new products, and some of
10 the endoscopic trials have numerous exclusions
11 in, you know, some of them are comorbidities,
12 but a lot of them have a very set upper
13 endpoint, upper age limit of, you have to be
14 under 65 to be in those trials, and so why is
15 that?

16 And the real upshot of that is to go
17 to Dr. Sullivan's slide on, which was I thought
18 very counterintuitive, that the trial data for
19 these endoscopic procedures showed, you know,
20 not that impressive results, and she showed

21 more impressive, or what she called higher
22 effectiveness in clinical practice once the
23 products were out on the market, using I guess
24 the postmarketing surveillance data. And so is
25 that an artifact from all this exclusionary

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1 work, and why, then, should we exclude people
2 over age 65 in these trials, because they need
3 to know the results, you know, that might be
4 applicable to them?

5 DR. PANAGIOTOU: Orestis Panagiotou
6 from Brown University again. That's an
7 excellent question, it's something that we have
8 performed in research in this area over the
9 years about generalizability to subgroups and
10 different populations. I cannot speak about
11 why these people are excluded from trials
12 because I'm not a trialist myself, so it's
13 something that I cannot address. If I were to
14 design a trial I may have set up different
15 criteria, but this is not my role.

16 And because of the new empirical
17 evidence funded by NIH, by AHRQ, the ability to
18 look at the registries and databases and
19 published literature to see who is in different
20 trials for different conditions, not only
21 bariatric surgery, so there is an almost litany
22 of sorts that most people over 55 are not
23 represented in clinical trials. That was the
24 main reason that we lowered a little bit our
25 threshold and we went to 55, so that we can

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1 have a population that resembled the age
2 criteria for Medicare as close as possible.
3 Then, this also relates to how we
4 interpreted evidence that exists or is
5 available or how we can apply evidence that is
6 available in the elderly and younger patients
7 when we treat older people, and of course the
8 evidence-based framework is not that we should
9 only rely on the design of the meta-analysis,
10 but how are we taking this meta-analysis and
11 combining it with what is available, what, with

12 what we've seen in our practice. So actually
13 it's an intersection, the Venn diagram, of both
14 quantitative and observational evidence, and
15 clinical evidence. So that is about why some
16 of these patients in these trials are not
17 eligible for our systematic review.

18 It doesn't mean that if an
19 observational study is available it is
20 necessarily a lower source of evidence or lower
21 strength of evidence compared to a randomized
22 trial. But when we analyzed the samples that
23 we had, we didn't only check the criteria in
24 our checkbook that said observational versus
25 randomized, we looked how the randomized trial,

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1 or the observational studies were randomized
2 and designed. Some of these trials, or some of
3 these studies have very minimal balance for, or
4 minimum adjustment for confounders, so I have a
5 study in front of me that only adjusts for sex,
6 BMI, age, (unintelligible) and then eight-year

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7 bariatric surgery and BMI at baseline. These

8 are the adjustments in their models.

9 So given that there may be lots of
10 medical confounders in these populations, we
11 felt that if an observational study is analyzed
12 and it doesn't really capture the unmeasured
13 confounder, this cannot be the same as a
14 randomized trial that is designed and
15 randomized like a randomized trial.

16 There's also the concept of, most
17 people when they approach a professional study,
18 they focus on confounders, but there's also
19 issues that relate to how the P zero
20 observation, you know, an intervention is
21 starting to be measured and addressed. And
22 none of the studies that we found actually
23 described how this P zero related bias or some
24 of these other modeling biases can be
25 addressed.

1 So we found very few studies that went
2 beyond regression models, which are models that

3 if you put too many variables in, it's going to
4 give you a wide confidence interval. So, very
5 few studies used like (unintelligible) course
6 or (unintelligible) that could give you a more
7 accurate estimate of the treatment effect.

8 Again, these studies may have
9 limitations, or these methods may have
10 limitations that relate to what variables you
11 put into your models. So as long as, if you
12 put four variables, as compared to an
13 interventional study that puts 50 or 100
14 covariates, again, this is probably very
15 different, and we interpreted the strength of
16 evidence accordingly.

17 Was there another point that I missed?

18 DR. SALIVE: Thank you.

19 DR. SULLIVAN: Hi, I'm Dr. Shelby
20 Sullivan from the University of Colorado School
21 of Medicine representing ASGE and ABE.

22 So to the first question about why
23 there is an increase in weight loss and
24 clinical effectiveness, for the clinical case
25 series that we see compared with the randomized

1 trials, and really even in particular, the
2 randomized sham-controlled trials as well, so
3 what we see pretty consistently at this point
4 is that there is a significant effect of sham
5 on weight loss devices in these studies, and
6 it's actually across different devices and is
7 pretty consistently 30 to 40 percent reduction
8 in weight loss that we see in sham trials.

9 So even though -- in particular we
10 have one study that we published recently on
11 the post procedure where we had patients who
12 had a run-in procedure, so they knew that they
13 had the procedure, and then followed up with
14 patients who had been randomized even after
15 they were controlled, but yet they didn't know
16 which group they were in. The group that was
17 in the unblinded run-in group had 40 percent
18 more weight loss than the active sham, or the
19 active group that was randomized and didn't
20 know they had the procedure, even though they
21 had otherwise exactly the same follow-up plan

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22 and essentially treatment; the only difference
23 was the sham, the effective sham.
24 We also have what we think is an
25 effect of having less individual therapy for

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1 these patients. So whereas in clinical
2 practice if a patient is not doing quite as
3 well or if there are other issues that are
4 going on, the practitioners will actually do
5 more individual care of those patients. In the
6 trials we were very specific, and I've actually
7 been involved in development of a lot of the
8 lifestyle therapy protocols for these studies.
9 They are very specific in what the study team
10 is actually able to do and how much time
11 they're able to spend with patients, so it's
12 equal across all study subjects. And of course
13 the people who are giving that therapy don't
14 know what group the patients are in, but it has
15 to be very specific and very, in terms of what
16 they're actually delivering, so we think that
17 that overall does reduce weight loss in both

18 the active arm and the control arm as well.

19 In terms of the other question you had
20 about patients not being enrolled who are over
21 the age of 65, the best thing I can say about
22 this is that in general when we were doing the
23 study design and trying to find a homogeneous
24 population in order to have the study designed
25 so that we had really similar patients in both

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1 the active arms and the control arms, and I
2 think that just in general there has been in
3 the past in particular some biases into
4 thinking that patients who have, were older
5 than 65 that we see, there might not be as much
6 of a problem with those patients. Now we
7 understand that that is not the case at this
8 point, and that weight loss is really
9 beneficial in these senior patients, but when
10 we're designing these trials, that it's, again,
11 to come up with a homogeneous population,
12 patients over 65 have not been included in

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13 these trials. It would be great to actually do
14 studies on these patients, but even at this
15 point, going back and doing studies on the
16 patients that are older than 65 through
17 randomized control studies is most likely going
18 to be cost prohibitive.

19 DR. CUYJET: I'm going to ask your
20 responses to be as terse and as concise as
21 possible when responding to questions, because
22 we have more panelists who want to ask
23 questions.

24 PANELIST: Could I just do a little
25 follow-up for something she said?

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1 DR. CUYJET: Go ahead.

2 PANELIST: I'm sorry. You said that
3 there was a 40, or a 30 percent weight loss in
4 the sham group, I thought you said?

5 DR. SULLIVAN: No. When you compare
6 active, it's when somebody knows they have a
7 procedure versus when they don't know whether
8 they had a procedure. When they really, you've

9 done a very good sham and those patients don't
10 know that they've had the procedure, whether or
11 not they've had it, that there is essentially a
12 reduction of about 30 percent, or an increase
13 of 40 percent of weight loss. So in the trial
14 they're specifically talking about a five
15 percent weight loss in the group that was in
16 the randomized portion of it. They had low
17 intensity lifestyle therapy, that's another
18 point that's important to know, is that the
19 intensity of lifestyle therapy also definitely
20 affects total amount of weight loss.

21 But in the patients that knew they had
22 the procedure, despite the fact that they had
23 the same exact treatment, had seven percent
24 total weight loss. The only difference was
25 knowing that they had the same treatment.

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1 PANELIST: So if they were randomized
2 and they didn't know, it was five percent, but
3 if it was the same thing but they knew it, it

4 August 30th MEDCAC Meeting Panel Proceedings JS and LA
was seven percent.

5 DR. SULLIVAN: If they knew that they
6 had it, seven percent. That's the only
7 difference.

8 DR. HUTTER: A brief comment. The
9 best way to get information from people over
10 65 --

11 MS. ELLIS: Can you state your name?

12 DR. HUTTER: Sure, sorry, Matt Hutter
13 from Mass General Hospital. The best way for
14 us to get information on people over 65 is by
15 having coverage with evidence or coverage with
16 accreditation. If there's coverage with these
17 procedures we're capturing it, we're capturing
18 it, MBSAQIP data so we can get that data for
19 you, and I think that will be important.

20 DR. CUYJET: Okay.

21 DR. WILLIAMS: Renee Williams, New
22 York University School of Medicine. I want to
23 thank everyone for their presentations.
24 Something I would like to have heard more
25 about, the potential health care disparities

1 within this population.

2 DR. CUYJET: May I ask you to speak a
3 little closer to the microphone, please?

4 DR. WILLIAMS: I said I would have
5 liked to have heard more about the healthcare
6 disparities, I thought that was a gap in the
7 presentations there, otherwise extremely
8 confident and informative.

9 I have one, or actually two questions
10 for Dr. Sullivan on the intragastric balloon.
11 Number one, you mentioned the serious adverse
12 events, that most of these were dehydration
13 from nausea and vomiting. Could you comment on
14 any other potential serious adverse events that
15 you saw? As one example, were there any
16 obstructions that were noticed in the trials
17 you mentioned?

18 And number two, I felt that these
19 balloons, while they're indicated in BMIs of 30
20 to 40, that they could potentially be a bridge
21 to surgery. Is there any information that
22 you've seen in that context?

23 DR. SULLIVAN: Absolutely. Again,

24 Shelby Sullivan, University of Colorado School
25 of Medicine, representing the ASGE and ABE.

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1 So to your first question about the
2 balloons and their serious adverse event rates,
3 so about 75 percent of the serious adverse
4 events that occurred in the trials were related
5 to nausea, vomiting and abdominal pain that
6 required IV fluids, so those were serious
7 adverse events because the patients had to come
8 into the hospital, get an IV placed and have
9 hydration. We have subsequently become much
10 better at actually treating those and actually
11 preventing these symptoms with more
12 medications, so at the time frame of these
13 trials, we just didn't have that kind of
14 experience.

15 The other serious adverse events that
16 occurred during the trials were mostly related
17 to either gastric perforation, pneumonia or
18 perforation of the esophagus. These were very

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19 low in their rates of incidence and were
20 similar to what we've seen in the clinical
21 experience outside of the U.S. as well.
22 There have been a couple of things
23 that have come up since then that were not,
24 that did not occur in the trials, and I'm sure
25 many of you have heard about the FDA release of

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1 information about deaths that occurred. These
2 deaths, first of all, when you look at the rate
3 of deaths, the ASGE published a meta-analysis
4 in 2015 and we found out that all of our
5 patients that were looked at in this cohort,
6 there was a .08 percent risk of death, and
7 those were primarily related to gastric
8 perforation that were in patients who had
9 previous orBEC surgery, and aspiration
10 pneumonia that occurred with device removal.

11 We know that these balloons cause some
12 delay in gastric emptying and it did seem that
13 patients having these balloons removed had a
14 lot of food sitting in their stomach, so that

15 there can be risk of that aspiration. So we
16 view this as teachable moments right now. In
17 my practice we actually have changed our
18 practice such that we only remove balloons with
19 general anesthesia so we can protect the
20 airway, and we would never put a balloon in
21 somebody who has a history of prior orBEC
22 surgery.

23 There have been deaths that have
24 occurred again as the FDA recently reported.
25 However, as the FDA very appropriately also

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1 reported, we cannot actually directly attribute
2 those deaths to the balloons themselves. There
3 have been deaths that occurred in patients who
4 had the balloons in place, but we can't
5 necessarily attribute these deaths to the
6 balloons themselves. You have to remember that
7 we also talked about balloons being used in
8 patients not only for bridge therapy for
9 bariatric surgery or for knee replacement, for

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10 example, but also potentially for patients who
11 need other organ transplants, and so those are
12 sick patients and so there may be instances
13 where deaths occur that are not necessarily
14 related to balloons themselves but related to
15 the sickness of the patient.

16 The other thing to remember as well is
17 that of the deaths that are reported, when we
18 take the information that the sponsors have
19 actually given to us in terms of the numbers of
20 the patients who have been treated, this rate
21 is still less than .01 percent, so that's
22 important to keep in mind, that it is in
23 general still a very safe procedure and really,
24 the safety is similar to what we see for
25 general endoscopic procedures.

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1 Does that answer all of your
2 questions?

3 DR. CUYJET: It does. Renee, did you
4 have another question? Do you have another
5 one?

6 DR. WILLIAMS: Just one more quick
7 question, and I don't know if there's an answer
8 to this. I think earlier, is it Dr. Sudan, had
9 mentioned that in African Americans there's a
10 worse resolution of comorbidities. Do we have
11 any thoughts as to why that is?

12 DR. SUDAN: Thank you, and first of
13 all, I sincerely appreciate you mentioning that
14 they were events and not talking so much about
15 disparities. And I think the disparity study
16 that we did, I want to highlight that African
17 American men in particular, I think suffered
18 disproportionately higher amounts of
19 hypertension and diabetes compared, and these,
20 this particular group was actually seeking less
21 bariatric operation for whatever reason, but
22 was underrepresented when you looked at the
23 prevalence of obesity, hypertension and
24 diabetes in other populations, compared to the
25 folks who were seeking bariatric surgery.

1 Why exactly that happened, we did not
2 look into the mechanisms of that, but it does
3 point out to the fact that this particular
4 population group does need better education and
5 perhaps more outreach that what they're
6 currently providing them.

7 DR. SCOTT: John Scott, Greenville,
8 South Carolina, an active care representative
9 for the ASMBS. And speaking in terms of
10 healthcare disparities, the thing that builds
11 general populations, the insurance covered
12 patients, and even the LCDs, that there are
13 barriers to getting surgical care. And for
14 people that have, that are in lower
15 socioeconomic statuses, the hoops that people
16 have to jump through to obtain surgical
17 services is difficult for a lot of people, and
18 often people will turn away from seeking
19 surgical care because they don't have
20 transportation means, they don't have the
21 financial means to go to recurring doctors'
22 appointments, to purchase, you know, diet
23 programs prior to surgery which some insurance
24 carriers provide, and so there are barriers to

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25 care that prevent people from obtaining

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1 surgical services.

2 DR. CUYJET: Okay. We only have 15
3 minutes left in this discussion so I'm going to
4 ask the panelists, if you have a question that
5 you feel compelled to ask, hold up a card. I'm
6 sorry to cut you short, but we've got other
7 panelists to get to.

8 DR. JIRAPINYO: A brief comment, I'm
9 Pichamol Jirapinyo from Brigham & Women's
10 Hospital, so I have a brief comment on the
11 bridge therapy for endoscopic bariatric
12 therapy. So we do have some successful stories
13 for people who are too big and too sick to get
14 surgery, and we place a balloon and the
15 patients were able to lose weight and the BMI
16 came down. So he had heart failure, he was too
17 sick to get a cardiac transplant, so we placed
18 a balloon and his BMI came down to 38, and now
19 he underwent successful cardiac transplant.

20 MS. ELLIS: Will you speak into the

21 microphone, please?

22 DR. JIRAPINYO: Oh, sorry, okay. So
23 the patient was too sick, he was big, he had
24 end-stage heart failure, so we do place a
25 balloon and the patient successfully lost

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1 weight, and then he was able to undergo a
2 cardiac transplant, and now his heart failure
3 symptoms are much better.

4 DR. CUYJET: Dr. Yates.

5 DR. YATES: Yeah, I have three
6 questions that should have succinct answers,
7 and it has to do with defining the Medicare
8 population we're talking about. Dr. Yates from
9 UPMC. I have a question for Dr. Panagiotou and
10 Dr. Trikalinos, thank you, but with a follow-up
11 that's going to be similar for Dr. Leslie, and
12 then a question for Dr. DeMaria.

13 And the question I have for
14 Dr. Panagiotou and Dr. Trikalinos is this: In
15 the papers you studied, in those patients that

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16 were Medicare eligible by age, did you age
17 stratify or look at the distribution of ages to
18 be able to see when there's an extension of the
19 procedure occurring, or where there is a very
20 rare occurrence of the procedure, given the
21 fact that people with morbid and super obesity
22 have shortened lives for the most part, at what
23 age stratification did you see it didn't occur
24 anymore, age 70 to 75, 75 to 80, where did it
25 stop?

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1 DR. PANAGIOTOU: So there were some
2 studies that provided results of, subgroup
3 results by different age groups. I'm sorry, my
4 name is Orestis Panagiotou, from Brown
5 University. So I was saying, there was some
6 studies that stratified the 55-plus age
7 population into different subgroups. Most of
8 them were studied up to 75 years old from what
9 I remember.

10 DR. YATES: So about 75, you stopped.

11 DR. PANAGIOTOU: That was, the stuff

12 that we saw, the maximum was about 75 years
13 old.

14 DR. YATES: I see. And the follow-up
15 question for Dr. Leslie, in the information
16 that you presented, and thank you for
17 presenting the, how significant the disabled
18 population is in the overall Medicare
19 distribution, in that population, is there any
20 stratification to see whether it just doesn't
21 happen anymore at a certain age?

22 DR. LESLIE: Dan Leslie, University of
23 Minnesota. So, we didn't do a full
24 stratification, we just know that a third is in
25 the age 65 and older and about two-thirds in

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1 the disabled, which would be under 65. A very
2 small fraction was end-stage renal disease,
3 about a hundred cases per year.

4 I think it's probably more going to be
5 anecdotal, and you can ask everybody the oldest
6 patient they've operated on and maybe 76 for

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7 me, I've heard a little older than that, and
8 it's always going to be physiologic age, and
9 that's generally how we would do things. They
10 can, you know, walk into a clinic and are very
11 vibrant, they may still have surgery at an
12 older age.

13 DR. YATES: And then a question for
14 Dr. DeMaria as representative of the metabolic
15 and bariatric surgery group. Since you threw
16 the gauntlet down I do have to say one thing
17 that is not on the record for this meeting, but
18 there is evidence that total joint replacement
19 does extend life and I can share the papers
20 with you, their population base as well as deep
21 down mining, so we'll share papers later, okay?

22 DR. DEMARIA: That would be great.

23 DR. YATES: I just, a collegial
24 comment there.

25 DR. DEMARIA: And I didn't mean to

1 malign the orthopedic surgeons of the world.

2 DR. YATES: That's all right, I didn't

3 come up to have a fight with you. But my
4 question for you is that it has come up that
5 there are exclusions for some of the RCTs and
6 that there are barriers to RCTs because of
7 exclusion. In your society's opinion when you
8 guys sit down and talk about this, what is a
9 fair exclusion criteria for upper age, and what
10 would you think is a real outlier by age? I
11 mean, are we really talking about 65 to 90 in a
12 Medicare population, or are we really talking
13 65 to 75?

14 DR. DEMARIA: Eric DeMaria from
15 Richmond, Virginia. So, I'm reminded of Dave
16 Flum's series back in the early 2000s looking
17 at mortality in Medicare, and he had age
18 brackets that went up to 90. And all of us
19 looked at that data and said we're probably not
20 talking about bariatric surgery in this data
21 set. I'm an old bariatric surgeon, which
22 translates into experienced, and I haven't
23 operated on a patient for a primary operation
24 over the age of 75, and I think if we polled
25 the bariatric surgeons here, we'd probably be

1 in about that ballpark, mid 70s, maybe a little
2 bit more, so we shouldn't really be talking
3 about people 90 years old in my opinion.

4 DR. CUYJET: I'm going to ask the
5 panelists to limit yourself to one question,
6 please.

7 DR. SULLIVAN: Can I just add one
8 point? This is Shelby Sullivan, University of
9 Colorado. There was a slide that I had that
10 unfortunately I couldn't show, but there was a
11 study that was published in 2016 based off of
12 annualized Medicare expenditures --

13 DR. CUYJET: Short and concise.

14 DR. SULLIVAN: -- from 1998 to 2008
15 that showed twice as much costs in the age 65
16 to 69 in the BMI 35 and above compared to the
17 everybody else group and that was, the trend
18 was similar for age 70 to 74, but not in the 75
19 and above.

20 DR. CUYJET: Okay. Dr. Zuckerman.

21 DR. ZUCKERMAN: I have more than one,

22 August 30th MEDCAC Meeting Panel Proceedings JS and LA
but quick questions.

23 DR. CUYJET: All right, but I want to
24 give everybody the chance to at least ask one.

25 DR. ZUCKERMAN: Yeah, well, I'd like

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1 my chance. This is for the men from Brown.

2 To follow up on the publication bias
3 issue, I looked at some of the studies and I
4 was really surprised that there were
5 preliminary data, so a study might be purported
6 to be a five-year study or even a two-year
7 study, but half the people were gone after 18
8 months, and sometimes more than half the people
9 were gone. And yet there was no, even though
10 those studies were sometimes published several
11 years ago, there's no other study of that same
12 group. And so both in terms of the publication
13 bias of what a journal will publish but also
14 what the authors will try to publish, and
15 particularly when they have a conflict of
16 interest of some sort, so I wondered if there
17 was any data at all on loss to follow-up and

18 how those people might be different and why
19 they've disappeared after such a short period
20 of time.

21 And also, in the studies that were
22 done on deaths, I'm assuming that they did look
23 at all death certificates, whether people were
24 still in a study or not, but you didn't look at
25 that, so --

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1 DR. PANAGIOTOU: Orestis Panagiotou
2 from Brown University. Yes, when we identified
3 publications from the same study, like one
4 example would be the SOS, the Swedish
5 observational study, or Obesity Study, we
6 looked at how the results look at the longest
7 follow-up, and we use the one that would give
8 us the largest sample size, so that we could
9 have enough number of events to have a powerful
10 determination of how the effect would look
11 like.

12 Of course what you're saying about

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13 attrition of follow-up is a very big concern,
14 and we saw one graph where we had multiple time
15 points for mini-gastric bypass, and we saw that
16 at five years only 45 percent of the people
17 were followed so this raises the issue, how
18 representative are people who go back or do not
19 go back. It might be that they're doing better
20 so they prefer to go back with their physicians
21 or, if it's like they were doing worse, they
22 decide to give up and they don't follow up with
23 observation appointments, so we don't know how
24 these people look in terms of weight loss.
25 Of course this is an attrition by, or

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1 this type of attrition is definitely something
2 that is taken into account when we interpret
3 the data, but we, given that we were working
4 with published data, we cannot really try to
5 correct for that and try to say what the effect
6 would look like if everybody was being followed
7 up.

8 DR. ZUCKERMAN: I'm sorry, I just

9 didn't understand the last sentence that you
10 just said. Say it a little more slowly,
11 please.

12 DR. PANAGIOTOU: So we have people who
13 do not, not a hundred percent of the people who
14 have interventions come back at five years, or
15 at every six-month appointments. And we saw,
16 we have this graph where we saw how many
17 gastric bypasses were performed in terms of
18 weight loss, and we see that it plateaus after
19 I believe the first year, if I remember
20 correctly, but 95 percent of the people who
21 undergo the intervention came back at one year,
22 and only about 45 percent came back at the
23 longest follow-up, which was five years later.

24 So we do not know what are the
25 differences between the people who come back

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1 and we have the data at different time points,
2 and those who do not come back.

3 DR. CUYJET: Okay. We're going to

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4 move on to the next question and if you guys
5 want to continue the conversations, you can do
6 that at a later point in time, but I want
7 everybody to have an opportunity to ask
8 questions. So, Dr. Hilkert.

9 DR. HILKERT: This is Bob Hilkert, the
10 industry representative from Novartis
11 Pharmaceutical. My question is actually to
12 anyone who feels they could answer it.

13 I'm interested in finding out more
14 about the respiratory outcomes, and I think,
15 you know, we're being asked to kind of evaluate
16 the quality of the evidence, and what I've
17 heard so far and from some of the readings, I
18 understand that there's some data on
19 obstructive sleep apnea, but I haven't heard
20 anything about any other respiratory outcomes.
21 Specifically, you know, is there less pneumonia
22 after bariatric surgery, is there less
23 restrictive lung disease, you know, what really
24 happens to these patients from a pulmonary and
25 respiratory point of view, can anyone comment

1 on that?

2 DR. LAMASTERS: Teresa LaMasters, a
3 bariatric surgeon from Iowa, and my quick
4 comment is I don't have the data off the top of
5 my head, but what we do have is a lot of data
6 regarding decreased inflammatory response all
7 over the body with bariatric surgery. So we
8 actually see a rapid improvement in asthma and
9 restrictive lung diseases.

10 And also doing these procedures
11 laparoscopically, which is 98 percent of the
12 techniques that we use, has a much, allowed us
13 to do these procedures on a much higher risk
14 pulmonary patient because there's less
15 pulmonary impact. So, I'm sorry I don't have
16 the data right off the top of my head.

17 DR. DEMARIA: Eric DeMaria again, from
18 Richmond. And I don't necessarily have exactly
19 the information you're seeking at the tip of my
20 tongue either, but I did want to say I was very
21 surprised to see the gentleman from Brown
22 suggest that obstructive sleep apnea relapses
23 after successful weight loss surgery, that is

24 not our clinical impression.

25 However, getting patients back to have

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1 follow-up sleep investigations is very
2 challenging, health insurance won't pay for the
3 normal study a year later, so it's a big
4 challenge to actually document. But what I can
5 tell you is that our patients stopped using
6 their appliances, they stopped using their
7 machines. They presented originally with
8 symptomatic sleep apnea, that's how we pick
9 them up, and their symptoms go away.

10 The other comment that I thought of
11 when you talked about pneumonia specifically is
12 the effectiveness of gastric bypass in
13 particular for gastroesophageal reflux, which
14 can lead to pneumonia through aspiration. It's
15 probably the most effective operation that we
16 have for gastroesophageal reflux disease, so
17 that may relate to the pneumonia issue.

18 DR. CUYJET: Okay. Dr. Betz, please.

19 DR. BETZ: Martha Betz, FDA. My
20 question is in regards to the data that is
21 collected in studies that were conducted
22 outside the U.S. and the applicability to the
23 U.S. population. I saw in Dr. DeMaria's
24 presentation and the presentation from the
25 technology assessment that the data was

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1 presented together, without any discussion
2 about differences in patient population, our
3 standard of care that may cause us to expect a
4 different benefit here in the U.S., so if
5 somebody could speak to that, that would be
6 helpful.

7 DR. DEMARIA: Gee, I guess I will,
8 Eric DeMaria again. So, obviously we're trying
9 to provide you with the best long-term high
10 quality information that we have around the
11 world. I would say the world is now a small
12 place, we interact constantly with people
13 internationally, it's not like procedures are
14 done in a completely different way overseas

15 today in our world.

16 The SOS study is probably the most
17 significant overseas study that we have and
18 it's the best long-term data in the world, so
19 that's why we use that data, but we do have
20 other studies in the U.S. that show exactly the
21 same kind of benefits and so forth, so that's
22 why we include them.

23 DR. CUYJET: Dr. Klein.

24 DR. PANAGIOTOU: Orestis Panagiotou
25 from Brown. I would like to, maybe we should

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1 have emphasized that in the report, that we
2 don't generate the data that we analyze. We
3 work with published data and whatever is
4 reported in the literature. Reporting's not
5 ideal when you try to write a 3,000-word paper
6 when you have spent two years and are not
7 getting that much information.

8 But when it comes to comparing these,
9 the different populations across countries or

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10 across different settings, although there is
11 empirical evidence that sometimes effect size
12 may be different areas, countries because
13 patient care infrastructure may be different,
14 as people mentioned, we're not, it was not our
15 task to try to say how people, how end users of
16 systematic reports or systematic reviews will
17 utilize this evidence. We present it, we have
18 an appendix that says where the study came
19 from, perhaps we can include some of this
20 information more clearly, but --

21 DR. CUYJET: You're using up everybody
22 else's time.

23 DR. PANAGIOTOU: Okay, sorry.

24 DR. KLEIN: Sam Klein, Washington U.
25 St. Louis. I appreciate the enthusiasm of the

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1 speakers. This is actually a little bit a
2 stretch of the previous question, because this
3 regards laparoscopic adjustable banding, in
4 which the data are very different in Australia
5 than potentially in the U.S. where the results

6 seem to be much more positive, so I wanted to
7 address this regarding U.S. data, and maybe to
8 narrow it to Dr. Rohrscheib or Dr. DeMaria or
9 Dr. Arterburn because you know everything there
10 is to know, David.

11 But the question, there was data shown
12 that reoperation is very common after
13 laparoscopic gastric banding, and which is
14 potentially a serious problem despite the
15 safety and even though its more modest
16 efficacy. So my question is, what is the
17 reoperation for, and how many, what percent
18 reoperation is there for actually removing the
19 band because of a problem, or to have another
20 operation to expand, increase weight loss?

21 DR. ROHRSCHEIB: I think I know the
22 paper you're referencing.

23 MS. ELLIS: Can you state your name,
24 please?

25 DR. ROHRSCHEIB: Dr. Sid Rohrscheib

August 30th MEDCAC Meeting Panel Proceedings JS and LA
1 from Illinois. The data that you reference was
2 not really clinical data, it was a tabulation
3 of payments, and what was described in that
4 report really has not been demonstrated in
5 anything clinically, and there is a question of
6 whether some of the coding that was used to
7 come up with the results that were reported
8 created a flaw.

9 The first thing to know about gastric
10 banding is the reoperations are of minimal
11 morbidity. There is definitely an overpayment
12 for some of these reoperations by CMS because
13 they're required to be in an inpatient setting.

14 DR. KLEIN: Just to get to the meat,
15 what percent reoperation, if you know, is there
16 because of a complication or problem where the
17 band is removed, and what percent of
18 reoperation is there to increase the weight
19 loss because the initial weight loss was felt
20 to be inadequate? That's really the question.

21 DR. ROHRSCHEIB: Right now there's
22 definitely a trend in those patients who, I
23 like to say lost efficacy from their band after
24 many years, to be converted to sleeve

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25 gastrectomy. That seems to be the most

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1 popular, if I can use that word, conversion,
2 and it simply trends what is now the most
3 popular procedure. I do not know the
4 percentage of revision to, or conversion to
5 sleeve, but it is very practice-specific, it's
6 very geographically dictated. And I think what
7 we've learned over the last ten years and some
8 of what I highlighted is banding is, has a
9 requirement to be done in a very dedicated
10 center that does primarily banding, and when
11 someone does primarily banding, they're going
12 to have reoperation rates of five to seven
13 percent, and zero mortality, and nothing of
14 great morbidity.

15 DR. CUYJET: Dr. Telem and Dr. Wolfe,
16 you're going to have to accept my apologies.
17 My task masters are telling me we have to stay
18 on schedule so we're going to move to the next
19 phase of the program, and if you have
20 questions, I would please ask you to direct

21 them to the appropriate persons afterwards.

22 This is the part on open panel, I will
23 lead, but maybe we'll start down at the other
24 end.

25 But I think from the presentations and

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1 what Doug alluded to previously, there are a
2 lot of unanswered questions, that the field of
3 bariatric surgery has progressed dramatically
4 from the Scandinavian study in 2007 to ten
5 years later, where it's encouraging that we're
6 having these conversations and you're raising
7 the questions that need to be asked.

8 I found it fairly impressive when you
9 were talking about sleep apnea, and
10 (inaudible), so those are just areas that we
11 don't know what the benefit or outcomes is
12 going to be, so let me start with Dr. Wolfe,
13 and you can start before we back up in terms of
14 your comments about the presentations.

15 DR. WOLFE: Anytime an evidence base

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16 is accumulated on a literature search, the
17 criteria for the search are critical, and it's
18 concerning to me when we hear that there was no
19 evidence regarding the effect of bariatric
20 surgery on diabetes. It's been discussed about
21 the age criterion and whether that was
22 appropriately applied or was not. It may be
23 that age was not a good criterion to have in
24 the search at all but rather burden of disease,
25 since we also heard that the disease burden

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1 among the Medicare disabled is greater than it
2 is among the over 65, but I can't say that you
3 would have found papers specific to the
4 Medicare disabled with a greater disease burden
5 had that been a criterion as well. But I think
6 you addressed the question about four times
7 regarding the use of age as a criterion and I
8 don't know that there's much more we can say
9 other than it's a limitation of the literature
10 body that you were presented with.

11 DR. CUYJET: Dr. Telem?

12 DR. TELEM: Thank you. I want to
13 thank all the speakers for their compelling
14 talks, and clearly the amount of time that was
15 put into making them.

16 I shared some of the same concerns
17 about the inputs of the AHRQ study in terms of
18 the age criterion, whether including that was
19 representative, understanding that the median
20 age of Medicare patients is 46, and some of the
21 RCTs that were excluded have mean ages of 49
22 with a standard deviation of eight, so figuring
23 out where to do that cutoff might be a little
24 bit arbitrary.

25 To say the data is not generalizable

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1 also concerned me a little bit. Dr. DeMaria
2 had one slide up that did show comparable
3 outcomes at least in the perioperative period
4 for patients over 65 as compared to the rest of
5 the MBS data. More long-term data would be
6 great, I know that's in the works, I wish it

August 30th MEDCAC Meeting Panel Proceedings JS and LA
7 was available today, and I know that everybody

8 is out trying to correct that.

9 One thing we didn't hear a lot about
10 today are access issues, namely in getting the
11 surgery and long-term follow-up which may be a
12 barrier. There's supposed to be a fair amount
13 of qualitative survey work that's looking into
14 maybe some of the barriers that are going on,
15 but I think a cleaner definition of maybe
16 trying to figure out how much of that is
17 attributable to patient, provider and societal
18 bias, or versus coverage decisions, would be
19 important in moving forward, but that is pretty
20 much what I have to say. Thank you.

21 DR. KLEIN: Yeah. I see nothing wrong
22 with the study you did as long as it's
23 understood what the criteria were for, you
24 know, the enrollment of the patients, so it's
25 valuable information.

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1 What I do see is that there is no real
2 gold standard data of randomized control trials

3 in Medicare populations and never will be, so
4 you have to use your best judgment for what the
5 data are in other populations, and there will
6 be more data in the future by going back into
7 looking at results from databases, and so I
8 think you have to just use common sense and not
9 simply exclude the ability of providing a
10 beneficial therapy for a group of patients
11 because there's no randomized control trials.

12 DR. BETZ: Yeah, I echo the previous
13 comments that there didn't seem to be clear
14 data presented on the Medicare population
15 today. We did talk about generalizability of
16 some of the data and that there were some
17 similar outcomes, but no clear studies in that
18 population, but as we mentioned, they may not
19 exist.

20 DR. HILKERT: So when I look at the
21 data, first I guess I'm struck by the fact that
22 this type of surgery and treatment is very
23 different from other fields, and for the
24 comments that the patient advocate sounded that
25 really stuck with me when he said, you know,

1 that we would never tell a cancer patient they
2 could only have one procedure for the rest of
3 their life.

4 I think we have to understand that
5 these procedures are done on a different
6 population that has different social issues
7 that would affect the ability to really obtain
8 high quality randomized information, but I
9 think we have to be, you know, imaginative in
10 the way we look at all the data, and look at
11 all different sources of data that we can. I
12 think the presentation from PCORI was very
13 enlightening about all the different ways we
14 can look at data to make the most intelligent
15 coverage decision for these surgeries.

16 DR. ZUCKERMAN: This is Dr. Zuckerman.
17 I guess I'm struck by not wanting to be
18 imaginative. Trained in epidemiology, I like
19 to look at data and I am very concerned about
20 the lack of data. I very -- well, a couple of
21 issues that have been raised.

22 One is the lack of, the loss to
23 follow-up that's huge. I mean, we're supposed
24 to be looking at two years or less, or more
25 than two years, and some of the data that I've

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1 looked at, actually all the data that I've
2 looked at for what seems to be the Medicare
3 population, showed a very large loss to
4 follow-up. I mean, if you lose more than half
5 your people after 18 months, that's not good,
6 and how could you make decisions based on data
7 like that.

8 And the other part of this is although
9 I understand that a lot of these Medicare
10 patients are disabled, I want to know who these
11 people are, why are they disabled? Did they
12 become overweight because they were already
13 disabled? Are they disabled because they're so
14 overweight? I mean, we know nothing about
15 them, and how do we make any kind of judgment
16 about how well they're likely to do, knowing
17 that they could be very very different from the

18 other patients in the same age groups. We just
19 don't know, so I'm frustrated by that.

20 I also just want to mention something
21 about exclusion criteria. I know that when
22 gastric banding was first approved by the FDA,
23 the studies excluded people with a family
24 history of autoimmune disease, and they did
25 that because of concerns about a reaction to

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1 the band. And since African American women are
2 particularly vulnerable to autoimmune diseases
3 like lupus and so on, that means they were
4 excluded from studies. I don't know if that's
5 true of other, you know, of the balloon or
6 other devices, but I know that traditionally
7 it's not unusual to exclude people for reasons
8 like that, and that really raises questions
9 about how generalizable the data are.

10 So I'm really struck by the lack of
11 information and how hard it is to vote even on
12 the question of short term versus long term

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13 when we're missing subgroup analyses where, we
14 haven't heard any presentations about exclusion
15 criteria. We know that generally in clinical
16 trials there's a desire to have healthier
17 younger people, and that they often are white,
18 and in this case unusually, they're mostly
19 women.

20 And the other part of that is it
21 sounds like we're going to have wonderful data,
22 it sounds like there are some huge data sets
23 that could be looked at long term, that could
24 make, give us a lot more information about who
25 these people are and what's happening to them,

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1 and we just don't have it yet.

2 DR. YATES: Dr. Yates. I would like
3 to thank all the speakers for all the hard work
4 and the wonderful presentations they made
5 today, and I'm going to take a slightly
6 different approach to this.

7 Surgery is a science of accretion of
8 knowledge, it's not a science that is out of

9 randomized control trials, it's a science of
10 accretion and experience. As the chairman of
11 Vanderbilt was famously quoted once, son, you
12 don't have to learn about all your own mistakes
13 by doing them, you can read about a few of
14 them. And over time, surgery grows from that
15 accretion of knowledge.

16 And it is very hard to do sham
17 surgery, it's very hard to do the randomized
18 control trials in surgery, and my hat's off to
19 those that have completed those. And as such,
20 we have to accept surgical literature for what
21 it is, which is something different than what,
22 say, the McMasters group expects in terms of
23 Level I and Level II evidence.

24 I think the answer was, it's very
25 enlightening how very robust the registry is

1 and its development, and I think that's very
2 important, and I think it's very important that
3 CMS support the registry accumulation of data

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4 and that we learn how to somehow give credit to
5 registry data such that it rises to the level
6 of Level I and II. And if it becomes universal
7 in term of its application and capturing
8 patients lost to follow-up because they may
9 move or something happens, registries are going
10 to hunt those down a lot better than a study
11 that's only funded for two or three years.

12 And so those are my comments, that I
13 think the evidence is what it is, and we have
14 to work with what we have in terms of what can
15 only be a less than Level I experience.

16 DR. WILLIAMS: Renee Williams, NYU. I
17 want to thank the presenters again.

18 Essentially, I think we have a lot of good
19 data, but I also think we have a lot of missing
20 data, so I think we just have to use our best
21 judgment in terms of making our decisions
22 today.

23 I really appreciate having a patient
24 perspective in terms of science, and I think
25 that what surprised me the most today was the

1 fact there is no coverage for I guess services
2 following bariatric surgery. That is something
3 that I actually didn't know and that was very,
4 I guess, enlightening for me.

5 DR. SALIVE: Marcel Salive, and so, I
6 enjoyed the meeting. I think, you know,
7 Medicare was able to cover a number of
8 bariatric procedures, and I was part of the
9 coverage team in 2006 on that decision memo.
10 And you know, I didn't hear a lot of complaints
11 about that memo, surprisingly, but I heard a
12 lot of, on other topics in the past. I believe
13 we did conclude at that time that there was
14 useful evidence pertaining to the Medicare
15 population. I think this progress since then
16 is actually quite considerable and I think that
17 the quality programs need to, you know, take
18 charge, and be a real quality program. And
19 you, the quality programs can I think do audits
20 of their data to make sure that they have
21 completeness of cases from the surgeons, which
22 I think is really a key issue that people have
23 been touching on, and it doesn't have to be the

24 responsibility of the payer to do that. I
25 think, you know, if you are a quality program

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1 looking at surgical outcomes, you know, those
2 missing data are very important to really
3 shrink them down and look very critically.

4 I think the progress shown from the
5 data that we saw over time is remarkable and
6 excellent and, you know, I think the point is
7 well taken that there is a large group of
8 people who are not getting surgery. I think
9 that's partly, a patient choice is involved
10 partly in that, so I think that's also more of
11 a societal problem and we can look at that.

12 So, I do think that a troubling point
13 to me is sort of this lack of really shared
14 decision-making on how to choose a procedure
15 and how to treat obesity in the population. It
16 seems like people, you know, I understand
17 skills and history and regional specialization,
18 but I think that there is some need for more of

August 30th MEDCAC Meeting Panel Proceedings JS and LA
19 a shared decision-making approach to this.

20 Thanks.

21 DR. OLLENDORF: Dan Ollendorf. I do
22 also want to thank all the presenters and those
23 who put a lot of work into the research that
24 informed this meeting. I'm going to be echoing
25 a lot of the comments that were already made in

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1 some ways, but maybe not so in others.

2 As an evidence reviewer, I'm heartened
3 to see some incremental gains in additional
4 long-term follow-ups since we did our own
5 technology assessments for the State of
6 Washington and for the California Technology
7 Assessment Forum a couple years ago. And as an
8 evidence reviewer, my esteemed colleagues at
9 Brown, I feel your pain in terms of really
10 trying to get the entry criteria right.

11 I think as Dr. Zuckerman notes, we
12 don't really know a lot about what the Medicare
13 disabled population looks like, and so whether
14 that is at all comparable to the larger set of

15 lower age studies for bariatric surgery remains
16 an open question.

17 But I prefer to highlight another
18 observation that Doctors Trikalinos and
19 Panagiotou, if I got that right, alluded to,
20 which is yes, we have these large studies that
21 are ongoing from PCORnet, the society
22 registries are both very robust and very
23 promising, but there were observational
24 studies, comparable observational studies that
25 the Brown group looked at. Less than 20

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1 percent of them made any attempt to control for
2 confounding between groups, so there's some
3 basic building blocks of observational studies
4 that can be applied in any clinical discipline,
5 including this one, and have not really been
6 applied with the same level of rigor that I'm
7 used to seeing. And so, we do not necessarily
8 need randomized control trials to answer many
9 of these questions, but what we do need is a

10 August 30th MEDCAC Meeting Panel Proceedings JS and LA
commitment to good rigorous science.

11 DR. MORA: Marc Mora, from Kaiser
12 Permanente. I want to once again thank you for
13 all the expertise and experience in the room.
14 It's reassuring to see how the field continues
15 to advance and how our knowledge continues to
16 expand.

17 One thing that I thought I'd hear more
18 about was the sort of system approach to
19 managing this chronic condition, behavioral
20 modifications and the behavioral health issues
21 that many of these patients face, the medical
22 management issues, lifestyle, as well as the
23 surgical approach, I think that's just an
24 opportunity for us to get better at providing
25 care for these patients.

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1 And I once again, I'd just comment on
2 the experience and expertise in the room, it
3 was really impressive to hear from all of you,
4 so thank you for your time today.

5 DR. CAMPOS-OUTCALT: Doug

6 Campos-Outcalt, Phoenix, Arizona. So I've been
7 on a number of these panels now and I've also
8 participated in a lot of clinical practice
9 guidelines panels, and I would say that it's
10 very common to have the specialists disagree
11 with the generalists and the methodologists as
12 to the quality of the evidence. The
13 specialists almost always feel that the
14 evidence they have is better than the
15 methodologists feel that it is, so it's not
16 unusual to be in that fix.

17 If I can reiterate the comment about
18 randomized controlled trials, I see this over
19 and over again. We can't do randomized
20 controlled trials. You don't need randomized
21 controlled trials to have good quality
22 evidence, you need good quality observational
23 studies, and I don't see those here. I see
24 observational studies that have been mentioned,
25 they have methodological flaws that keep them

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1 from being updated to high quality. And that's
2 something which if you admit that you can't
3 really do randomized control trials, fine, then
4 let's strive to make your observational studies
5 the highest quality you can, and that means
6 you've got to control for confounders and
7 effect modifiers and so forth.

8 The other thing to remember is we're
9 not being asked to make a coverage decision
10 here, what we're being asked is to assess the
11 quality of the evidence, what is the evidence
12 here. Medicare makes the decision on coverage,
13 and I've been on panels where the panel didn't
14 think the evidence was very good but a coverage
15 decision was made anyway, a lot of times
16 coverage with evidence development.

17 So we're being asked to assess the
18 evidence and not make a coverage decision and
19 that's, those two may not be consistent. I may
20 transparently say I don't think the evidence is
21 very good, and secretly wish we were covering
22 something, but that's not what I'm being asked
23 to do.

24 DR. ALBRIGHT: Karen Albright, UAB. I

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25 guess I would echo my colleagues' comments so

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1 far, particularly the last comments. I would
2 say specifically, I was hoping in terms of
3 observational research that we would see at
4 least moderate if not larger efforts to achieve
5 balance between groups, whether that's inverse
6 probability weighting or propensity score, that
7 change, and then to have the statistics
8 actually fit with this study design and to make
9 sure that we're using, you know, paired
10 statistics if that's what's needed.

11 And I would only add that in terms of
12 evidence, I would have liked to hear more about
13 functional outcomes, life space, things that
14 matter to patients, and a little more granular
15 data on the burden of disease, you know, do you
16 or do you not cross this A1c line to have
17 diabetes, but its impact, you know. Some
18 speakers brought up the importance of prior
19 insulin use. Also, I would argue it's
20 important, the duration of your disease or the

21 severity of your disease, so the burden of
22 disease is something that I think was also
23 lacking.

24 DR. CUYJET: Okay. I'll close up,
25 Dr. Cuyjet again. I'm going to put on my

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1 public health hat and go up to about 30,000
2 feet. There are a lot of unanswered questions
3 that we need to answer from my co-panelists'
4 conversation at lunch, and you can go back to
5 the (unintelligible) seven-country study which
6 is almost 17 years old now. You can cut back
7 to the Honolulu Heart Study, some of the
8 epidemiology data that's been published by
9 Poulter in Australia, who was the first of the
10 colonization of diet. So the more population
11 shift from a granular diet to a more western
12 diet, both the incidence and prevalence of
13 diabetes tracks right along.

14 So I think for all of us in this room,
15 there are questions that need to be answered,

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16 or continue to be answered in terms of what is
17 the best procedures, who are the best patients
18 to recommend those procedures to, but as
19 physicians, insurance policy folks, we heard
20 from NCHPH, I think we all need to make a
21 larger commitment to the public health side of
22 the equation, so less video games, less fast
23 foods, less television, less computer time. We
24 need to be physically active and really make a
25 healthy choice in our diet. And at the end of

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1 the day, what we would like to see is fewer
2 obese people in the Medicare population about
3 which we have to have these conversations.
4 So I would like to thank you all for
5 your participation and input and insights, it's
6 been interesting, to say the least. Thank you.
7 MS. ELLIS: So now during this portion
8 of the meeting is when the panel will vote, so
9 if you will just give us a few seconds, we're
10 going to hand out the keypads. The panel
11 members, they will vote. Panel members, once

12 Dr. Cuyjet, he will read all of the questions;
13 after he reads the question, then he will go
14 one by one, you will cast your vote, your vote
15 will show up on the screen. Remember, the last
16 vote that you punch on the key device will be
17 your vote. After all the votes are in and we
18 get the mean up on the screen, Dr. Cuyjet will
19 call each individual person and you will say
20 your vote. Could you please state your name
21 and then say your vote, so that it can be heard
22 for the record. And also, don't forget, you do
23 have a separate score sheet in your folder as
24 well to record your vote, okay?
25 I just need one second.

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1 (Pause.)
2 DR. ZUCKERMAN: I have a question
3 about most of the questions. I just want to
4 make sure that I understand that this is a
5 question of these should be appropriate, that
6 we consider these appropriate outcome issues;

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7 is that it?

8 DR. CUYJET: Yes.

9 DR. ZUCKERMAN: Not that they've been
10 proven to be, but that we believe that they
11 should be considered appropriate.

12 DR. CUYJET: The voting question is
13 basically just assessing our confidence in the
14 data presented and addressed for each of the
15 questions.

16 DR. ZUCKERMAN: I couldn't hear you.

17 DR. CUYJET: I was discussing what our
18 confidence is in the level of data that were
19 presented to address each of these questions.

20 DR. ZUCKERMAN: Okay. I've identified
21 number two and three, and four, but I thought
22 one was different.

23 DR. CAMPOS-OUTCALT: Yeah, I would
24 agree with that. I think that question one is
25 how confident are we that these are outcomes

1 that should be looked at, not that were looked
2 at, or that there was evidence that they should

3 be looked at, how important do we feel these
4 are as outcomes to be explored, that was my
5 interpretation of that question.

6 DR. SALIVE: So also, I have a point
7 on this question. The primary outcome is, you
8 know, generally viewed as most important, and I
9 found that in the literature. There is also, I
10 believe, an FDA view of primary outcomes used
11 for making regulatory decisions, and I think
12 scientifically they're used for calculating the
13 size of the trial. There are other types of
14 outcomes like secondary outcomes, and so to me,
15 if it's for decision-making on coverage, you
16 know, that would be why it would be primary
17 outcomes here in this meeting and so, you know,
18 to me, some of these, I wouldn't want to make
19 coverage decisions on some of these listed, I
20 would not be confident making coverage
21 decisions based on some of these outcomes.

22 DR. CUYJET: As I said before, we're
23 not making a recommendation in terms of
24 coverage decisions but we are making a
25 recommendation based on our score from one, low

1 confidence, to five, high confidence, and
2 question one is basically seven questions for
3 each of the different parts. So if you think
4 the data submitted is convincing --

5 PANELIST: I think we have to decide
6 what that question is, because I interpret that
7 as missing a word; it should be how confident
8 are you that the following is a meaningful
9 primary health outcome as available in research
10 studies from bariatric surgery? I mean, if
11 this is a question, I mean, it's not us trying
12 to tell people what to do.

13 DR. CUYJET: No, but we had a
14 conference call about this.

15 PANELIST: Yeah, maybe we need a CMS
16 consult here.

17 MS. ASHBY: So, it's a meaningful
18 health outcome, right?

19 PANELIST: I think the distinction
20 we're trying to draw with our questions about
21 this question is, are we expressing confidence

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22 that these outcomes have been addressed in the
23 available evidence, or are we expressing our
24 level of confidence that these are outcomes
25 that should be measured in studies? Should be

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1 measured, okay.

2 DR. ZUCKERMAN: Okay. And do you want
3 to distinguish between primary and, a few most
4 important ones, so that you can't have all of
5 them be considered primary outcomes? I mean,
6 do you want us to distinguish between like the
7 three most important or the two most important?

8 MS. ASHBY: So, unless you disagree,
9 we put down primary. Marcel has laid it
10 out. If you want to go that far, that's fine,
11 if you want to discuss other issues with it, I
12 believe Dr. Cuyjet, you could ask those
13 questions. But I would ask the question first
14 to vote on as we have it; does that make
15 sense?

16 DR. CUYJET: Yes. That was the
17 original discussion we had in the phone

18 conference.

19 MS. ASHBY: Yes. And then after you
20 answer that question and vote, you can ask are
21 there any comments on it.

22 DR. CUYJET: Okay. All right,
23 question one. How confident are you that the
24 following are meaningful primary health
25 outcomes in research studies of bariatric

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1 surgery? The first that you're going to
2 address is the weight loss, and one is --

3 MS. ELLIS: Everyone should have their
4 keypads so you can go ahead and vote.

5 (The panel voted and votes were
6 recorded by staff.)

7 MS. ELLIS: I need everyone to push
8 the keypads one more time; we're missing two
9 persons' votes. Just push the button one more
10 time.

11 DR. CUYJET: There we go. All right.
12 So, the second area is postoperative

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13 complications, so how confident are you that
14 the following are meaningful primary health
15 outcomes in research studies of bariatric
16 surgery based on what was presented today?
17 (The panel voted and votes were
18 recorded by staff.)
19 MS. ELLIS: If everyone could just
20 push their buttons one more time, just to make
21 sure. I apologize that we're having technical
22 difficulties, so what we're going to do is we
23 will vote -- oh, there it is, something
24 happened.
25 Okay. We will start with Dr. Karen

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1 Albright. If you could, since we forgot to say
2 our votes for question one, so could you state
3 your vote for question one and question two,
4 please. I'm sorry, 1.A and 1.B, thank you.
5 DR. ALBRIGHT: Karen Albright, UAB.
6 1.A, five; 1.B, four.
7 MS. ELLIS: Thank you.
8 DR. CAMPOS-OUTCALT: Doug

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9 Campos-Outcalt. 1.A, three; 1.B, five.

10 DR. MORA: Marc Mora. 1.A, four; 1.B,
11 four.

12 DR. OLLENDORF: Dan Ollendorf. Five
13 for both 1.A and 1.B.

14 DR. SALIVE: Marcel Salive. Five for
15 1.A and 1.B.

16 DR. WILLIAMS: Renee Williams. Five
17 for 1.A and 1.B.

18 DR. YATES: Adolph Yates. Five for
19 1.A and 1.B.

20 DR. ZUCKERMAN: Diana Zuckerman. Five
21 for 1.A and 1.B.

22 DR. HILKERT: Bob Hilkert. Five for
23 1.A and four for 1.B.

24 DR. BETZ: Martha Betz. Five for 1.A
25 and five for 1.B.

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1 DR. KLEIN: Sam Klein. Five, 1.A;
2 five, 1.B.

3 DR. TELEM: Dana Telem. Five, 1.A,

4 August 30th MEDCAC Meeting Panel Proceedings JS and LA
and five, 1.B.

5 DR. WOLFE: Bruce Wolfe. 1.A, five,
6 and 1.B, four.

7 MS. ELLIS: Thank you.

8 DR. CUYJET: Hopefully we'll move to
9 question 1.C, how confident are you that the
10 following are meaningful primary health
11 outcomes in research studies of bariatric
12 surgery, C, diabetes and metabolic outcomes.

13 (The panel voted and votes were
14 recorded by staff.)

15 DR. ALBRIGHT: Karen Albright, UAB.

16 MS. ELLIS: One second. We're still
17 missing the one. I apologize for the
18 inconvenience. We're going to see if we can
19 get another keypad.

20 DR. CAMPOS-OUTCALT: Are the keypads
21 mandatory? Couldn't we just go down and give
22 our votes, and somebody tally it up and do a
23 quick mean?

24 DR. CUYJET: I could do that.

25 MS. ELLIS: Okay. In the meantime,

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1 what we will do is, we are on question 1.C. If
2 you could go down the line and state your
3 votes?

4 DR. ALBRIGHT: Karen Albright, UAB.

5 Four.

6 DR. CAMPOS-OUTCALT: Doug

7 Campos-Outcalt, five.

8 DR. MORA: You guys are quick. Marc

9 Mora, four.

10 DR. OLLENDORF: Dan Ollendorf, five.

11 DR. SALIVE: Marcel Salive, five.

12 DR. WILLIAMS: Renee Williams, five.

13 DR. YATES: Adolph Yates, five.

14 DR. ZUCKERMAN: Diana Zuckerman, five.

15 DR. HILKERT: Bob Hilkert, four.

16 DR. BETZ: Martha Betz, five.

17 DR. KLEIN: Sam Klein, five.

18 DR. TELEM: Dana Telem, five.

19 DR. WOLFE: Bruce Wolfe, five.

20 MS. ELLIS: Okay, thank you.

21 DR. CUYJET: We'll move on to

22 question D. How confident are you that the

23 following are meaningful primary health

24 outcomes in research studies of bariatric
25 surgery as it pertains to cardiovascular

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1 outcomes?
2 DR. ALBRIGHT: Karen Albright, UAB.
3 Four.
4 DR. CAMPOS-OUTCALT: Doug
5 Campos-Outcalt, five.
6 DR. MORA: Marc Mora, four.
7 DR. OLLENDORF: Dan Ollendorf, five.
8 DR. SALIVE: Marcel Salive, one.
9 DR. WILLIAMS: Renee Williams, five.
10 DR. YATES: Yates, five, and they need
11 to respell my name. It's a P-H at the end of
12 Adolph.
13 DR. ZUCKERMAN: Diana Zuckerman,
14 three.
15 DR. HILKERT: Hilkert, four.
16 DR. BETZ: Martha Betz, five.
17 DR. KLEIN: Sam Klein, five.
18 DR. TELEM: Dana Telem, five.

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19 DR. WOLFE: Bruce Wolfe, four.

20 DR. CUYJET: So part E, how confident

21 are you that the following are meaningful

22 primary health outcomes in research studies of

23 bariatric surgery as they pertain to

24 respiratory outcomes?

25 (The panel voted and votes were

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1 recorded by staff.)

2 MS. ELLIS: We just need one second.

3 There we go. Now if you could go down the line

4 and state your vote?

5 DR. ALBRIGHT: Karen Albright, four.

6 DR. CAMPOS-OUTCALT: Doug

7 Campos-Outcalt, five.

8 DR. MORA: Marc Mora, three.

9 DR. OLLENDORF: Dan Ollendorf, two.

10 DR. SALIVE: Marcel Salive, one.

11 DR. WILLIAMS: Renee Williams, five.

12 DR. YATES: Yates, five.

13 DR. ZUCKERMAN: Diana Zuckerman, two.

14 DR. HILKERT: Bob Hilkert, two.

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15 DR. BETZ: Martha Betz, three.
16 DR. KLEIN: Sam Klein, five.
17 DR. TELEM: Dana Telem, four.
18 DR. WOLFE: Bruce Wolfe, four.
19 DR. CUYJET: Okay, 1.F. how confident
20 are you that the following are meaningful
21 primary health outcomes in research studies of
22 bariatric surgery as they pertain to
23 musculoskeletal outcomes?
24 MS. ELLIS: We're just going, if you
25 could because the system is acting up, we have

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1 nine voters and we only have eight, if you
2 could just say your vote and don't worry about
3 the devices this time, thank you all.
4 DR. ALBRIGHT: Karen Albright, four.
5 DR. CAMPOS-OUTCALT: Campos-Outcalt,
6 five.
7 DR. MORA: Marc Mora, three.
8 DR. OLLENDORF: Dan Ollendorff, two.
9 DR. SALIVE: Marcel Salive, one.

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10 DR. WILLIAMS: Renee Williams, four.

11 DR. YATES: Yates, five.

12 DR. ZUCKERMAN: Diana Zuckerman,

13 three.

14 DR. HILKERT: Bob Hilkert, two.

15 DR. BETZ: Martha Betz, three.

16 DR. KLEIN: Sam Klein, five.

17 DR. TELEM: Dana Telem, four.

18 DR. WOLFE: Bruce Wolfe, four.

19 DR. CUYJET: Okay. The last part of

20 question one, how confident are you that the

21 following are meaningful primary health

22 outcomes in research studies of bariatric

23 surgery as they pertain to quality of life?

24 DR. ALBRIGHT: Karen Albright, four.

25 DR. CAMPOS-OUTCALT: Campos-Outcalt,

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1 four.

2 DR. MORA: Marc Mora, four.

3 DR. OLLENDORF: Dan Ollendorf, five.

4 DR. SALIVE: Marcel Salive, three.

5 DR. WILLIAMS: Renee Williams, five.

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6 DR. YATES: Yates, five.

7 DR. ZUCKERMAN: Diana Zuckerman,
8 three.

9 DR. HILKERT: Bob Hilkert, three.

10 DR. BETZ: Martha Betz, four.

11 DR. KLEIN: Sam Klein, five.

12 DR. TELEM: Dana Telem, five.

13 DR. WOLFE: Bruce Wolfe, four.

14 DR. CUYJET: Let's move on to question
15 two. How confident are you that there is
16 sufficient evidence for an intervention (to
17 include open and laparoscopic surgery and
18 endoscopic procedures) where the benefit
19 outweighs the harm for, A, short-term, two
20 years or less from surgery weight loss?

21 DR. ALBRIGHT: Karen Albright, four.

22 DR. CAMPOS-OUTCALT: Campos-Outcalt,
23 three.

24 DR. MORA: Marc Mora, three.

25 DR. OLLENDORF: Dan Ollendorf, four.

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- 1 DR. SALIVE: Marcel Salive, five.
- 2 DR. WILLIAMS: Renee Williams, five.
- 3 DR. YATES: Yates, five.
- 4 DR. ZUCKERMAN: Diana Zuckerman,
5 three.
- 6 DR. HILKERT: Bob Hilkert, four.
- 7 DR. BETZ: Martha Betz, four.
- 8 DR. KLEIN: Sam Klein, five.
- 9 DR. TELEM: Dana Telem, five.
- 10 DR. WOLFE: Bruce Wolfe, five.
- 11 DR. CUYJET: Okay. Part B, how
12 confident are you that there is sufficient
13 evidence for an intervention where the benefits
14 outweigh the risk, the harm for mid-term,
15 defined as more than two but five or less years
16 from surgery, weight loss?
- 17 DR. ALBRIGHT: Albright, three.
- 18 DR. CAMPOS-OUTCALT: Campos-Outcalt,
19 three.
- 20 DR. MORA: Marc Mora, three.
- 21 DR. OLLENDORF: Dan Ollendorf, three.
- 22 DR. SALIVE: Marcel Salive, four.
- 23 DR. WILLIAMS: Williams, five.
- 24 DR. YATES: Yates, five.

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25 DR. ZUCKERMAN: Diana Zuckerman, one.

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1 DR. HILKERT: Hilkert, three.
2 DR. BETZ: Martha Betz, three.
3 DR. KLEIN: Klein, five.
4 DR. TELEM: Telem, five.
5 DR. WOLFE: Wolfe, five.
6 DR. CUYJET: Okay, again, same
7 question, benefits versus harm, benefits
8 outweigh the harm for long-term, more than five
9 years after surgery weight loss.
10 DR. ALBRIGHT: Albright, three.
11 DR. CAMPOS-OUTCALT: Campos-Outcalt,
12 one.
13 DR. MORA: Marc Mora, dos, two.
14 DR. OLLENDORF: Ollendorf, one.
15 DR. SALIVE: Marcel Salive, three.
16 DR. WILLIAMS: Renee Williams, four.
17 DR. YATES: Yates, five.
18 DR. ZUCKERMAN: Diana Zuckerman, one.
19 DR. HILKERT: Hilkert, two.
20 DR. BETZ: Martha Betz, two.

21 DR. KLEIN: Klein, five.
22 DR. TELEM: Telem, four.
23 DR. WOLFE: Wolfe, five.
24 DR. CUYJET: Okay. Question three,
25 this is a response where the score is greater

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1 than 2.5, the question is filled out implicit
2 in question one, and that includes,
3 postoperative complications, diabetes and
4 metabolic outcomes, cardiovascular outcomes,
5 respiratory outcomes, musculoskeletal outcomes,
6 and G, quality of life.

7 (Inaudible discussion between
8 panelists.)

9 DR. ZUCKERMAN: But on our forms it
10 has been stated as just one opportunity for
11 short-term, mid-term or long-term, and there's
12 not specific ones for each thing to write on
13 our yellow sheet is the problem. We could do
14 it separately on the machine if it were
15 working, but it's tough to do it on our written

16 August 30th MEDCAC Meeting Panel Proceedings JS and LA
forms.

17 MS. ELLIS: In looking at the scores,
18 basically a lot of the scores were high, they
19 were three or above, we only had a couple ones,
20 so it doesn't appear that any of them are less
21 than 2.5, so what we will do is we will vote on
22 all of them.

23 DR. CUYJET: Okay, so let me --

24 DR. ZUCKERMAN: As one vote, just one
25 vote?

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1 DR. ALBRIGHT: As a composite?

2 DR. CUYJET: As a composite.

3 DR. ZUCKERMAN: But things are a
4 little different in terms of whether the data
5 presented deal with how much --

6 DR. CUYJET: This question could be
7 better phrased, but acknowledging that, let's
8 just answer what's, based on this, so we're
9 going to answer all seven of those parameters
10 in question one.

11 DR. MORA: Just one thing, though.

12 Marcel just pointed out that question two
13 already deals with weight loss, so that means
14 that it's B through G that we should be
15 addressing in question three.

16 DR. CUYJET: I didn't hear you.

17 DR. MORA: So, question two already
18 states weight loss, which is 1.A, so what we're
19 really talking about in question three is 1.B
20 through G.

21 MS. ELLIS: Right.

22 DR. ZUCKERMAN: So, should we just
23 write them in, then, so they all look like
24 question two? So we should write it all in for
25 six or however many?

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1 DR. CUYJET: Well, for question three,
2 the question for weight loss should be a given
3 based on your response to the first two
4 questions.

5 DR. ZUCKERMAN: Yeah, we're not voting
6 for weight loss but there's six other ones.

7 Are we voting separately for each of these
8 three things for six different outcome
9 measures? Is that what you want us to do, or
10 do you want us to vote once, saying at least
11 one of these things we're confident about?

12 DR. CUYJET: I think the intent of the
13 question was to address it in an aggregate
14 fashion.

15 DR. ZUCKERMAN: Well, do we have any
16 direction from CMS on this?

17 SPEAKER: In aggregate, please.

18 DR. CUYJET: So question three is, for
19 those outcomes listed in question one with a
20 voting score of greater than 2.5, how confident
21 are you that there is sufficient evidence for
22 an intervention, to include open and
23 laparoscopic surgery and endoscopic procedures,
24 where the benefit outweighs the harm for
25 short-term, again defined as two years or less

1 from surgery, intervention outcomes?

2 DR. ALBRIGHT: Albright, four.

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3 DR. CAMPOS-OUTCALT: Campos-Outcalt,
4 two.

5 DR. MORA: For question 3.A, Marc Mora
6 votes three.

7 DR. OLLENDORF: Ollendorf, four.

8 DR. SALIVE: Salive, two.

9 DR. WILLIAMS: 3.A, five, Williams.

10 DR. YATES: Yates, 3.A, five.

11 DR. ZUCKERMAN: Zuckerman, two.

12 DR. HILKERT: Hilkert, four.

13 DR. BETZ: Martha Betz, two.

14 DR. KLEIN: Klein, five.

15 DR. TELEM: Telem, five.

16 DR. WOLFE: Wolfe, five.

17 DR. CUYJET: Again, for those outcomes
18 listed in question one with a voting score
19 greater than 2.5, how confident are you that
20 there is sufficient evidence for an
21 intervention, to include open and laparoscopic
22 surgery and endoscopic procedures, where the
23 benefits outweigh the harm for mid-term,
24 defined as more than two but less than five
25 years from surgery, outcomes?

1 DR. ALBRIGHT: Albright, three.
2 DR. CAMPOS-OUTCALT: Campos-Outcalt,
3 two.
4 DR. MORA: Marc Mora, I have an
5 intermediate confidence at three.
6 DR. OLLENDORF: Ollendorf, two.
7 DR. SALIVE: Salive, two.
8 DR. WILLIAMS: Williams, four.
9 DR. YATES: Yates, five.
10 DR. ZUCKERMAN: Zuckerman, one.
11 DR. HILKERT: Hilkert, two.
12 DR. BETZ: Martha Betz, two.
13 DR. KLEIN: Klein, five.
14 DR. TELEM: Telem, five.
15 DR. WOLFE: Wolfe, five.
16 DR. CUYJET: Okay. Question three,
17 part C, for long-term outcomes more than five
18 years after surgery for interventions?
19 DR. ALBRIGHT: Albright, three.
20 DR. CAMPOS-OUTCALT: Campos-Outcalt,
21 two.

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22 DR. MORA: Marc Mora, two.
23 DR. OLLENDORF: Ollendorf, one.
24 DR. SALIVE: Salive, one.
25 DR. WILLIAMS: Williams, three.

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1 DR. YATES: Yates, five.
2 DR. ZUCKERMAN: Zuckerman, one.
3 DR. HILKERT: Hilkert, two.
4 DR. BETZ: Martha Betz, two.
5 DR. KLEIN: Klein, five.
6 DR. TELEM: Telem, four.
7 DR. WOLFE: Wolfe, five.
8 DR. CUYJET: All right. Question
9 four, how confident are you that the predictors
10 of success in the Medicare population, such as
11 patient characteristics and pre and
12 post-procedure standards of care, for any
13 bariatric therapy is known?
14 DR. ALBRIGHT: Albright, two.
15 DR. CAMPOS-OUTCALT: Campos-Outcalt,
16 one.
17 DR. MORA: Marc Mora, two.

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18 DR. OLLENDORF: Ollendorf, one.

19 DR. SALIVE: Salive, one.

20 DR. WILLIAMS: Williams, three.

21 DR. YATES: Question four, four for

22 Yates.

23 DR. ZUCKERMAN: Zuckerman, one.

24 DR. HILKERT: Hilkert, two.

25 DR. BETZ: Betz, two.

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1 DR. KLEIN: Klein, one.

2 DR. TELEM: Telem, three.

3 DR. WOLFE: Wolfe, four.

4 DR. CUYJET: Okay, we're going to have

5 some discussion. The voting is completed but I

6 would like the panel to state what the

7 predictors of success and the corresponding

8 benefits for bariatric procedures and

9 surgeries, and I will give Dr. Albright the

10 opportunity to start.

11 DR. ALBRIGHT: So, to that comment I

12 would say that I felt I got more information

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13 from the reading list than the presentations

14 today, maybe it was me, maybe it was the focus
15 of the presentations, but I don't know that I
16 feel confident in what those predictors are, or
17 that I could speak to them intelligently.

18 DR. CAMPOS-OUTCALT: Yeah. I voted
19 one, so I don't think I can answer this
20 question. I think that I didn't see any
21 evidence that we could predict.

22 DR. MORA: Yeah, I don't have anything
23 to add.

24 DR. OLLENDORF: I think I'll just
25 harken back to the technology assessment. So

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1 there were some models out there, most of them
2 were not validated. I think we already know
3 that there's a disconnect between what's been
4 published in terms of bariatric surgery in the
5 Medicare eligible population and what's
6 actually happening on the ground in terms of
7 who is getting the surgery, so I think there is
8 just a need for more evidence to be generated

9 in the relevant population, and then more
10 predictive work done.

11 DR. SALIVE: Yeah, I agree with that.

12 DR. WILLIAMS: No comment.

13 DR. YATES: We're on number four, this
14 is Yates. In the Medicare age population,
15 traditional Medicare age population there's a
16 lack of evidence in that population, but I
17 thought four was applicable only because the
18 average age of the overall Medicare population
19 is easily represented by the surrogate data
20 from younger patients out of Medicare.

21 And in particular, I thought type of
22 procedure, gender, age, and collective markers
23 for metabolic syndrome all are predictive from
24 the nice review from Dr. Panagiotou and
25 Dr. Trikalinos.

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1 DR. ZUCKERMAN: Okay. You know, I
2 voted one because I thought that it wasn't
3 clear how well we could predict among the

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4 Medicare population, and especially the
5 disabled, because I did not make the assumption
6 that Medicare patients who are on Medicare
7 because of disability are similar to
8 non-Medicare patients of the same age range, I
9 just felt we had no data to say that was true
10 or not true.

11 DR. HILKERT: Yeah, I agree with
12 everyone on the panel. I would like to see
13 some good subgroup analyses so we can really
14 see and understand who benefits the most from
15 this surgery. It seems like all takers,
16 everyone with a certain BMI should have this
17 surgery, but I'm not sure that's really the
18 right answer.

19 DR. BETZ: Martha Betz, no comments.

20 DR. KLEIN: So, I think most of the
21 data actually probably include a Medicare type
22 of population even if the percentage of
23 Medicare patients are low. There might not be
24 much difference between those who are not on
25 Medicare versus those who are on Medicare in

1 terms of disabilities and the age groups. But
2 what is lacking is the older age group, we have
3 very little data for people age 65 and over,
4 only one paper that I saw was presented today
5 but not yet published by Chris Still. All the
6 other data was age 60, or 55 and above, and so
7 I think that's really lacking, and coming up
8 with some guidelines regarding how to choose in
9 the older adult population, who is safe to have
10 the operation and who will benefit from the
11 operation.

12 DR. TELEM: I voted three. I think
13 more data are needed but I did think that there
14 was some generalizability that could be applied
15 to the Medicare population around procedure
16 choice, gender, socioeconomics and race
17 ethnicity.

18 DR. WOLFE: I voted four. This
19 question really needs better definition as to
20 what is success, and more information about
21 patient-reported outcomes will be important
22 here, because what I or you might call success
23 may or may not be what the patients call

24 success. But you know, overall I think the
25 success rate is rather high, and that's why I

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1 voted four.

2 DR. CUYJET: I'm going to add to
3 things that impact better outcomes,
4 socioeconomic status, family support,
5 geographic location, and Dr. DeMaria said as an
6 experienced bariatric surgeon, he hadn't
7 operated on folks over the age of, what was it,
8 75. I don't know if that same conclusion
9 applies to 80 or 85, it may depend on the
10 physiologic status, and that's one of the
11 questions we need to answer going forward,
12 particularly as surgical procedures become more
13 and more refined with fewer complications, so
14 that's an area for discussion and exploration
15 going forward.

16 DR. ZUCKERMAN: It just occurred to me
17 that it wasn't clear to me that if a patient
18 wasn't on Medicare, I'm sorry, wasn't on

19 August 30th MEDCAC Meeting Panel Proceedings JS and LA
disability and therefore not on Medicare

20 because of disability, that they even have
21 health insurance if they were in their 30s or
22 40s, so I just wondered if that is an inherent
23 difference between the people in the clinical
24 trials and the population we're concerned with.

25 DR. CUYJET: Okay. Next, we would

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1 like your thoughts on important evidence gaps
2 that have not been previously or sufficiently
3 addressed, and this might be one of them,
4 what's the cut point for age.

5 What else do people think that we need
6 more information on, or evidence?

7 DR. WOLFE: I would be happy to
8 address that. We're very anxious to fine-tune
9 the candidates as well as the interventions.
10 We heard about a wide range of interventions,
11 from endoscopic to major surgical. I've
12 chaired the last consortium, NIH consortium for
13 the last 12 years, and we've made a great
14 effort to provide the data so we can have

15 better personalized care, and we've not been
16 particularly successful in identifying the --
17 you know, the weight loss is highly variable,
18 we have trouble predicting that. The diabetes
19 remission is 60 percent, we have some clues on
20 how to predict whether that will occur or not
21 that we heard about today, but it's incomplete.
22 So more data to specifically allow us to
23 predict outcomes of specific indications for
24 surgery among specific patients will be
25 helpful.

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1 DR. CUYJET: And I would add, we heard
2 some information about A1c comes down and
3 people coming off medications, but we don't
4 know the duration of the effects and we don't
5 know which populations are going to have the
6 best outcomes over a longer time frame.

7 DR. WOLFE: That's a pertinent issue
8 because what should the endpoint be regarding
9 diabetes, is it remission, is it better

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10 control, is it long-term complications, is it
11 survival? It could be any of those, but
12 certainly the STAMPEDE trial, which is probably
13 the most celebrated, the endpoint is A1c, it's
14 not remission, because the entry criterion was
15 absolutely uncontrolled diabetes. If that's
16 your population, then the remission rate will
17 be low, whereas in the LABS-3 diabetes trial,
18 endpoint was an exclusion, so their remission
19 rate is 92 percent, so it depends a great deal
20 on what's the entry criteria.

21 DR. OLLENDORF: Okay. I would just
22 append to that there's kind of a general call
23 out there for these so-called core outcomes and
24 standardized measures. And so even if we're
25 thinking that remission is a good outcome to

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1 measure, you heard about four or five different
2 definitions of it today, so you might want to
3 think about how to standardize those measures,
4 and the same thing would apply for
5 postoperative complications. In other

6 surgeries there are standard classification
7 systems for the severity, and we could do the
8 same thing here.

9 DR. CUYJET: The second part is
10 discuss any known treatment disparities. I'll
11 go back to the classic CABG study in the
12 Medicare population, where black men had poor
13 outcomes despite the same insurance coverage
14 and same procedures. And as a trialist in the
15 past, I would encourage future studies be very
16 inclusive in the populations that are enrolled
17 in the studies, so we have some good
18 information.

19 We've heard that black women tend to
20 have poor outcomes, I forget who said that, but
21 we need to make a real effort to try to
22 understand the treatment differences among
23 different populations at risk.

24 DR. ALBRIGHT: I would like to add to
25 that. I think the group has done a nice job of

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1 noticing that there's predominantly women, and
2 so a simple setting would be data to get for
3 men, and if you could do the same for ancestry
4 or race ethnicity, then we would know more
5 about the people that we're actually caring
6 for.

7 DR. CUYJET: Any other comments?

8 DR. ZUCKERMAN: Yeah. I just wanted
9 to add that diversity is really important, but
10 also the subgroup analysis. If you've got
11 diversity but you mush everybody together and
12 most of them are white women, then it's going
13 to hide any differences and make it harder to
14 know, you know, who is benefitting the most and
15 who isn't benefitting much at all, and whether
16 certain people are at greater risk of having
17 the risk outweigh the benefits.

18 DR. CUYJET: Let me just make one
19 other comment, because I had a conversation
20 with Joe Nadglowski, who's not here anymore --
21 oh, you're back there? There you go. We don't
22 turn back and look at ourselves, so I was
23 asking him about the implicit association test.
24 For those who aren't familiar with it, it's a

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25 test up at Harvard that's been validated among

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1 a bunch of different domains. So dealing with
2 obesity implicit associations, I wanted to look
3 at the data being presented not having my
4 biases filtered, what I'm hearing or seeing.
5 And I think sometimes when we look at the
6 disparities issue, we need to take a look at us
7 as providers and how we interact with our
8 patients. There may have been conversations in
9 some of the presentations, but there are
10 conversations and then there are conversations,
11 so that's just a secondary thought, but it does
12 contribute to differences in outcomes.

13 DR. WILLIAMS: Just as a comment I do
14 think is very important from a diversity
15 standpoint, is to make a concerted effort to
16 recruit diverse populations. I mean, I'm not
17 sure what happened here in all the research
18 studies that populations are not
19 (unintelligible) as an option, I don't know if
20 they're looking at that or not, but I think by

21 doing that, we'd have a much more comprehensive
22 group of data.

23 DR. YATES: I would add that we worry
24 a lot about access in our field, and I think
25 that one of the things that has to be looked at

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1 and available through Medicare because they
2 have the data, is the AHRQ property index be
3 generated from administrative data sets, and
4 look at access to bariatric surgery. And also
5 using those ZIP codes, you can calculate urban
6 versus rural because there is very very
7 different types of poverty, and rural poverty
8 in Appalachia and rural poverty in a bad part
9 of town are both poverty and both have barriers
10 to access.

11 DR. WOLFE: This is challenging. We
12 started examining the Medicaid population as
13 our first disparity in the LABS analysis, and
14 immediately we discovered that the Medicaid
15 population is very different, older, heavier, a

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16 much greater comorbidity burden. So if you
17 just compare the outcomes at a given point in
18 time, it doesn't adequately take into account
19 where you started. The same could be true for
20 the rural or Medicare and so forth, so these
21 are all important subpopulations which will be
22 part of enabling us to do better personalized
23 care. And what we mostly have is generalized
24 data of the entire population, which is useful
25 but doesn't completely resolve the questions.

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1 DR. WILLIAMS: And when we think of
2 barriers to care, we need to understand that
3 patient opposition barriers also exist, and
4 that has to be taken into consideration.

5 DR. CUYJET: Okay. The last piece of
6 this is, considering both existing and new
7 procedures and devices as well as potential
8 barriers to care, discuss any mechanisms that
9 might be supported by CMS that would more
10 quickly generate an improved evidence base that
11 would underpin improved care and

12 decision-making for the Medicare population
13 affected by obesity.

14 DR. YATES: This is Dr. Yates
15 speaking. Two things that Medicare, CMS can
16 help with. One would be, and this is a tough
17 one, is to harmonize the coverage policies for
18 bariatric surgery amongst the administrative
19 contractors and the Medicare Advantage
20 Organization, so that apples are apples when
21 people go to look for bariatric surgery.

22 There's a lot of -- I'll leave local
23 coverage determination debates for later.
24 Well, it's called smoothing out the LCDs.

25 But the second thing would be to, any

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1 kind of carrot and stick, even if it's a
2 value-based purchasing process that requires
3 bariatric surgery programs to be part of
4 registry data, especially those that are
5 validated, would be very important. I think
6 that the evidence for that is clearly, it's

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7 clearly seen from the requirement for
8 cardiothoracic programs being part of SDS, as
9 well as what's being generated out the MBSQIP
10 requirement that any surgical training program
11 has to be part of MBSQIP. And if you can get
12 bariatric surgery across-the-board coverage, it
13 makes registry data more robust and more real.

14 DR. CUYJET: Okay. Any other
15 comments?

16 DR. TELEM: I want to say, I want to
17 second the belonging to a registry as part of
18 the bariatric program, and the importance of
19 that data in capturing the true long-term
20 outcomes that will benefit the patient. So
21 that any program performing bariatric surgery,
22 whether it's freestanding and doing endoscopic
23 procedures or surgical procedures, should be
24 required to report into our registry.

25 DR. CUYJET: Well, one of the things

1 we heard today was about data collection, and
2 the more information you have, the better you

3 can design trials, and the better decisions you
4 can make based on the outcomes. Given that the
5 surgical and endoscopic techniques are going to
6 continue to evolve, so they're going to get
7 better. We just need to define a Medicare
8 population that will most benefit from the
9 improvements in technique.

10 DR. CAMPOS-OUTCALT: Yeah. I think
11 this is a good example of where coverage with
12 evidence development is, could be very helpful,
13 because without coverage we're not going to get
14 the data that we need in this population, so to
15 me, the coverage, Medicare could help here with
16 coverage with some kind of parameters, and then
17 collect data over time to see, get some of the
18 answers to the questions you just raised.

19 DR. SALIVE: Yeah. To build on that,
20 I believe that specifically the gastric balloon
21 is a good example of that, where the evidence
22 we heard was not, I would say compelling to me
23 anyway, on some of the endoscopic balloons.
24 And some of the trial evidence is provocative,
25 but it needs probably a little bit of coverage

1 with evidence development to gain enough
2 evidence for full coverage from Medicare.

3 DR. ZUCKERMAN: Yeah, I want to second
4 that, that I thought that the evidence was just
5 much better for some procedures than others,
6 obviously much better for the ones that have
7 been around longer, and if you want long-term
8 data you actually have to have something that's
9 been around long term. But then things change,
10 products change, even the way surgery is done
11 changes, so it's sometimes very difficult to
12 make sense of data that were collected ten
13 years ago, or even five years ago if the
14 patient population is from five to 15 years
15 ago. So I think that's an inevitable barrier,
16 but it is tough, and I think that combined with
17 having analyses that puts all bariatric surgery
18 together instead of looking at specific
19 procedures and comparing them, that makes it
20 very hard to make judgments about what's best
21 for whom.

22 DR. CUYJET: Okay. I would like to

23 thank everyone for their participation and

24 presentations, some very interesting

25 information. Do we have to gather any other

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1 comments?

2 MS. ELLIS: No. I would like to thank

3 everyone also for coming out.

4 MS. ASHBY: Yes, and I'd like to echo

5 that as well. We have a wealth of information

6 that was discussed today, we have a lot to

7 consider. I thank everybody for their

8 participation, this has been very helpful to

9 us, and thanks again. Safe travels, everyone.

10 (The meeting adjourned at 3:20 p.m.)

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