CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare Coverage Advisory Committee

November 4, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland
Panelists

Chairperson
Ronald M. Davis, M.D.

Vice-Chairperson
Barbara J. McNeil, M.D., Ph.D.

Voting Members
David J. Margolis, M.D., Ph.D.
Brent J. O'Connell, M.D.
Clifford Goodman, Ph.D.
Jonathan P. Weiner, Ph.D.
Jed Weissberg, M.D.
Michael Abecaassis, M.D.
Kieren P. Knapp, D.O.
William F. Owen, Jr., M.D.

HCFA Liaison
Steve Phurrough, M.D., M.P.A.

Industry Representative
G. Gregory Raab, Ph.D.
Panelists (Continued)

Non-Voting Guest Panelists

Sam Klein, M.D., M.S.

Henry Buchwald, M.D., Ph.D.

Harvey Sugerman, M.D.

Executive Secretary

Kimberly Long
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PANEL PROCEEDINGS

(The meeting was called to order at 8:06 a.m., Thursday, November 4, 2004.)

MS. LONG: Good morning and welcome, committee chairperson, members and guests. I am Kimberly Long, an executive secretary for the Medicare Coverage Advisory Committee. The committee is here today to discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of bariatric surgery for the treatment of morbid obesity.

The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of impropriety. The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests. To determine if any conflict existed, the Agency reviewed all financial interests reported by the committee participants. The Agency has determined that all members may participate in the matters before the committee today. With respect to all other participants, we ask in the interest of fairness that all persons
making statements or presentations disclose any
current or previous financial involvement with any
company engaged in bariatric surgery or products
used in the surgery. This includes direct
financial investments, consulting fees, and
significant institutional support. If you haven't
already received a disclosure statement, they are
available at the table outside of this room.

We ask that all presenters adhere to
their time limits. We have a large number of
presenters to hear from today and a very tight
agenda, and therefore cannot allow extra time.
There is a timer at the podium that you should
follow.

And now I would like to turn the
meeting over to Dr. Steve Phurrough.

DR. PHURROUGH: Thank you, and let me
also welcome the public as well as the panel. We
appreciate your time and efforts to assist us in
this particular endeavor. We think this is an
important issue. Just to clarify what currently
Medicare is considering, we have current coverage
decisions on our records about what we do and
don't pay for in the arena of bariatric surgery.
We made some policy decisions this year that
allows us to consider either expanding or contracting that particular coverage. The actual things that we do or don't pay for has not changed and the purpose of this meeting is to get some expert advice on what the evidence demonstrates around the benefits of bariatric surgery in our population, both the over and under 65 population that we have responsibility for.

There are obviously a whole host of other issues around the treatment of obesity other than bariatric surgery. We are not addressing those today. If you are here to advocate for these, let me suggest that you save that for another meeting that we will have in the near future around other issues other than bariatric surgery. Today's question is what's the evidence around the use of bariatric surgery, if in fact a patient is determined by their physician to be eligible for that.

We will take the information that we receive from the panel today and use that information to determine whether in fact we should open a national coverage determination to potentially change our current coverage policies. That's the purpose of this meeting today, we think
it's a very important question for our patient
population and we look forward to both input from
our guests today as well as the panel discussion,
so thank you again.

DR. DAVIS: Thank you very much,
Dr. Phurrough and Kim. Let me just make a few
comments myself and kick off the meeting. I'm
Dr. Ron Davis, I am director of the Center for
Health Promotion and Disease Prevention at the
Henry Ford Health System in Detroit, and pleased
to have the opportunity to chair the Medicare
Coverage Advisory Committee in this particular
meeting, and in a few moments we will go around
the table and ask members of the committee to
introduce themselves and make any conflict of
interest disclosures that might be appropriate.

I do want to thank in advance the
presenters and CMS staff and others who have
reviewed the literature and presented an abundance
of information to the members of the committee and
who will do so throughout the meeting, and also
the members of the committee for their
participation. And we do have a rather heavy
agenda, no pun intended, so I will do my best to
keep us on track as we move through all of the
people who have requested the opportunity to
address the committee, and still allowing the
committee enough opportunity to have full
discussion amongst the members of the committee.

Then of course we have the questions
that we have been asked to answer, which will be
taken up toward the end of the meeting and if we
have time, we will have open discussion about
other topics of interest, areas where more
research might be needed, the query that CMS
posted on its web site as to whether a registry of
persons who have had bariatric surgery might be
beneficial, and so on.

So, let me now proceed again to
introduce myself and to review conflict of
interest disclosures for myself. The formal
disclosure that I made in writing to CMS staff or
by e-mail, I should say, was that no, I have not
received financial support from any company
engaged in bariatric surgery and I haven't
previously served on nor do I currently serve on
any advisory committee or panel dealing with this
topic, and I haven't been contacted by any party
prior to the meeting to discuss today's topic.

I do want to make two disclosures,
though, that are not addressed by those questions. My institution, Henry Ford Health System does have a bariatric surgery program; however, I have no authority over it, no formal role in it, and I have had minimal contact with it since it was formed. Also, as I mentioned at prior meetings of the MCAC, one of my extracurricular activities is as a member of the board of trustees at the American Medical Association; however, I am not officially representing the AMA at this meeting. Barbara?

DR. MCNEIL: I'm Barbara McNeil, I'm vice chair of this organization, this committee, and I am chairman of the Department of Health Care Policy of the Harvard Medical School, a radiologist at the Brigham and Women's Hospital in Boston, and I have no conflicts.

DR. MARGOLIS: Hi, my name is David Margolis, I'm a dermatologist and epidemiologist at the University of Pennsylvania. In filling out this form, since they specifically asked, it listed two companies, one was Johnson & Johnson, and I actually gave a lecture on pharmacoepidemiologic techniques to a group of medical people there last year. At the time I was
unaware that they had any bariatric products. I
have no other conflicts.

DR. GOODMAN: I'm Clifford Goodman, a
vice president of the Lewin Group, a health care
policy consulting firm, background in technology
assessment of evidence-based medicine. I have no
financial conflicts or other conflicts. I should
just mention that last month I moderated an
invited round-table examining the safety of
bariatric surgery at the Agency for Health
Research and Quality; however, this was not an
advisory panel, it did not make recommendations,
it was a discussion round table only.

DR. O'CONNELL: My name is Brent
O'Connell, I am a physician with Highmark Blue
Cross Blue Shield in Pennsylvania. I have some
conflicts. I have been on the Blue Cross Blue
Shield Technology Evaluation Center which reviewed
this topic and that is in your handouts today. I
have no financial interest in the topic. The
third thing you need to know is that one company
did contact me offering to provide information and
assistance, which I declined.

DR. WEINER: I'm Jonathan Weiner,
professor of health policy management at Johns
Hopkins School of Public Health and a health services researcher and outcomes researcher. I have no personal conflict of interest although I'm sure among my 30,000 colleagues at Johns Hopkins, all the treatments are being provided, but I have no involvement in any of that.

DR. WEISSBERG: Jed Weissberg. I'm a gastroenterologist at Kaiser Permanente and associate executive director for quality in that organization. Like Brent and Barbara, I served on the Blue Cross Blue Shield TEC which considered this topic but have no financial interests.

DR. ABECAASSIS: Mike Abecaassis, I'm a professor of surgery at Northwestern University in Chicago. I have no conflicts of interest. In my department, or the department that I am a part of, there are surgeons that perform bariatric surgery, but I have no issues related to that.

DR. KNAPP: I'm Kieren P. Knapp, D.O. I am a family physician, past president of American College of Osteopathic Family Physicians, and I have no conflicts of interest.

DR. OWEN: Good morning. I am Bill Owen, I'm a professor of medicine at Duke University, I'm also chief scientist at Wechsler
International Health Care, I have no conflicts of interest.

DR. RAAB: I'm Greg Raab, an independent health policy consultant. I noticed in the financial interest question that I was given that Johnson & Johnson was specifically mentioned and I wanted to point out that I have performed research for Johnson & Johnson but have no relationship with their businesses that deal with bariatric surgery.

DR. KLEIN: I'm Sam Klein, the director of the Center for Human Nutrition at Washington University School of Medicine in St. Louis. I receive research support from TransNeuronics for a multicenter trial that's being conducted in this country, and am also on the medical advisory board of EnteroMedics. I was recently on a panel from the American Society for Bariatric Surgery that evaluated gastric obesity surgery.

DR. BUCHWALD: I'm Henry Buchwald, I am professor of surgery at the University of Minnesota, I am a guest panelist and I have been in this field for many years. I am a practicing surgeon as well as a professor of surgery in the field of bariatrics. I am past president of the
American Society of Bariatric Surgery and the
International Federation of Surgery for Obesity.
I've participated in many seminars on bariatric
surgery and I consult for Ethicon and
Transneuronics, and I have recently been called in
a telephone conversation by Blue Cross Blue
Shield.

DR. SUGERMAN: I'm Harvey Sugerman, I'm
emeritus professor of surgery at Virginia
Commonwealth University and retired general
surgeon. I spent many years doing bariatric
surgery. I am currently the president of the
American Society for Bariatric Surgery for which I
receive some financial funding, as well as editor
of a new journal called Surgery for Obesity and
Related Diseases for which I also receive
financial support. I have also been a member of
the surgical advisory board for Ethicon
Endosurgery at Johnson & Johnson, and have been on
speaker panels supported by U.S. Surgical
Corporation. I was an initial investigator with
the FDA A trial for INAMED Corporation on the
laparoscopic adjustable gastric band.

DR. DAVIS: Barbara.

DR. MCNEIL: Ron, Brent's remark about
Blue Cross TEC reminded me that I also serve on that and was on the panel that reviewed it 14 months ago.

DR. DAVIS: Thank you everybody, and if anyone thinks of another disclosure that they forgot to make a few moments ago and would like to make later in the meeting, that would be fine.

I would also like to let the presenters know in advance that before they make their remarks, we would appreciate any appropriate conflicts of interest disclosures on their part as well.

So with that, I think we're ready to proceed with the agenda, and the next item is the CMS summary of evidence and presentation of voting questions. Dr. Ross Brechner.

DR. BRECHNER: Good morning. With such a distinguished panel, a fellow like me gets a little bit nervous giving a talk, and it reminds me of the famous scientist who made such a phenomenal discovery that he was paid half a million dollars for a year to get around the United States in a chauffeured car and give his talk in different kinds of cities. Somewhere about two months into this, the chauffeur turned
to the scientist and said you know, you've got a pretty easy job. You just drive around, give the same talk time after time, and you make a fortune. Well, the scientist said you know, I worked long and hard for this, and I don't understand what the problem is with you, but I deserve this. And the chauffeur said yeah, but you know, it could be done by anybody. I could do it.

Well, they made some kind of arrangement and in the next city the chauffeur was dressed as the scientist and the scientist was dressed as the chauffeur, and the chauffeur came up to the stand and gave a flawless speech and was smiling to himself when the moderator said suddenly, we're going to take questions from the audience. Well, someone raised their hand and they said well, look, if we take this data and we do a three-way analysis of variance and we then take out this confounder and put in this confounder, split this group into four groups and do this and that, et cetera, what would happen? Well, the chauffeur looked at him and said you know, that question is a pretty basic and simple question. In fact, it's so basic I'm going to let my chauffeur answer it.
(Laughter.)

DR. BRECHNER: With that, I'll get started. I do want to thank everyone on the slide for their health. It was a team effort, we all worked together. In my talk after the introduction, I will be talking about Medicare coverage, the epidemiology of obesity, and then the current mechanisms and types of bariatric surgery. I will follow with our procedure for evidence review and the results, the conclusions, and then finally the questions for the MCAC panel.

Obesity in the United States has been on a marked rise for 20 to 30 years until recently, 27 percent of our population is overweight and 34 percent is obese. Treatment for obesity consists of modalities like diet, exercise, life style modification, behavioral modification, medications, some combination of those, or bariatric surgery.

Some definitions are in order for the talk. BMI is defined as the body mass index and equals the body weight in kilograms divided by the height in meters squared.

Classes of obesity, Class I, 30.0 to 34.9 BMI; Class II, 35.0 to 39.9 BMI, and Class
III, 40 or more, known as extreme obesity. Morbid obesity is a BMI of 35 or more with at least one comorbidity, or a BMI of 40 or over. And the percent extended weight loss is the weight loss resulting from bariatric surgery divided by the preoperative weight, minus an ideal body weight as designated in standard life tables, times 100 to get the percentage.

Now CMS is aware that the rate of bariatric surgery is increasing. CMS desired a review and assessment of evidence including quality. We ultimately want to assure that we have the highest quality of outcomes. In the past, Medicare has paid for treatments for obesity if there was a benefit category for that treatment and if the obesity caused or was aggravated by another disease. We could not pay for obesity treatment if there were no comorbidities.

Some of the language for this is up on the board: Although obesity itself is not an illness, it may be caused by an illness. Obesity can aggravate other diseases. And services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of
treatment for one of these illnesses.

Now the language on the top, obesity itself cannot be considered an illness, this is the language that was removed from the NCD manual in July 2004 by CMS. Now we continue to pay for certain treatments of all kinds if there is a benefit category and if obesity is caused by or aggravated another disease. The types of treatments that we have for obesity that are covered has not changes.

Congress, with respect to benefit categories, determines the services that we cover and these categories are listed in the Social Security Act, Section 1861. With reference to obesity, these benefit categories exist for surgery or physician counseling, but they do not include exercise, diet counseling for obesity by a dietitian and obesity drugs.

Since 1979, Medicare has had a bariatric surgery policy that may reimburse when it's considered medically appropriate and the obesity is related to a comorbidity.

What are some of our next steps for coverage? As Dr. Phurrough mentioned, the public is welcome to submit requests to expand coverage
to patients who do not have comorbidities for treatments that have a benefit category. CMS will review the policies to determine if current coverage of bariatric surgery should be modified.

The first mechanism for bariatric surgery is restrictive surgery. In restrictive surgery the stomach is mechanically reduced in terms of size so that the amount of food that can be taken in is greatly diminished. In malabsorptive surgery, the stomach is bypassed and the food goes to the small intestine at some level in the small intestine. And then there are surgeries that are combinations of those.

Now in vertical banded gastroplasty or VBG, a restrictive kind of surgery, some stapling is done here and a band is placed here, and this small pouch is created. It's hard to fill up your stomach like you used to with a small pouch.

In laparoscopic adjustable gastric banding, or LAGB, another type of restrictive surgery, the band is wrapped around the stomach just inferior to the esophagus, creating another small pouch with the same result as the first type. This band can be inflated or deflated depending on the needs of the patient, and it's
done through this access port.

Now Roux-en-Y, or RYGBP, which is a combination type surgery, there's a transection of the stomach, number one, right here, and then 75 to 150 centimeters down the bowel there's a transection and the distal part of that transection, lumen is brought up and anastomosed over here and the proximal part is anastomosed down below, causing malabsorption.

The biliopancreatic diversion with duodenal switch, the first thing that occurs is a transection of the bowel just below the stomach and then once again, much further down, there is another transection, and the proximal part of that is brought up to the stomach, and this is called the new duodenum, that's where the word duodenal switch comes from, and then the other end, the proximal end is connected way down close to the ilium to once again create malabsorption. Notice that in this surgery, there is also a resection of the stomach.

With respect to the epidemiology, the NHLBI in 1998 published this table and simply put, the message from this table is that as BMIs get higher, the risk for different kinds of illnesses
gets higher, and the same thing occurs with weight circumference. So when the two of them are combined, there is even a higher risk. Some of these illnesses are coronary heart disease, hypertension, type 2 diabetes, sleep apnea, certain cancers, and musculoskeletal disorders.

Now, in a study by Zizza in North Carolina, the number of females that are obese throughout the state as compared to the number of males at a ratio of ten to nine, almost one, with females being slightly higher.

The RAND TA in the late '70s, they reported that from the late '70s to the new millennium, Class I and II obesity showed a 50 percent increase. Persons of an age greater or equal to 20, of those persons, 55 percent are overweight or obese. They also reported that the rate of extreme obesity in Class III had multiplied by four between 1986 and 2000.

Flegal reported that in persons over the age of 75, the prevalence of a BMI greater than or equal to 35 was 6.4 percent.

Buchwald in his meta-analysis reported that the current percent of the U.S. population greater than or equal to 100 pounds overweight is
Steinbrook reported that for extreme obesity, beginning with the early '90s at 2.9 percent prevalence, extreme obesity rose to 4.7 percent by 2000.

The rate of bariatric surgeries is increasing. When it first started, it was low, less than one per 100,000, in the '90s to 2000, progressed from 2.7 to 6.3 per 100,000, in a study by Pope of the National Inpatient Sample.

Steinbrook in the New England Journal of Medicine reported that the number of bariatric surgery cases in 2003 was upwards of 100,000, which translates to a rate of about 30 per 100,000 in the population. In North Carolina in the same study by Zizza, adjusting for other factors, the odds of a female having bariatric surgery as compared to a male was over five to one.

Now in our evidence review, we performed literature searches to locate papers on surgery for obesity. We focused and confined the overall search to April 2003 to the present because at the time we started the search, we started this review, the latest TA, the latest technology assessment that we could review was the
Blue Cross Blue Shield in June 2003, and we went back a couple of months to allow for the time that they had from completing that data to publishing it. We extended our search back in time for papers on the elderly.

We found 22 acceptable papers and we utilized five technology assessments. The technology assessments were the NHLBI assessment in 1998, the one that RAND did for AHRQ which was published recently in 2004, Commonwealth of Massachusetts technology assessment in 2004, the Blue Cross Blue Shield from 2003, along with a technology assessment done by the University of Pittsburgh for AHRQ in 2003.

Now the outcomes that we looked at, a list up there, sustained weight loss, short-term mortality, longevity, that is long-term mortality, comorbidities and complications.

With respect to the outcome of sustained weight loss, four of our 22 articles had data on sustained weight loss, one on the elderly. Four of five TAs had data on sustained weight loss, but none had data on persons over 65. With respect to the sustained weight loss, there is no data comparing those with comorbidities having
surgery to those without comorbidities having surgery.

In the NHLBI tech assessment with respect to bariatric surgery, they reported that it was acceptable to use VBG and RYGBP, remember, this is 1998, if the patient has acceptable operative risks, and they also reported that RYGBP showed a greater long-term weight loss than VBG.

In this graph, this is about the Swedish Obesity Study for all surgeries combined. The first line, to adjust you, is on control groups. The next three lines are for surgery. The bottom one is gastric bypass. And these are weight changes that they're showing, the weight at start and weight at the finish. Now for all combined surgeries, these three lines, there was weight loss of 20 kilograms on average at the end of eight years but for bypass surgeries, it was eight to nine kilograms more than the others over those eight years. This was a nonrandomized control trial of 37-to-57-year olds and it is still going on.

Dolan reported that for BPD, there was a greater weight loss in BPD than in banding, and at two years, showed that it was 64 percent excess
weight loss for BPD and 48 percent for banding.

Sugerman demonstrated that after five years in persons over the age of 60 having bypass, there was a 50 percent excess weight loss, and in that study he reported at five years a 27 percent absolute weight loss, percent of body weight.

Gonzalez in his study of persons over the age 50 having bypass reported that there was a 68 percent weight loss at greater than or equal to 18 months after the surgery.

Regarding short-term mortality, seven of our 22 articles had data on short-term mortality, one on the elderly. Three of the five TAs had data on short-term mortality but none had data on persons over 65. Once again, with respect to short-term mortality, there is no data comparing those with comorbidities to those without comorbidities having surgery.

Flum, in a study of Washington state patients, reported that the short-term mortality rate was 1.9 percent overall, in experienced surgeons 0.5 percent, and in inexperienced surgeons defined as a surgeon who had done 19 or fewer cases, it was approximately 6.0 percent.

In the meta-analysis by Buchwald, he
reported that for restrictive surgery, the short-term mortality rate was 0.1 percent, for bypass 0.5 percent, and for BPD/DS, 1.1 percent.

And Sugerman in his article on bypass surgery in persons over the age of 60, in 80 patients had no mortality, representing a short-term mortality rate of 0.0 percent, that's no short-term mortality.

Pope, in his study of the National Inpatient Sample, demonstrated that the rate for short-term in-hospital mortality was 0.37 percent, and that stayed the same from 1990 to 1997. This seems to be confirmed by Fernandez, who found in-hospital mortality rate of 0.4 percent in his study.

In the Massachusetts technology assessment, they reported that the short-term mortality rate for LAGB was less than 0.5 percent, for VBG less than 1.4 percent, and overall 0.1 to 2.0 percent.

In Herron’s review, he reported that for BPD the short-term mortality rate was 0.5 percent to 2.5 percent, and for all the other surgeries 0.0 to 1.0 percent.

Fernandez reported risk factors for
short-term mortality, including preoperative weight being higher, age being higher, and being male gender.

With respect to longevity, there were two out of our 22 articles that had data on longevity, and one on the elderly. Zero of the five TAs had data on longevity, none had data on patients over 65. With respect to longevity, there is no data comparing those with comorbidities having surgery to those without comorbidities having surgery.

Now in a study that was a nonsurgical modeling by Fontaine in the New England Journal of Medicine, the years of life lost were measured, and for a BMI of 40 as compared to a BMI of 24, black males had more years of life lost than white males and white females and black females. This varied as the BMI increased. This is for 40, but it went, the years of life lost increased for higher BMIs across all ages and at an older age, the effect decreased markedly and in fact at age 60, black females actually in his modeling had an advantage, they gained years of life.

Now in Flum's study he showed that there was a longevity benefit if the patients
survived to one year after surgery and if that happened, they had a 33 percent lower hazard ratio.

Regarding comorbidities, nine of our 22 articles had data on comorbidities, one, or two of them on the elderly; there is actually two of them. Three of five TAs had data on comorbidities but none over the age of 65.

In Pope's National Inpatient Sample, from 1990 to 1997, in 1990 20.8 percent showed at least one comorbidity and in 1997, 31.4 percent showed at least one comorbidity.

In Residori's study, he found that there was at least one pre-op metabolic comorbidity in 57 percent of his patients.

Gonzalez in his study of persons greater than or equal to 50 years of age, 90 percent had at least one comorbidity. Resolution of those comorbidities was as high as 90 percent, although a little lower for hypertension at 56 percent. Of note is the fact that one-third of the diabetes mellitus cases and one-half of their hypertension cases that they diagnoses were previously undiagnosed.

In Sugerman's study of persons over the
age of 60, he reported that there were 3.8
comorbidities per patient, as compared to 2.4
comorbidities per patient for those persons under
the age of 60.

In the Swedish Obesity Study, the odds
for developing diabetes mellitus was six times
higher over the same period of time in no surgery
controls as compared to persons that had surgery.

Now with respect to hypertension, that was a more
equivocal, there were more equivocally equal, and
you can see these two numbers here, but when they
looked at the RYGBP patients, there was an
improvement in hypertension in the surgical group
as compared to the control group.

In Dixon’s Adelaide study, he reported
that just under 50 percent of all the
comorbidities that he found improved or resolved.
He also reported that 60 percent of patients that
had any comorbidity were medication free at three
years after surgery.

In the meta-analysis by Buchwald for
all types of surgery, diabetes mellitus resolved
in 77 percent, or improved or resolved in 86
percent. Hypertension resolved in 62 percent, or
improved or resolved in 78 percent.
Hyperlipidemia improved in 78 percent. And obstructive sleep apnea improved or resolved in 83 percent. Now, for individual surgeries in that same meta-analysis, he reported that BPD had almost a 99 nine percent resolution of comorbidities, in RYGBP that figures was 84 percent, and in banding it was 48 percent.

In Dolan’s study comparing BPD to LAGB, he reported that the resolution of comorbidities was similar after both procedures, 66 percent hypertension to 100 percent in obstructive sleep apnea or OSA.

On the outcome of complications, five of our 22 articles had data on complications, two on the elderly. Three of five TAs had data on complications, but none had complications solely in persons over 65. With respect to complications, there is no data comparing those with comorbidities having surgery to those without comorbidities having surgery.

The complication rate in LAGB was lower than other procedures as stated in the Massachusetts technology assessment. Dolan reported in his study a complication rate of 56 percent in BPD versus a 6.3 percent complication
rate in LAGB.

Herron in his review reported that bypass surgery had lower reoperative rates, and Pope reported that those reoperative rates for RYGBP was 1.6 percent, for LAGB 7.7 to 10 percent, for VBG 11.3 percent, in his National Inpatient Samples analysis.

The Massachusetts technology assessment reported that LAGB had lower wound infection rates than other surgeries.

Felix reported that in all laparoscopic cases, there was a conversion rate to open on 3 percent of the cases and that the risk factors for such conversion were higher age, higher weight, and being male.

Fernandez reported that the risk factors for leak after surgery were being male, having diabetes or having had a laparoscopic RYGBP versus an open RYGBP.

And the RAND TA reported that wound infection rates ran from 2.3 percent for laparoscopic procedures to 11.4 percent for open.

Livingston reported that the malnutrition prevalence after surgery was 2.5 percent VBG, 16.9 percent RYGBP, and 5 percent
With regards to frequency of complications in hospital, the risk factors for complications is reported by Livingston for being of higher age and being male. The most common complication he found in hospital was pneumonia, 2.6 percent.

In Pope's study, of the NIS from 1990 to '97, he reported that dehiscence after surgery decreased from 2.2 percent to 1.4 percent between those two years, and respiratory complications decreased from 7.4 percent to 5.9 percent.

In the RAND TA they reported that laparoscopic procedures have fewer wound infections and incisional hernias than the other procedures.

Conclusions. There is a paucity of data comparing those with comorbidities having surgery to those without comorbidities having surgery.

Weight loss via surgery may be an attainable goal.

Combination procedures show greater weight loss than purely restrictive procedures.

Sustained weight loss may resolve or
improve comorbid conditions.

Short-term mortality is between 0.5 percent and 2.5 percent, or let's say less than 0.5 percent. Experienced surgeons have a lower rate of short-term mortality.

Laparoscopic procedures have fewer complications than open procedures. LAGB may have the lowest complication rate.

The data on the Medicare population aged 65 or more is sparse, especially outcome data. There is little data on precise numbers of patients with one or more comorbidities in many studies. What we need from here on out are high quality studies on clinically important gaps.

Now for the questions for the committee. There are two sets of questions; the first five questions apply to the persons with obesity who have at least one or more comorbidity. The second set will apply to persons who have no comorbidities and have obesity.

Question one. How well does the evidence address the effectiveness of bariatric surgery in the treatment of obesity in patients with one or more comorbidities, compared to nonsurgical medical management?
How confident are you in the validity of the scientific data on the following outcomes?

Sustained weight loss, long-term survival, short-term mortality, comorbidities.

How likely is it that bariatric surgery, including RYGBP, banding and BPD will positively affect the following outcomes in obese patients with one or more comorbidities compared to nonsurgical medical management? Weight loss sustained, long-term survival, short-term mortality, and comorbidities.

Four, how confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients with one or more comorbidities? And the three different surgeries are listed with both an open and lap option.

Based on the scientific evidence presented, question number five, how likely is it that the results of bariatric surgery in obese patients with one or more comorbidities can be generalized to, A, the Medicare population aged 65 plus, B, providers, facilities and physicians in community practice.

Now the previous five questions, as I
mentioned earlier, are asked again as they pertain to patients with no comorbidities having bariatric surgery compared to nonsurgical medical management.

DR. DAVIS: Thank you very much, Dr. Brechner. Why don't we allow for a few questions for Dr. Brechner if anybody has any. Yes, Dr. Goodman.

DR. GOODMAN: Dr. Brechner, so as I understand it, the reason that your literature started in 2003 was simply to pick up from where the Blue Cross Blue Shield tech assessment ended in 2003.

DR. BRECHNER: Well, at the time that we started, or we got notice that we were going to do this, yes, it was late July, so we were looking at tech assessments that were available, and after that two of them popped up as being available, so that one was written in 2003, in June, so what we did was we figured that if they published it in 2003, they probably had data up to a month or two before, so to play it safe we went back to April 2003 to search the general literature, but we went back further for information on the elderly.

DR. GOODMAN: But your analysis is
confined to the lit search period that you accessed?

DR. BRECHNER: Unless the TA covered it.

DR. GOODMAN: Unless the TA covered it, in which case you defaulted to the TA?

DR. BRECHNER: Well, I default to the TA if I had no other information. If I had newer information I used that instead.

DR. GOODMAN: And you mentioned the NHLBI tech assessment.

DR. BRECHNER: Yeah.

DR. GOODMAN: And that was confined to RCTs only collected by the Cochran collaboration, correct?

DR. BRECHNER: I don't think so. I think they had evidence grades of A, B, C and D in their summary, and --

DR. GOODMAN: I believe they confined it, but we can check. I just wanted to point out, then, that the bodies of evidence considered among the different assessments might not have the same scope or depth.

DR. BRECHNER: Well, that's definitely true.
DR. DAVIS: Yes, Dr. Weissberg.

DR. WEISSBERG: Ross, I appreciated that summary. The critical distinction between with or without comorbidities has been with us since 1991 and has been made much of. Do you think that that distinction is still as relevant today, given that 40 to 90 percent of patients when looked for will actually demonstrate comorbidities?

DR. BRECHNER: That’s a decision for you guys to make based on the evidence today. I just couldn't find any information on, in the studies on persons that didn't have comorbidities at surgery. I think that from when we reviewed all the papers, and there were a lot of papers that we reviewed, there were many papers that had, I think, patients in the studies that were operated that may not have had comorbidities. The problem was that in just about every one of those studies, they were concentrating on the resolution of comorbidities and left out the opportunity, for better words, of looking at those two groups compared to each other.

DR. DAVIS: Yes, Mike.

DR. ABECASSIS: Ross, I also want to
thank you for that review. So if you take diabetes, for example, as one of the significant
comorbidities, there are many different ways to define diabetes. A lot of people define diabetes
for the purposes of these studies as somebody who's on either insulin or maybe an oral agent,
but that's not the way diabetes is defined I believe by different societies and associations
that have looked carefully into the complications of diabetes. So my question is, did you find any
uniformity in the papers that you did review with respect to the definition of, for example,
diabetes?

DR. BRECHNER: No, I didn't find much uniformity. A lot of the time it wasn't defined, it was just listed as diabetes.

DR. DAVIS: Barbara.

DR. MCNEIL: The question of comorbidities, I think is an important one, and I was trying to get at where Jed was going, and I was looking at the patient characteristics table in Dr. Buchwald's meta-analysis. And if you look at some of those data, for example, it says that the data say that 40 percent of the patients had hypercholesterolemia, so that presumably is a
standard definition, and that 25 percent had
impaired glucose tolerance, and that 60 percent
had degenerative joint disease, or 50 percent had
degenerative joint disease. And for example for
the degenerative joint disease, it looked to me as
if that might not correlate 100 percent with
diabetes or high cholesterol, so therefore you
could take the diabetes number and the cholesterol
number, and some big fraction of the joint disease
number because I wouldn't expect, as I said, there
to be any real correlation, and perhaps get some
estimate of the percentage of patients with
comorbidities going into the surgery. Does that
make sense? And if you did that, it comes out to
probably be pretty high.

DR. DAVIS: Dr. Sugerman?

DR. SUGERMAN: I'd like to make two
points at this stage. One is the Pope paper that
you mentioned that showed an increase in
comorbidity from 26 to 37 percent. I've talked to
Darby Pope, who's a resident at Dartmouth
Hitchcock, and he admitted the fact that those
data are extremely tenuous and weak. They were
based upon claims data and you know, many
dischARGE summaries won't have those data in it,
so it's a very poor look at comorbidities. It's a good look at the number of operations performed, but not a good look at comorbidities.

And just as an aside, when we looked at our patients who had BMIs of 40 or greater, 3,000 patients in our series, 98.1 percent of them had one or more comorbidities, and that excluded even looking at quality of life. So most of these patients, almost every patient who has a BMI of 40 or greater has a comorbidity.

DR. BRECHNER: Yes. You know, it was hard for me to tell because a lot of the papers reported X comorbidities without saying exactly how many of their patients had one or more, they concentrated over the broad range of doing that. And the Pope paper, his methodology was good with the sample that he had, and I agree that that figure that he listed is questionable, but I couldn't tell from the paper, there was no mention of this in terms of limitations, and we're looking for hard data.

DR. SUGERMAN: Again, the problem is there has not been any motivation to look at the patients who don't have any comorbidities, because when we look at the criteria for surgery, it's a
BMI of 40 or greater.

DR. DAVIS: Thank you again, Dr. Brechner, to you and your colleagues at CMS for pulling together that very informative literature review.

We're going to move on with the agenda and begin with scheduled public comments. And Dr. Walter Pories has worked with others in arranging for this initial slate of presenters. It is Dr. Wolfe who will begin, and we're going to let this group of presenters speak until about 9:45 and then we're going to take a break and then we'll continue on with scheduled public comments.

DR. WOLFE: Thank you. My name is Bruce Wolfe, I am professor emeritus of surgery at UC Davis and practice bariatric surgery in Sacramento. I am co-chair of the NIH bariatric surgery consortium which is known as LABS. I have received financial support both for research and honoraria in the past from U.S. Surgical Corporation and Ethicon Endosurgery. My present research is funded by NIH. My expenses for travel to today's conference will be reimbursed by the American Society for Bariatric Surgery, known as
the ASBS. I serve on the medical review committee of Blue Shield of California.

Dr. Pories has organized a group presentation, a decision was made to consolidate those talks, so not all of the listed speakers will in fact speak.

I would like to begin by recognizing the contributions of Secretary Thompson in recognizing the problem of obesity and addressing it. I would like to thank Chairperson Davis and the members of the panel for the opportunity to present, and particularly thank the executive secretary Miss Long for her patience and assistance in helping us prepare our presentation.

Dr. Brechner has already addressed the increased demand for bariatric surgery, the obesity epidemic. Epidemiologic research demonstrates that obesity is a life threatening disease and surgery is the only effective treatment which is presently available. These factors have combined to create this increased demand for bariatric surgery.

This slide from the Swedish Obese Subjects Study has already been shown. I focus on the control patients who did not undergo surgery
but underwent the best nonsurgical treatment available. We see the characteristic transient 
weight loss with nonsurgical treatment followed by 
a regain of the weight, and in fact in six to 
eight years a net gain of weight among those 
patients. It is this observation that is 
fundamentally the reason that in practice it is 
not possible to recruit or retain patients in 
nonsurgical arms comparing nonsurgical with 
surgical therapy.

We recognize as researchers in the 
field the classification scheme for the quality of 
the data and that we do not have randomized 
control trials or Level I data regarding surgical 
versus nonsurgical controls to present today. We 
will present data that represent the distillation 
of three years of initiatives by the surgical 
community and others, including the recent ASBS 
consensus conference, the AHRQ-sponsored 
technology assessment, and other technology 
assessments as we have heard, as well as the 
NIH/NIDDK-funded consortium on surgery or LABS.

Today we will be presenting the 
aggregated results of many observational studies 
that together represent the preponderance of the
evidence to address the five questions that have been posed to the panel. The basic operations that are in use have already been discussed as well; they are restrictive and bypass operations. It's beyond the scope of this conference to get into the precise mechanism by which these operations accomplish weight loss.

First, the gastric bypass. Several authors have reported series with ten or more years of follow-up. Dr. Pories reported on 600 patients with 97 percent follow-up, a weight loss at two years of 70 percent of excess body weight, 58 percent at five years, and 55 percent at ten years. We've seen data on postoperative complications, they range from 5 to 20 percent. Long-term complications consist of ventral hernia in 10 to 30 percent, a problem that is essentially eliminated by the laparoscopic approach to gastric bypass. Late nutritional deficiencies do occur but are preventable and treatable by appropriate supplementation.

The open versus laparoscopic approach is of interest inasmuch as the great majority of bariatric operations are done in this country by laparoscopy at this time. The benefits of
laparoscopy for all procedures include diminished injury response leading to diminished postoperative pain. That is thought to be fundamental in reducing the disturbance of pulmonary function that abdominal surgery produces and lowering the complication rate of pulmonary complications. There's diminished stimulation of hypercoagulability of blood, there's more rapid recovery, and most importantly, there's diminished wound complications.

This is some of the data from a prospective randomized trial conducted by Winn and myself at UC Davis that showed in laparoscopic versus open gastric bypass less use of intensive care unit, shorter hospital stay, more rapid return to activity, and other benefits as I indicated.

This is a summary slide with several reports on laparoscopic gastric bypass outcomes showing weight loss in the range of 70 to 80 percent in keeping with the data for open gastric bypass. Our data which has been presented but not published at 3.5 years in the randomized trial shows that the weight loss is identical among the two groups. It is therefore reasonable to pool
together the outcome results regarding weight loss for laparoscopic and open gastric bypass.

Complications of Roux-en-Y gastric bypass do occur. In the randomized trials the incidents were similar although the specific complications were somewhat different. Mortality rates are in this column to the right that have been reported in range from 0 to 3 percent.

The laparoscopic adjustable gastric band has been described by Dr. Brechner as well. There are, the band has been available in the United States for just three years and so we're dependent on international data for follow-up beyond that. There are three trials that have data out six to eight years demonstrating excess body weight loss in the range of 50 to 59 percent.

As has already been mentioned, the complication rate for laparoscopic adjustable gastric banding is not zero, but most authors report no mortality, the range is up to 1.2 percent in these series, and other complications that are mechanical related to the band itself do occur and are generally manageable.

This is still one more technology assessment done by the Australian government in
which they performed a similar technology assessment as what we've heard about already today. And what they found was that the mortality for laparoscopic adjustable gastric band was very low, at .05 percent, morbidity of 11 percent, as opposed to Roux-en-Y gastric bypass, the mortality of 0.5 percent and higher morbidity. The vertical banded gastroplasty is an operation that is used much less frequently in the United States at this time and so we won't be focusing on that operation.

The weight loss they showed was that at two years the Roux-en-Y gastric bypass has superior weight loss to the banding, but at four years both operations result in significant weight losses, the weight losses are closer together at four years than at two.

The diagram for biliopancreatic diversion with or without duodenal switch has also been shown this morning. The results are seen here. A single surgeon, Dr. Scopinaro, who basically devised the procedure, a very large series with excellent results, 78 percent excess body weight loss at 12 years and acceptably low complications. 3.2 percent stomal ulcers with H2
blockers, 12 percent without, a certain amount of protein malnutrition, 7 percent, concern regarding bone demineralization as malabsorptive procedures may lead to net calcium loss.

The modification of the duodenal switch in which the anastomosis is post-pyloric shows a similar weight loss at 80 percent at two years, and also acceptably low complication rates. Of interest, the duodenal switch appears to avoid the problem of stomal ulcers for the most part, malnutrition complications do occur following malabsorptive procedures.

Both of these procedures, particularly the duodenal switch has been reported as having been accomplished by laparoscopy. There are five such cohorts, the data is very similar with regard to the complications and outcomes. Length of stay is shortened by the laparoscopic approach.

The impact of bariatric surgery on comorbidity is of interest as we have also heard. This and following slides are adopted from the meta-analysis published by Dr. Buchwald very recently in JAMA. This meta-analysis includes several thousand, approximately 7,000 cases, and is obviously very current. What we see is that
weight loss is basically quite good for all of the procedures. The relatively short follow-up for the banding procedures in the meta-analysis as a result of the shorter time the band has been available may disadvantage the band in these results. Otherwise, the results are quite similar with regard to the maintenance of weight loss.

Perhaps most impressive is the resolution of diabetes by surgical weight loss. While the exact definition of diabetes is not indicated in those papers, most of us use the standard definition, which is blood sugar fasting less than 126. And resolution of the diabetes is reported in 80 to 90-plus percent of the patients in these series. Again, the shorter follow-up for band is perhaps a disadvantage with the methodology used in this study.

Similar improvement with hyperlipidemia in excess of 80 percent, hypertension 60 to 70 percent as we saw, not quite as impressive as the data for diabetes and dyslipidemia. The resolution of obstructive sleep apnea syndrome, which is being found to prevail in this patient population at a much greater frequency than has been recognized in the past, some say greater than
50 percent if you study the people in detail, resolution occurring in 80 or more percent for all of the procedures.

Finally, fatty liver, steatohepatitis is an increasingly recognized problem in patients with morbid obesity, it's predicted by some to replace hepatitis C as the most common indication for liver transplant in the near future, and data of Kral showing that it does respond to weight loss induced by surgery.

Other comorbidities, of which there are numerous, are similarly improved by weight loss. The common theme is the response of the comorbidities if they are indeed obesity-related or caused comorbidities would be expected to resolve with weight loss and indeed that is the pattern we see. It doesn't matter which operation it is, if the weight is lost, then these comorbidities if they are properly attributed to the obesity, do indeed improve or resolve.

Thank you for your attention.

DR. FLUM: Thanks to the committee for giving me the opportunity to speak today. My name is David Flum, I'm a gastrointestinal laparoscopic surgeon at the University of Washington. I'm also
an outcomes researcher with formal training in surgical epidemiology and technology assessment.

We've divided this presentation today to give you separate perspectives. This perspective is from a health services broader perspective, if you will, one that deals with some of the issues of survival, both short and long term, and health utilization outcomes that are relevant in trying to make decisions and assessments about bariatric surgery.

By way of housekeeping, my present funding includes NIH funding from NIDDK. I'm the principal investigator in the consortium for bariatric surgical research and in the past I've received funding from INAMED for a small research project. My travel expenses today were paid for by the Society for Bariatric Surgery and as I said, I'm pleased to be here.

Obviously when we're dealing with the issue of survival and long-term survival with bariatric surgery, the issue of what is the alternative comes to bear. We know that this year approximately 400,000 lives will be lost due to obesity alone. Intuitively as clinicians, we know that as you reduce comorbid conditions such as
diabetes, perhaps the banner comorbid condition,
we expect long-term survival to be achieved, since
we know that diabetes is linked to a worsened
survival.

But this also assumes a low rate of
perioperative death related to the procedure of
course, and you have heard today many case series
and voluntary databases, the preponderance of
which speak to very low risk of mortality with
bariatric surgery. To view this as a skeptic,
someone who really critically evaluates outcomes
in the surgical community, our group tried to look
at the population at large to assess the variable
mortality in the rear world, if you will. We
looked at over 60,000 patients in the state of
Washington who had been hospitalized with
diagnostic codes related to obesity and morbid
obesity, of which approximately 3,000 underwent a
gastric bypass operation.

As noted earlier, we identified a 1
percent risk of in-hospital mortality,
considerably higher than others have noted, and
approximately a 2 percent risk of 30-day
mortality. Now, although those numbers are
considered alarming by some, or certainly higher
than what you've heard before, when we tried to understand, if you will, what was underlying that higher rate of morbidity and mortality, strike that, mortality, we found that surgical inexperience was really linked to it more than anything else, and if the surgeon had done less than 20 procedures, there was clearly almost a five times higher risk of death. And when you looked at those more experienced surgeons later on in their curve, if you will, the mortality rates that you've heard today from the case series will ring true even in the community at large. That's the caveat that I would offer.

And I tried to contextualize that mortality rate, you know, that 1 percent in-hospital mortality rate. This is unpublished data from a MedPAR analysis that's recently been performed looking at a couple of thousand patients who had bariatric surgery for obesity with gastric bypass DRG, showing a 1 percent mortality rate in hospital, almost identical to the state of Washington's data. And by way of context, total joint replacement was listed as 1 percent, with bypass at three percent. That's important because joint replacement, essentially an elective
operation often due to the ravages of obesity, but
it helps to put in context the mortality data I
have shown.

Now this is the short-term data.

Obviously when you're considering survival, it's
the balance of long and short term, and although
we feel most confident as a surgical community
talking about diabetes as an important comorbidity
that's reduced, and we point to lots of evidence
that shows the other comorbid conditions improve,
survival has been the one that we have been, it
has been the hardest to demonstrate for lots of
obvious reasons. We need long periods of time for
follow-up and appropriate cohorts.

There have been three studies that help
to inform this, one by Ken McDonald which
demonstrated that a 28 percent mortality rate in
patients on the waiting list and a 9 percent
mortality rate in patients who had the operation
for gastric bypass in a large cohort.

There is this study in Washington state
that shows, by our group, that shows a crossing of
the lines at about one year. Patients who had a
gastric bypass seemed to do better than those who
did not have a gastric bypass outwards of 10 and
15 years. And the data that supports that at 15 years, 16 percent of the people in the nonoperative cohort had died, compared to 11.8 percent of the people in the operated cohort. This was particularly emphasized in the younger-aged group and after one year as mentioned, there was a third lower risk of death in the operated cohort than nonoperative.

The last bit of evidence that supports this comes out of Canada, which details the cohort of patients performed at McGill, and a control if you will of patients derived from administrative data in Quebec. They looked at a thousand patients in the operative group and five to one matching, if you will, for the control. They found a 6 percent rate of aggregate mortality in the nonoperative group and a .68 percent rate of mortality in the operative group, a relative risk of .11 or a risk reduction of 89 percent in that cohort. They also found significant drop-offs in new-incident cases of cancer, infectious disease, musculoskeletal disease, all of these conditions an significant drop-offs in utilization.

We have some time restrictions today that will probably limit our exploration of the
issue of cost and health care utilization, but this study in particular was helpful in demonstrating that the costs of bariatric surgery are amortized over about three-and-a-half years, and this is reinforced by lots of work that we have performed and I would be glad to comment on that later. Once again, thank you for the opportunity to present today and I look forward to your questions.

DR. WADDEN: Good morning. I'm Tom Wadden, professor of psychology at the University of Pennsylvania School of Medicine. Thank you for the opportunity to speak today on behalf of the North American Association for the Study of Obesity, of which I'm vice president, and also on behalf of the American Society for Bariatric Surgery. In terms of disclosure, I received a one-time honorarium from Ethicon Endosurgery for participating in a meeting, and I'm paying my own travel expenses today.

I originally had ten slides in my presentation which Dr. Pories has reduced to five in the interest of time, surgeons like to cut, so thank you, Walter.

(Laughter.)
DR. WADDEN: So I will be making some remarks that are not supported by slides. I think it's important that we talk about the adverse physical effects of extreme obesity today and of the benefits resulting from weight reduction. I want to talk some about the adverse psychosocial consequences of extreme obesity, which include depression, eating disorders, impaired quality of life. In addition, persons with extreme obesity suffer marked prejudice and discrimination that truly can scar their lives.

A recent population study by Anjoc and colleagues showed that persons with a BMI of 40 or greater had nearly five times the rate of major depression as persons of average weight. You can see that persons with a BMI of 35 or greater had nearly double the rate of major depression in the past year. Major depression is a frightening condition in which you feel like your life is worthless and you have little hope of getting better.

In addition, approximately 25 percent of bariatric surgery patients suffer from binge eating disorder. This condition is characterized by the consumption of large amounts of food in a
brief period of time and patients feel out of control of their eating and it feels compulsive, and again, people are very distressed by this condition, this is not pleasurable eating.

Even if they do not experience frank depression or eating disorders, a significant majority of patients with extreme obesity report impairments in health-related quality of life. The SF-36 is a scale that measures quality of life in eight different domains with higher scores going up to 100 indicating better functioning. In this slide, scores of the normal population are shown in the yellow part of the bar, so the higher the score the better the functioning, whereas the bariatric surgery candidates prior to surgery are shown in the green color. So you can see that surgery candidates report marked impairment starting on the left, in physical functioning. They report impairments in their role performance at work and in recreational activities. They report reduced vitality, and an important thing to note in the third column there is that they report bodily pain. This is a physically distressing condition.

I want to discuss improvements in
psychosocial function that occur with weight loss following surgery. It's important to note that research in this area is limited, there are no randomized controlled trials as others have discussed previously. Most studies have been small and few of the patients have been 65 years or older. However, there are some strengths, including the Swedish Obese Subject Study that you've heard about, and the use of well validated measures. Depression clearly improves following weight reduction with bariatric surgery, as shown by the SOS study. It's also shown in a recent study by Dr. John Dixon, who found that reductions in depression were maintained at four years. You also see that there are marked improvements in quality of life; now the yellow shows the performance of patients after bariatric surgery, and they now meet the values of normal samples. Finally, it's hard to quantify the emotional hardship that patients with extreme obesity experience from the prejudice and discrimination directed at them. It is perhaps best captured by this slide. This is a study showing that patients who have lost 100 pounds, kept it off for three years or more, reported that
they would prefer to be normal weight and to have
a major disability, including blindness or limb
amputation, than to return to morbid obesity
again.

So this brief review has shown that
extreme obesity is associated with significant
psychiatric comorbidity and suffering and it is
dramatically relieved by weight loss following
bariatric surgery. Thank you.

DR. STILES: Good morning. My name is
Sasha Stiles, I am a medical physician and I also
have an M.P.H. in administration and planning.
Can you hear me now? I would like to say as a
disclosure that I am an employee of Kaiser
Permanente and as such I speak to all Kaiser
employees and also the state offices in California
because of my role. I am the medical director for
bariatric surgery for Kaiser South San Francisco
and Northern California. I'm also the national
clinical lead for bariatric surgery for the Kaiser
Permanente Care Management Institute.

I'm a primary care doctor and I've been
one for over 25 years. I have seen many of my
patients die from their severe obesity over this
time. Now with bariatric surgery, they have a
chance to survive but also to thrive. I know of no other intervention which can so profoundly ameliorate or resolve the medical, social and psychological comorbidities of severe obesity. Patients seeking or referred for bariatric surgery that I see routinely have undergone five to seven, and often 15 to 20 prior attempts at other weight loss and dietary treatments.

After surgery for colon cancer, my patients receive radiation, chemotherapy, and long-term follow-up. If they have a recurrence, we blame the disease. If a severe obese patient begins to gain back their weight, we blame the patient's lack of will power or we blame the surgery, forgetting that it is really the disease of severe obesity which we are trying to treat.

Research points to conditions which must be evaluated preoperatively, high BMI, pulmonary function tests, EKG abnormality, steep apnea, hypertension. Preoperative weight loss has now been even shown to be predictive of long-term success. At Kaiser Permanente I personally evaluate all patients and rigorously strive to improve or stabilize all their chronic diseases before surgery. We have weekly education,
nutrition and exercise programs. We have psychological assessments and treatment options. We have case management for special conditions and weekly support groups by a trained facilitator.

The SOS study found a 32 percent decrease, 32-fold decrease in diabetes in their surgical group versus control. We all know Pories' landmark work. I can tell you that my diabetic patients are the absolutely most grateful. No longer do they have to fear a life of amputations, dialysis, heart attacks and blindness. Preoperatively, my sleep apnea patients are predictive of increased sick leave, divorce, impaired work performance and ill health. Buchwald's meta-analysis shows 85 percent resolve after surgery, and I find this too. The more weight you lose, the less pain in your weight bearing joints. The most common wish, and this is really true, that my patients tell me and that they wish for after surgery is to run around after their grandchildren and you know what, they really do.

Pseudotumor cerebri resolves within four months, relief of massive headaches, and spinal taps. If any of you have seen this
disease, it really is quite remarkable what we can
do. GERD and asthma vastly improve, and inhalers
are frequently thrown away by six months.
Venostasis resolves; my teachers can now stand up
in front of their class instead of sitting behind
their desks with their Una boots, and they're free
of pain and swelling. Urinary incontinence vastly
improves. Do you know how great it is for a woman
not to concentrate on where all the bathrooms are
in her life?

Also, sick leave by two years after
surgery has been decreased by 10 to 18 percent. I
see my patients going back to work. These are
sometimes patients who have been off work for 10,
15 and more years. At Kaiser Permanente we have
detailed follow-up by multiple providers in person
and over the phone over the first six months.
Thereafter I run regular long-term follow-up
groups where several patients, myself and the
staff develop treatment protocols for the rest of
their life. We do this every six months like
clock work for all our patients. All patients are
also evaluated for their long-term care issues by
the appropriate member of our team, dietitian,
psychologist, bariatric surgeon or myself. And we
also have postoperative support group classes
which are educational classes which are held
weekly, where we have actually 60 to 80 patients
at least a week, and more.

Finally, there is just no other model
out there which can hold a candle to the
possibility that this surgery gives my patients.
As a primary care doctor, I also feel strongly
that the best surgical outcomes are gained with a
pre-op and long-term postoperative
multidisciplinary chronic disease management
approach which is what we do at Kaiser Permanente
on many diseases, and I can tell you it works. It
promises to maximize the benefits of this
incredible surgery. This surgery offers hope when
there really was none to my patients. Let's work
together and make this work. Thank you very much.

COL. STRADDIFF: Good morning. My name
is Robert Straddiff and I'm a retired U.S. Army
colonel with 32 years service. I was both a fixed
wing and helicopter pilot for the majority of
those years and put in two combat aviation tours
in Vietnam. My military career progressed and as
it progressed, my duty assignments gradually
became staff jobs, but I always maintained my
flight status. I only mention these things to highlight the fact that I was subject to annual flight physicals and the strict weight standards required to remain on flight status.

After my retirement I accepted a civilian position at Fort Lee, Virginia. While there, I continued my normal PT program of a three-to-five mile run four or five days a week. I retired from my civilian job in '92 and a few months later my problems began. On one of my runs I experienced severe pains in my left knee. X-rays revealed I had bone on bone contact. I had two choice, a try at physical rehabilitation or a knee replacement. I opted for rehab and all went well until the summer of '94 when I blew out my right knee and I went to the rehab group once again.

But the weight gain was dramatic and I didn't seem to be able to control it by diet alone. By this time both knees were too painful for any comprehensive exercise program, so the pounds kept mounting up. Along with the weight gain came the inability to get a good night's sleep. I was now experiencing sleep apnea and started to sleep sitting up in an easy chair in my
bedroom. I slept this way for months, when I noticed that there was moisture around the calf areas of both legs. I was diagnosed with and treated for venostasis dermatitis.

It was during this time that I happened to read an article in the Richmond Time-Dispatch concerning the gastric bypass work that Dr. Sugerman was doing at the Medical College of Virginia. I expressed a desire to look into it and my doctor encouraged me to see Dr. Sugerman for more details. After my initial consultation and evaluation, I decided to have the surgery. I knew that if I didn't, I wouldn't survive. By this time my weight was 360 pounds and I had begun to have angina problems. I was desperate, I could barely walk, I was now using two canes, and I was in constant pain in my knee joints. I found myself a near recluse.

I knew I had to do something and quickly, so at the age of 69 I had Roux-en-Y bypass surgery done in February 2002. The first month was the worse, not much pain, and the pureed foods were not much to be recommended, but the change was dramatic. In six months I had lost 80 pounds, the ulcers were gone, the apnea had
gradually disappeared and I was back in my bed
getting a good night's sleep. Almost as rewarding
as the weight loss was my ability to get back
exercising and this time it was a swimming
program.

In October of 2002 I had a complete
knee replacement on my left knee, continued
swimming, and by Christmas of 2002 I had lost
another 60 pounds. Since my bypass surgery I have
gone from 360 to 160, or 65, for a total of a
195-pound weight loss. Another follow-up from the
weight loss is that right knee replacement is now
unnecessary, I can get along just fine, and even
take an occasional two-mile walk.

That concludes my remarks. Thank you
very much.

MS. TANNER: Good morning. My name is
Stella Tanner, I'm 68 years old, and I had
laparoscopic gastric bypass surgery two years ago
at age 66, and I have lost 75 pounds.

The last few years before my surgery
were absolutely horrible. I dreaded waking up
each morning to another day of excruciating pain
and total exhaustion. I had sleep apnea, I used a
Bi-PAP machine at night. I was taking increasing
amounts of blood pressure medication. I was plagued with incontinence that required constant attention, infections and discomfort. I suffered from migraine headaches and my doctor was concerned with my increasing blood sugar level.

My surgery was not cosmetic, but it was a desperate attempt to enable me to once again take care of my family and my home, and I have been rewarded with much more than that. This operation absolutely saved my life. In the past 18 months my husband and I have traveled to Alaska, we have been to the beach several times, been to more football and baseball games than you can possibly imagine, golfed for two weeks all over California, and recently spent two weeks in Italy. Instead of being an invalid in excruciating pain, my life is absolutely wonderful, and it's all due to this surgery.

Please continue this surgery for Medicare patients. I am extremely grateful that I was provided with this coverage and I will spend the rest of my life trying to repay the world for my good fortune. Other senior citizens deserve this same opportunity. Thank you.

DR. PORIES: Mr. Chairman, members of
the panel, my name is Walter Pories. I am a bariatric surgeon, a professor of surgery and biochemistry at East Carolina University, a principal investigator and co-investigator for several NIH grants, and the president of the Surgical Review Corporation, which paid for my expenses to come here. I've also lectured for Johnson & Johnson and the Tyco Corporation.

Before I start, I want to thank Miss Long for her mothering us through this process, we're very grateful.

My assignment is to address the fifth question, can we generalize these excellent outcomes to community practice and the Medicare population? Or to phrase it more precisely in terms of the needs of our society, can we provide excellent bariatric surgery to the Medicare population? To achieve this aim, we would need to meet a very difficult and rigorous challenge, to follow the lead of industry in delivering a consistent and high quality surgical product. A very difficult goal, some might say unattainable. To reach it, we would need to standardize our operations, standardize patient care paths, monitor the providers, rigorously collect short
and long-term data, and verify that information by site visits.

Well, surgeons want good results at least as much as you do, and with a remarkable move, the membership of the ASBS voted to address quality clinical outcomes by using evidence-based medicine in establishing standards for bariatric surgery. The ASBS addressed this issue by supporting the founding of an independent organization, the Surgical Review Corporation to pursue this goal and to designate those who meet these tough standards, and they are tough, as the ASBS centers of excellence.

The Surgical Review Corporation is a totally independent nonprofit organization in which the board of governors include the stakeholders in bariatric surgery, including the CEO of Blue Cross Blue Shield, of a Blue Cross Blue Shield, a CEO of a malpractice carrier, two former presidents of the American College of Surgeons, and a consumer. Most telling, only three of the 12 members are bariatric surgeons. Let me emphasize our independence. There are no relationships between the SRC and the NIH or the American College of Surgeons, or industry.
As the president of the Surgical Review Corporation, I report to you that we are well underway. Over 250 centers have already applied for provisional status with contracts that they will follow these stringent ground rules. We expect to name our first centers by June of next year. This is a remarkable beginning. We are as intent on answering the fifth question as you are.

The surgical community will consider as favorable any initiative by CMS that would help advance our knowledge of the impact of bariatric surgery based on practical evidence gained in practice in the Medicare population. The SRC would be more than pleased to facilitate such an activity. Thank you.

DR. FLUM: This is David Flum again. I was asked to bat cleanup, if you will, to help frame the discussion that we've had so far within the context of your evaluative questions, the two pages of evaluative questions you have regarding obesity patients with comorbidities and obesity patients without comorbidities. Once again, it's been a privilege to speak with you today and also let you know that the messages that Bruce Wolfe and I have put forward today really represent more
than 30 to 50 surgeons that have had input into this discussion today. It's hard to speak for all the surgeons, but collectively we're trying to demonstrate our sense of the literature.

You know, as a critic of the surgical and scientific literature what you're seeing today is an overwhelming number of observational studies. Your second question deals with how confident can you be in the validity of the scientific data to support all the questions listed there, and the validity brings up the question of what type of validity. Obviously this is not type one data, it would be unethical in fact to randomize patients to an intervention that had a one to two percent mortality rate and a diet, and it's simply not feasible either.

But there is another type of validity which is face validity that we're all familiar with. Face validity speaks to the preponderance of evidence and we now have 15 studies that demonstrate long-term weight loss being sustained beyond five, upwards to ten years, and at least five studies that demonstrated out beyond 15 years. We have three studies, as I mentioned, that looked at long-term survival, all of them
with agreeably flawed comparator groups but speak
to a general sense of face validity. We have lots
of evidence that details 30-day mortality with
really good, a preponderance of evidence speaking
to a general sense of at least reported outcomes
for 30-day mortality. And we know the JAMA
article related to comorbidities speaks to
preponderance of evidence, the 18,000 patients
pooled from multiple studies that speak to face
validity.

So in the absence of that gold standard
data, what we can say is that the surgical
community as advocates for our patients, as people
who see the clinical outcomes, and as people who
balance research that's out there, limited as it
may be, we think the preponderance of evidence
supports the validity and a high level of
confidence in the validity of the scientific data
for all those points that I just mentioned.

It should also be mentioned that our
colleagues in internal medicine and preventative
health have nicely looked at the other side of
this, which is what are the nonsurgical
approaches, and have really demonstrated quite
nicely, Kathleen McTighe's article for the U.S.
Preventative Health Task Force really comes to mind, demonstrating the futility of long-term solutions that are nonsurgical and the lack of data beyond one to two years for the vast majority of nonsurgical alternatives. That's question number one for you.

Question number four speaks to all the different types of procedures that we are and how confident are we as a surgical community that the procedures will have a significantly important clinically important net health benefit. Clearly we've demonstrated and reported multiple observational studies. The preponderance of evidence once again speaks to support for these procedures.

And all the studies have an issue of publication bias and that has to be dealt with when considering face validity. We're not seeing the series of less than good outcomes, I suspect, but face validity is based on what it is, and there are clinical outcomes and then there's observational studies, and we believe this is the best evidence there is to date.

The last question has to do with the issue of how generalizable is the data that you've
heard today to the Medicare population, specifically those greater than 65, and to providers in community practice. To the first point about those greater than 65, one thing we know about outcomes in bariatric surgery is that age seems to have a direct, an independent effect; the older you are, the less performance or the worse outcomes you have.

Clearly, you've heard passionate responses from patients who have had the surgery who are older, and those are very important messages to hear, but we know that there is an age relationship to adverse outcome, and simply there is a limitation in the data that's available on this topic, although certain cases series even by Dr. Sugerman have shown very low or no mortality in certain case series in certain hands.

We can't speak to the more generalizable issue of the population greater than 65, but I think it's important to recognize that in the Medicare population that's covered right now, more than 80 to 90 percent of the patients who are covered are under the age of 65. This is the Medicare disabled groups, so clearly the critical emphasis is in that population.
To the last point about the generalizability of the data we've presented today to the community at large, in our work in Washington state we've had a hint towards that, how generalizable is this data, and we really won't know until we have more population level evaluations of this issues, and the centers of excellence may be a wonderful way to get that sort of population level assessment.

The last issue is the whole second page, of how to assess obesity patients with no comorbid conditions. Dr. Sugerman has helped to highlight this point. We don't have a lot of information on this topic for two reasons. One, because to date, surgeons can't operate on patients with BMI of 35 to 40 without comorbid conditions, there will be no data available because we can't operate on this population, it's not a covered benefit for the most part.

Of patient greater than on 40, you would be hard pressed to find surgeons or physicians in general who take care of patients with a BMI greater than 40 that would say that they have, or that they don't have any comorbid conditions. If you scratch under the surface just
a little bit, you'll find comorbid conditions that are not well reported or not obviously listed in administrative databases, or people just not asking about things like urinary incontinence and sexual dysfunction and gastroesophageal reflux.

So I thank the committee and look forward to any of your questions, but that's the way we wanted to contextualize this information.

DR. DAVIS: Thank you very much. We're going to take a break in a moment, but I'm not sure that all the presenters from the past hour or so made a conflict of interest disclosure. If anybody missed one and failed to indicate whether or not they have a financial conflict of interest and who funded their travel to this meeting, perhaps you could do that now and we could get that into the record, or the transcript, and then we could take a break and then continue on with the presenters.

COL. STRADDIFF: I am Colonel Straddiff. I have no conflicts of interest.

DR. DAVIS: And your funding to this meeting was provided by?

COL. STRADDIFF: Myself.

MS. TANNER: I'm Stella Tanner. I do
not have any conflicts of interest and my husband is paying for my stay.

DR. STILES: I'm Sasha Stiles and I forgot to say, I'm sorry, the ASBS paid for my stay and coming here.

DR. DAVIS: And any financial conflicts of interest?

DR. STILES: No, sir, I just work for Kaiser Permanente.

DR. DAVIS: Thank you very much. We'll take a 15-minute break and then continue on with the public comments.

(Recess.)

DR. DAVIS: We have a series of presenters who will continue for the next, oh, hour or so. And hopefully before the lunch break we will have an opportunity for questions from the members of the committee. Mary Lee Watts.

MS. WATTS: Good morning. My name is Mary Lee Watts.

DR. DAVIS: While we're working on the microphone, I just want to remind the presenters for this next segment to, again, make their conflict of interest disclosure and indicate how you were funded to the meeting. Thank you.
MS. WATTS: My name is Mary Lee Watts. I have a masters in public health and I am a registered dietitian. I am currently serving as manager for legislative and political affairs at the American Dietetic Association, ADA is paying my way to this meeting today, and I have no other conflicts.

The ADA commends the committee for its leadership to undertake a rigorous analysis process to determine if scientific and medical evidence demonstrates effectiveness and appropriateness of bariatric surgery for the Medicare population. The rapid rise in the prevalence of overweight and obesity among all segments of the U.S. population is of grave concern, as the health and quality of life of those afflicted plummets, and health care costs and societal burdens continue to soar.

ADA has considered the evidence under review in today's meeting and wishes to make the following comments:

First, data for more than eight to ten years post surgery is needed to have stronger confidence in the ability of bariatric surgery procedures to result in sustained weight loss,
improvement in comorbidities and long-term
survival, particularly in the elderly population.
Existing data indicate that short-term benefits do
exist, including the potential to improve quality
of life for obese patients.

Second, the existing data are
potentially biased in that studies and case
reports were generated by premier investigators at
major academic institutions and medical centers.
It's not clear if the rapid increase in surgeries
in the greater community is associated with the
same incidence of complications and adverse
events.

Third, it is unclear whether weight
loss is appropriate for obese elderly Medicare
beneficiaries without comorbidities. ADA
recommends a preventive approach that offers the
possibility of restoration of a healthy weight
before the comorbidities associated with obesity
become entrenched and organ damage occurs.
However, the contribution of obesity to mortality
in the elderly has yet to be conclusively
established. This suggests that a revision of
weight recommendations in older people,
particularly the upper normative range, seems
prudent.

The longitudinal study of aging found that thinner older people were more likely to die than those who were normal weight or overweight. Mortality was actually lower in older people with a BMI greater than 28.5. According to a 2001 analysis, 10 of 13 studies failed to show a significant association between a BMI greater than 27 and mortality from all causes in 65-to-74-year olds. In the few studies that did show an association, the increased risk became apparent at BMIs greater than 31, and the association disappeared in those aged 75 years and older.

Therefore, ADA requests that the Medicare Coverage Advisory Committee do the following:

First, require coverage of pre and post-surgical medical management of patients undergoing bariatric surgery. Such management should include a multidisciplinary team of registered dietitians, psychologists, exercise physiologists, and others who are qualified to conduct nutritional and behavioral interventions and physical activity counseling.

These interventions should also do the
following: Assess surgical candidates' ability to comply with post-surgical protocols, minimize short and long-term complications such as gastrointestinal adverse effects, and prevent weight regain.

We urge you to consider analysis of insurance claims data to analyze both financial and clinical outcomes associated with bariatric surgery and require demonstrated clinician adherence to evidence-based practice guidelines and best practices for quality patient care and optimal outcomes.

Thank you, members of the committee, for giving ADA the opportunity to share our comments about bariatric surgery for the Medicare population.

DR. DAVIS: Thank you. Next,

Dr. Fischer.

DR. FISCHER: Good morning. I would like to thank the panel for the ability to talk. My name is Dr. Josef Fischer and I am testifying on behalf of the American College of Surgeons, which has 66,000 fellows. I am a regent of the College. I am also the Mallinckrodt professor of surgery at the Harvard Medical School and chair of
the Department of Surgery at the Beth Israel Deaconess Medical Center. I am also the College's representative to the Blue Cross Blue Shield Association medical advisory panel, part of their technology evaluation center. Bariatric procedures are performed in my hospital although I no longer do them. I have no conflict of interests that I am aware of. My way is being paid by the American College of Surgeons because I am chairing the Health Policy Steering Committee in Washington tomorrow.

The data from the Swedish Obese Subject Study or SOS are cited in the Blue Cross Blue Shield Association technical assessment and show a 16.3 percent decrease in total body weight six years postoperatively for those undergoing bariatric surgery. You have seen those slides several times. This is compared with a .8 percent increase in weight over the same period with nonsurgical treatment.

You also have heard the technical evaluation that CMS commissioned from the RAND Corporation showed that the incidence of comorbidities of hypertension, diabetes, hyperlipidemia and sleep apnea following surgery
has improved, although at differing amounts and rates depending when measurements are made. There is a profound reduction in diabetes over a 5.5-year mean follow-up and the data also suggests that the incidence of hypertension initially drops, but by six years postoperatively it rises virtually to preoperative levels, suggesting that other factors are important as well.

It is not yet possible to answer some of the crucial questions concerning the aged population. According to the technical assessment of obesity, treatment of obesity among the elderly, the all-cause risk of mortality associated with obesity diminishes with age, raising questions about the benefit of reducing obesity in this population.

Because there are age-related differences in underlying physiology in general and fat distribution in particular, one should be cautious about generalizing the findings in the younger population to those above 65 and certainly among those who are above 70 years of age. Furthermore, there are few studies among surgical mortality and morbidity in the aged.

In September of 2000, the College
published a statement on recommendations of facilities performing bariatric surgery which addresses issues such as professional staff, the operating room and hospital facilities. The statement makes two points essential to the success of bariatric surgery that are pertinent here this morning. The first is that having a full range of equipment and furniture appropriate for the bariatric patient in the operating room and throughout the hospital facility is essential. The second is having an interdisciplinary staff led by an experienced bariatric surgeon to provide care and counseling throughout the extended preoperative period and in the long postoperative period. Preoperative psychiatric screening and pre and postoperative nutritional counseling, preoperative screening by internal medicine and endocrinologists are the most important but not the only services that we believe must be made available. At the present time, coverage of medically necessary pre and postoperative counseling and screening varies from carrier to carrier.

In conclusion, the College supports programs for what has become an epidemic of great
public health concern to the nation, morbid obesity. It urges CMS to continue to collect data on outcomes for various bariatric procedures. In addition, CMS must in our view take steps necessary to assure coverage of preoperative and postoperative care, especially preoperative psychiatric screening and pre and postoperative nutrition counseling. Thank you very much for listening.

DR. DAVIS: Thank you. Dr. Dixon.

DR. DIXON: I'm John Dixon from Melbourne, Australia. I'm a clinical researcher in regard to obesity. I am a physician in a full-time position heading up a research program. I've received research grants and assistance from INAMED Health, U.S. Surgical, Novartis Australia, and Tyco. My costs for coming here are being covered by INAMED Health, but I have other commitments in North America.

Severe obesity, as you are aware, is a serious disease. There's overwhelming evidence that all procedures under consideration provide significant weight loss when compared to nonsurgical measures. We looked at systematic reviews, we looked at the Swedish Obesity study,
but we also have to see, as David Flum mentioned earlier, the numerous excellent observational studies demonstrating significant sustained weight loss at five years when other therapies provide minimal effect at this time.

I wanted to mention briefly some of the systematic review that was done by the Australian College of Surgeons and Australian government with regard to the laparoscopic adjustable gastric band. This looked at 64 publications and its aim was to compare this procedure with Roux-en-Y gastric bypass and VBG, and to look particularly at safety and efficacy.

You've seen this slide earlier. This looks at the efficacy of the laparoscopic adjustable band showing sustained weight loss after five years and as you know, there are many studies, this is Hadoff in 2001, there are many studies showing weight loss beyond that time. For up to the first two years, however, there is less weight loss with the LAGB compared with the Roux-en-Y gastric bypass and this systematic review found no difference thereafter.

There were, however, differences in short-term mortality and the mortality rate with
laparoscopic gastric bypass in the published literature is one in 2,000, which compares with one in 200 for Roux-en-Y gastric bypass. I won't cover vertical banded gastroplasty. With this procedure there is also a very low short-term morbidity, and overall morbidity. It's interesting that very similar to the death rates that David Flum has found with gastric bypass, there's a strong association of morbidity with the number of patients in the series. Experience counts in these series.

Now over the last seven years I have spend a lot of time, including my doctorate, in looking at and documenting the problems of obesity and the effect of weight loss on obesity. I have published numerous articles individually looking at all these factors from Type 2 diabetes right through all of those to probably what's most important in your elderly population, quality of life. And there is a strong body of evidence supporting the improvement or resolution in comorbidity with treatment.

Now, there is also a growing body of evidence, and these are just some of the studies that show that it's cost effective to treat
obesity. And certainly the British study showing that the cost per quality adjusted life here of less than $11,000 for all surgical cases is important, and there are further data on this to come.

Mortality is also crucial, yet I think not as important when it comes to the elderly where quality of life is going to be the main reason for intervening, but there are a number of statements there. I must say that more recently, we have looked at mortality data and it's very consistent with the Canadian data and that of David Flum, and it really does look like there is now consistency that bariatric surgery in fact saves lives.

Now, I want to talk a little bit about some of the features that I think are important with the LAGB system that allow low mortality, allow broader applicability, particularly to the elderly. There's low morbidity and mortality, it's technically achievable, it's a short procedure, short hospital stay. It's adjustable, so it's able to be gently moved along. There's a low risk of nutritional complications, and it can be readily reversed.
Weight loss is our most important, is our best treatment for those severely obese. Those with morbid obesity, those with some serious morbidity, the only treatment that's working is bariatric surgery, and we should have this available for all of our patients. Thank you.

DR. DAVIS: Thank you very much.

Dr. Allen.

DR. ALLEN: My name is Jeff Allen, I'm associate professor of surgery at the University of Louisville. I receive financial support in the form of research as well as a paid consultant, and I'm a preceptor for U.S. Surgical, Karl Storz, Ethicon, and INAMED. In this particular instance, INAMED has reimbursed me for my travel expenses.

I would like to give you hopefully a more personal view of bariatric surgery with emphasis on the gastric band. I would say that perhaps many of the committee members are immune to some of the squabblings and arguments we have as bariatric surgeons, arguing whether a gastric band or a gastric bypass, or a BPV is best, but I think it's very refreshing to see everyone come together and really advocating bariatric surgery in general, and I feel equally as comfortable
advocating a gastric bypass up here, but today I'm
wearing a gastric band hat.

At the University of Louisville prior
to FDA approval, we became a C site trial site for
BioEnterics, which is now the INAMED band, and I
began placing bands in 2001 after a fellowship in
Australia, and we had a gastric bypass program in
place at that point. In that time period since
then we have seen 1,448 patients in our clinic.
About half have had gastric bypass and half have
had gastric bands, and of the gastric bypass it's
probably two to one laparoscopic to open. Our
patients are heavy, with a pre-op weight of 306
pounds with a BMI of 49.

I did look at our database and there
are some folks who we have operated upon and put
bands in who had Medicare as either their
secondary insurer or maybe even their primary
insurer and somehow or another we operated on
them. There are 16 of those, their pre-op weight
was 319 pounds, which are a little bit heavier,
and this ranges up to a patient with a body mass
index in excess of 86, so these are very heavy
sick people.

Comorbidities are what we see; all but
10 percent of our band patients have some significant comorbidities. We use a technique called pars flaccida, I mention it only to put a picture on what we do. This is an empiric thing that we've learned, perhaps even in the A trial, the technique for placing and adjusting these bands is different, it's simply improved.

It's important to know that there are some unique and common complications with gastric banding. Three of our patients, we've had to convert to an open operation. That means 461 were done laparoscopically, and that's a tremendous benefit. There's a much higher rate of laparoscopic completion than a gastric bypass. We had one death, somebody we presumed to have a PE, but it was likely due to an arrhythmia after a negative autopsy. Post-op obstruction was a complication that we saw fairly frequently initially; we have not seen any in the past year with the advent of a larger band. We're getting better in how we do these things.

We've learned how to prevent obstruction by taking that fat pad that you can see down there, and you can see it laparoscopically like this, and then sizing the
less curved fat pad. All these things are simply improvement and it's a learning curve both for me as an individual and as surgeons in general doing these.

Gastric prolapse remains the most common complication associated with this device. We have about 5 percent, and it's simply when the stomach herniates up through the band as you can see here, and here on the laparoscopic picture, here on an x-ray, and here endoscopically. I think it's very helpful to see these pictures and see exactly what we're talking about.

Sometimes the bands erode. This is unusual, it's happened three times we've had to take all those bands out. Apart from that, I've taken about 15 bands out of these 400, including some of the erosion, some of the obstructions I've mentioned earlier, so it's certainly not a perfect operation but I feel it's really the best one as far as minimal complications, minimal mortality.

Now, looking at the Medicare specific group, there were no deaths and there was one patient who had a gastric prolapse. These seemed to mimic our total group.

Weight loss data, 202 patients have
one-year follow-up; their average weight loss is 41 percent. In the Medicare specific group, seven patients have one-year follow-up; their average weight loss for some reason is better, 52 percent. And if you look at pre-op SF-36 scores in this group, 28 to begin, one-year post-op 47, dramatic improvement, and we know the value of the SF-36.

In the big group, 91 patients have two-year follow-up with an average weight loss of 50 percent, and seven patients at 60 percent. So unlike the gastric bypass perhaps, the patients lose weight a little built longer, and slower.

So in conclusion, we find that American weight loss with gastric band in my hands is very similar to what we see internationally. I think the key is the low mortality and serious complication rate makes it a particularly attractive operation or surgical option for the Medicare populations. There's a high rate of laparoscopic completion and marked improvement in physical function as seen in these SF-36 scores.

Thank you so much and we appreciate your consideration.

DR. DAVIS: Thank you. Dr. Provost.

DR. PROVOST: David Provost. I'm
associate professor of surgery at the University of Texas Southwestern Medical Center in Dallas. We've received research grants as an institution from Karl Storz, U.S. Surgical, and I have received consultant fees from U.S. Surgical and INAMED, and travel for this meeting was paid for by INAMED.

What would like to speak about briefly is our experience with laparoscopic banding specifically in the Medicare population. We've heard about the band that's placed around the top of the stomach, it's adjustable, its perioperative morbidity is low, and with this we can see a rapid return to normal activity and gradual weight loss.

We have been placing the gastric band since October 2001. Over that time period we've placed 94 bands in Medicare patients. I have broken these out into two groups. The first is a group of patients who are over 65, we have 33 of these patients. Their mean age was 67.8 years with a range of 65 to 75, and their mean body mass index was 48.1. The larger group, and this larger group has actually been my experience with bypass patients as well, the majority of Medicare patients who we will operate on will be those who
are under age 65 on Social Security for long-term disability. 61 patients with a mean age of 48.4, higher BMI in this group, mean of 54, with a range of 35 to 104.1. In these patients, all bands with the exception of one which was placed at the same time as the repair of a giant abdominal wall hernia, and they were placed laparoscopically. There was a single conversion, there were no perioperative mortalities.

    If we look at weight loss in these two groups, again, the weight loss will be slower than what's seen with the bypass. We have short-term follow-up at this point, but what we do see is good progressive weight loss in both groups. Again, the weight loss begins to be a little bit slower initially with the younger age group, but they were a bigger group so if you actually look at pounds lost, they are quite equivalent. At 18 months we see weight loss approaching 50 percent in the entire cohort.

    I would like to talk a second about comorbidities. The first column, again, is the percent of the total patient population who had these comorbidities at the time of surgery; the second column is those who have seen improvement
and/or resolution. Again, this was assessed in those patients who were beyond three months post-surgical follow-up, and what we see is that there is a high prevalence of diabetes mellitus, asthma, heart failure, joint disease, reflux, hyperlipidemia, hypertension, back pain and sleep apnea in these patients. The incidence of most of these comorbidities seems to be, is higher in the younger Medicare population. Again, these are patients who are disabled primarily because of their obesity and what we do see is marked improvement in these comorbidities with weight loss surgery.

Again, the band has not been available, so I can't give you long-term results, we've seen the foreign results. So we have had good results in the Medicare population with a low perioperative morbidity and mortality, with good improvements in their comorbidities. I would like to comment that all of these patients for the most part had comorbidities because that's what Medicare covered at the time. There is a subgroup of patients who we have operated on where we haven't been reimbursed who had a comorbidity of joint disease.
or impaired functional status, which was not considered a significant comorbidity by Medicare. But if you take a 30-year old who's on Social Security because of the weight of 500 pounds and impaired functional status, those are the patients who you're looking at a lifetime of Social Security and Medicare coverage, where we can get them back into the work force at a young age, and I think we've seen that several times in our patient population.

Thank you very much.

DR. DAVIS: Thank you. Dr. Fisher.

DR. FISHER: My name is Barry Fisher. I'm a bariatric surgeon in Las Vegas, Nevada, and I'm here speaking on behalf of our patients who need surgery but are deprived financially. My pension fund has some stock in INAMED Health. I'm a proctor and speaker for INAMED Health and Ethicon Endosurgery, and I am in line to receive an educational grant from Ethicon. My transportation and lodging to this meeting were paid for by INAMED Health. I have served on the NIDDK advisory panel, a medical advisory panel for INAMED Health, and chairman of a committee for advances in bariatric surgery. Although I am
listed here as being associated with two medical
schools, I am a clinical teacher at those. We're
in a community practice.

I am here to address only three of the
questions found in the greater concerns, medical
versus surgical therapy, three different surgical
approaches, the resolution of associated medical
problems.

In 1995 there was a study published by
Louis Martin which unequivocally demonstrated the
failure of medical treatment for morbid obesity
when compared to the long-term success of surgical
intervention. You've seen the results of the SOS
study and this confirms what Louis Martin
reported. 89 percent at five years durability of
surgical treatment, 83 percent at seven years,
with complete return of lost weight in those
patients who were treated by diet alone.

We have been performing obesity surgery
for over 14 years, now limiting our practice
exclusively to bariatric surgery. We've had
experience with three different surgical
procedures and concurrently performed open,
laparoscopic gastric bypass and laparoscopic
banding, presently limiting our practice to
laparoscopic Roux-en-Y and laparoscopic banding, as these seem to offer the best outcomes at the lowest risks.

90 percent of our patients had one or more comorbidity, 100 percent over the age of 65 had or exhibited one or more comorbidities in our practice. In 2001 we adopted a detailed database of our cases, now totalling 826 patients. We analyzed this comparing the efficacy of gastric bypass to lap banding. The first question we addressed was whether open and laparoscopic gastric bypass were equally efficacious, and this slide demonstrates the analysis of our whole practice.

It shows good long-term follow-up. There was no significant difference in weight comparing open and laparoscopic gastric bypass, and the lap band patients' early weight loss was clearly less than that of the Roux-en-Y patients, with difference beginning to narrow with time. All three produced excellent and durable weight loss after three years in our programs.

We then further analyzed this group using a matched pair case control model and in this we matched patients by BMI and date of
surgery, and observed that there was no difference
subsequent when we analyzed it in terms of age and
preoperative weight in these matched pairs.

In this matched pair analysis we
confirmed that the gastric bypass is more
effective than the lap band during the first two
years with the difference in weight loss
diminishing with time. In addition, Pories
reported that gastric bypass patients regained
substantial weight in later years and many authors
have confirmed that. This may be understood as
these operations, the gastric bypass and the lap
band affect the patient in different ways and
their weight loss is therefore subsequently
different.

With regard to mortality and
complications in our practice since 2001, they are
shown in the following two slides. Mortality risk
seems to be higher with the gastric bypass.
Specifically, the one-year mortality of 0.68
percent compared to the zero mortality in our
patients at one year. And the subsequent
conclusion here, however, is that the return to
the operating room is different with a higher
return to the operating room after gastric band
than is observed in our laparoscopic gastric bypass patients. In addition, there is a significant difference in return to the operating room between laparoscopic and open gastric bypass due to wound complications.

With regard to associated medical problems, it is clear that in the two large data series that we analyzed when making our decision, that there was no significant difference in resolution of comorbidities. In our own practice, 42 percent diabetes reduced to 1 percent diabetes at one year; we define it as less than 126 blood sugar and a hemoglobin A1C of less than 6.

In conclusion, surgery is more durable than medical therapy, there is no significant difference in the efficacy, and both reduce operative -- laparoscopic approach significantly reduces operative complications due to the high incidence of wound problems. Both laparoscopic Roux-en-Y and lap band effectively reduce weight, improve health and quality of life. Lap Roux-en-Y may carry with it a higher mortality risk and the Medicare population should be offered the choice.

Finally, Medicare pays for chronic renal dialysis and other chronic conditions that
do not result in permanent cure and where the
outcome is dependent on patient compliance. You
have to apply the same yardstick in your decision
to cover treatment for this epidemic condition
because the country is watching. In addition, we
do not do Medicare patients because coverage
decisions are made by carriers. In our area,
every case has been challenged, and 50 percent of
our cases in our series were denied even though
they had clear evidence of comorbidities. This
committee and CMS must come out with a clear and
unencumbered statement of coverage. Thank you.

DR. DAVIS: Thank you. Dr. Hess.

DR. HESS: Good morning. I'm Dr. Hess,
I'm in private practice. I have no one supporting
me as far as finances of any kind and my trip here
was supported by my wife but she doesn't know it
yet. Thank you.

We do the biliopancreatic bypass, we
take out half the stomach and we bypass part of
the stomach so we can absorb fat here, we restrict
it here, we save the pylorus, everyone sort of
knows what it is. My statistics are like everyone
else's. We do have an average of 51 BMI in our
first 1,000 patients. My first ten-year weight
loss study was in April of 2003, has 120 patients. We had 111 of them or 92 percent of those at ten years, and that's a 76 percent excess weight loss at that point. We also grade them by the parameters because averages sort of give you funny answers sometimes, 80/60 and so forth, but everybody above 50 we call satisfactory. And we took that same 111 patients and we have 76 percent in the good to excellent range and we have 94 percent in the satisfactory range.

We also have some advantages to this operation. It is a pyloric saving operation. It has rare marginal ulcers and we had no dumping syndrome, we don't particularly like the dumping syndrome. We use no foreign materials, and it is functionally reversible easily at the distal Roux-en-Y, and if you operate the stomach the right size you never have to touch it again, because that's the tough spot.

Comorbidities, we cure them or we prevent them or markedly improve them. Diabetes type 2, we got a 98 percent cure rate. I think they're 100 on sleep apnea, hypoventilation syndrome was markedly improved, hypertension improved, hypercholesteremia it absolutely
improves, and the others things do too.

This is our graph of 105 patients who are all type 2 diabetics, their average blood sugar was 200, this is a six-year graph. Everyone here is normal after six months, none taking any medicine, one half were taking insulin, one half were taking a hypoglycemic agent. This guy had severe sleep apnea, very heavy. He's 12 years post-op and this is the way we think they should look. We think we should be thinking about long-term results.

We do have some major complications. Gastric leak, 0.7 percent; revisions are between 3 and 5 percent, you don't know because time adds up on these revisions; we had a half a percent we reversed. A couple had cancer, a couple got into drugs. We have had eight deaths out of over 1,400 patients, and 90 percent of those were the very severely obese patient.

This is our last slide, just done last month. It's 182 patients and we have 92 percent follow-up at the 10-year point, some of these are 12 or 15 years, but at 10 years we got 75 percent excess weight loss. We feel that we should be looking at long-term, one operation for life and
not be reoperating these things, because that's
where all the risks are. Thank you very much.

DR. DAVIS: Thank you. Dr. Blackstone.

DR. BLACKSTONE: I'm Robin Blackstone,
I'm a community surgeon from Scottsdale, Arizona.
I do work as an educator for Ethicon Endosurgery
and I'm on the board of directors for Viking,
which is a medical device company. Other than
that, I guess you could say that my patients paid
my way here today through our practice. I have
not received any compensation for being here
today. Thank you very much for allowing us to
speak, and thank you, Mrs. Long, for all your
e-mails in regards to this.

I wanted to bring you the perspective
of a community practice which has been developed
since July of 2001. In that time we decided, both
myself and my hospital, that we would jointly put
together a program using the American College of
Surgeons guideline SAGES, and the American Society
of Bariatric Surgery guidelines, and the program
was developed along those guidelines. The program
philosophy focuses on education of the patient.
We established a prospective database in which
each patient is entered prior to surgery so that
we can track longitudinally all of their safety
data as well as resolution of comorbidities. We
have long-term follow-up as you'll see, to the
extent that we can in a three-year-old program,
and our goal is to create a community of support,
both psychological and medical for these patients,
and to communicate with the primary care provider
network that was going to care for these patients
long term.

The program I've just outlined here,
and I won't go into it further. Let me just say
that most of the patient have done an extensive
randomized trial of their own weight loss
therapies which has been self funded prior to
coming to see us, and those who have not done any
type of thing like this, will do it once they are
in our program where we have a dietitian and
psychologist who works with them during this
period regarding behavior modification, and to
show them that this can benefit them, so they use
surgery as a tool.

Basically in our program, we use the
National Institutes of Health criteria, which was
established, as you know, in the consensus
conference of '91. We initially operated on
18-to-60-year olds. We now have 47 patients between 60 and 71 that we have operated on. They need to have failed supervised medical weight loss attempts, they have to have a good understanding of the surgery and its risks, they have extensive psychological evaluation including MMPI and other tests, as well as interviews. And if they are identified as needing some type of ongoing support, they are referred into that prior to surgery.

These are the two procedures that we currently perform. The gastric bypass Roux-en-Y was the first procedure that we began with after a fairly extensive four-month period of training and preparation for the hospital, which included of course sensitivity training as well as equipment issues. We also have enjoyed the dedication of our hospital team in providing us with consistent OR support, so we have pretty much the same team operating, doing anesthesia on a daily basis, which I think insures quality. We also have a bariatric unit with nurses that are dedicated to the bariatric patient group. In January of 2003 we began doing gastric band, we have now done about 50 gastric bands, we have not done any in
the Medicare population.

These are, I wanted to give you an idea of what our Medicare population look like as compared to our total. 37 Medicare patients, 805 in SBC. This gives you an example of the complications that we've enjoyed. We've had zero 30-day mortality in either group of patients, and this data is through July of this year. It gives you an idea of how that mortality is in context, and I just wanted to point out that we do know that even gall bladder surgery has some mortality and compared to the mortality risk of these patients long term, I think will be good.

I wanted to say, too, that our age population is about the same as Medicare in general. Most of our patients are younger, they have a significant number of comorbidities. We have zero patients in the Medicare population with no comorbidities. Some of these comorbidities, though, would not be actually reimbursed by Medicare. This is the distribution of comorbidities in our patient population, similar to the distribution that you see nationally.

Our excess weight loss was 760 out of 805 patients followed up. Comorbidity resolution
rates in our Medicare population parallel what you've seen demonstrated in the meta-analysis and other studies. And our diabetes resolution, out of 164 diabetics treated through the end of July, you can see that 31 remain on oral therapy after 17 months, and most have resolved that and this was the mechanism of their resolution.

In the arena of social outcomes, 26 of 37 patients were able to be contacted. Four patients were working full time. Again, this is a disabled young population who is mostly not working.

In conclusion, most of the Medicare population that are being treated are between the ages of 25 and 64. They have a higher degree of comorbid disease and in our group 44 percent were diabetic versus about 21 percent in our study at large. Surgical therapy was the most effective treatment. It does consider risk, but the risk of not treating is higher. Outcome and process improvement will be hallmarks of a program that Medicare treatments and other payers' patients should be treated through.

We have just applied for the ASBS center of excellence designation, and have been
designated a center of excellence by a very large employer and a couple of other insurers. And I think a high volume comprehensive community with a continuum of care and this kind of comprehensive treatment, really is your best way to treat these patients in a safe environment. Thank you.

DR. DAVIS: Thank you. Dr. Bessler.

DR. BESSLER: Good morning and thank you to the panel for the opportunity to present to you. My name is Marc Bessler, I am an assistant professor of surgery at Columbia University. By way of conflicts, I have received research support from Tyco, United States Surgical, TransNeuronics Corporation, and my trip today was covered by INAMED.

I briefly just want to address the issue of comorbidity resolution and safety of these operations. We talked about the operations already. We undertook a study to compare the outcomes of both gastric bypass to adjustable gastric banding and not so much to point to one versus the other as better, but to show that they are both potential options for patients.

We reviewed 572 patients that were operated on since we started doing banding, which
was part of the C trial in February of '01. A quarter of those patients approximately elected to have gastric banding and the other three quarters had gastric bypass, mostly laparoscopically. We also did a matched case control which I'll show you.

This is the weight loss data. The square is looking at the excess BMI loss and the circle is looking at excess weight loss. You can see at two years 46 percent excess weight loss for banding and 65 percent excess weight loss for gastric bypass, very similar to all the other data I guess you've seen today, except again, this is from the United States and compared in the same center done by the same surgeons with the same definitions, the same scale, et cetera and so forth, so it's not compared across studies and I think adds some value.

This is our matched trial because the patients who had the lap band were slightly older by two years and slightly heavier by two BMI points, and we wanted to control for that, so when we matched for that the results as you can see are pretty much the same.

We looked at sweet eaters versus
non-sweet eaters, and found no difference in our
weight loss in our gastric banding or our gastric
bypass patients whether they were sweet eaters or
non-sweet eaters, and I think that issue can
probably be put to rest at this point with a large
study that was also published from Australia.

The BMI does seem to affect weight
loss. This is statistically lower BMI -- I'm
sorry, lower percent excess weight loss if the
patient has a BMI over 50 with gastric bypass, but
it didn't reach significance it the patient had a
BMI over 50 with banding, and that may be due to
the different mechanisms of these operations over
time.

What's not up here, I guess this was
added, was the comorbidity resolution. Up front,
40 percent of our patients had hypertension, 21
percent diabetes, 30 percent approximately
hyperlipidemia, and in the mid to high 60s
arthritis, and that was similar between the band
and bypass groups. We had a slightly higher
incidence of urinary incontinence and obesity
hypoventilation syndrome in our gastric bypass
group, and again, that may be due to the female
predominance and the weight difference.
The resolution of those comorbidities between the two groups were identical except for, and I want to find the data for you here, hypertension was 71 percent resolved in our gastric bypass group and that was higher, and also a higher resolution was 90 percent for osteoarthritis, 90 percent for GERD, and 90 percent for urinary incontinence, versus in the 70s for our adjustable banding, but again, significant resolution of these diseases. I think it's clear that these operations benefit our patients, 90 percent of whom have comorbidities and equivalently so.

The last important point, also perhaps previously made, is that risks of these operations, we had no mortality in either group, but the morbidity was 15 percent for our gastric bypass patients and 6.6 percent for our lap band patients. Although more patients returned to the operating room for relatively minor procedures with the lap band, the major complications were higher in the gastric bypass group, perhaps offsetting the difference in weight loss. I think both these and other operations need to be available to our patients because it really does
improve their quality of life, as you have already seen, and I thank you for the opportunity to present.

DR. DAVIS: Thank you, Dr. Still.

DR. STILL: Good morning. My name is Christopher Still. I am the medical director at the Center for Nutrition and Weight Management at Geisinger Medical Center in Danville. I do serve as a medical consultant for Ethicon in a scientist advisory board. I have no other conflicts of interest and I paid my own way this morning.

What I would like to thank the panel for allowing me to come to present is obesity treatment and outcomes of obesity treatment in the rural community setting. Just to give you some historical perspective, we started our comprehensive management program in 1994 and in 2001 we added the modality of bariatric surgery. We do live in a rural community place and we offer services to 31 counties in central Pennsylvania. We have a comprehensive weight management program that includes diet, behavior modification, exercise, pharmacotherapy if weight loss plateaus, and then if appropriate, bariatric surgery after a six-to-eight month process. We do have a
multidisciplinary team approach including myself
as the medical director; we have a bariatric
medicine fellow; we have two physician assistants,
three nurse specialists, five registered
dietitians, two behavioral psychologists, four
bariatric surgeons, and a myriad of research
coordinators and technicians, and also an
insurance coordinator.

Just to show you the overall statistics
of our weight management center, the average BMI
of all comers is 46 with a corresponding weight of
284 pounds. 38 percent of these individuals
suffer from diabetes, 27 percent from obstructive
sleep apnea, 18 percent from steatohepatitis or
fatty liver, and 22 percent from depression. Our
active number of patients in our database is about
4,300. We see about 45 to 50 new patients per
week and we operate on about 10 to 15 patients per
week. So clearly surgery is not our main focus of
our comprehensive weight management program, but
it is the most effective modality, as I will show
you. Approximately 9.2 percent of all of our
patients are Medicare patients.

Just to show you some medical
management one-year outcome data, as I said, 9.2
percent of these were Medicare patients. 38 percent of the medical management were diabetic.

The average weight loss was nine pounds or a reduction in body mass index by 1.2. There was a modest but important reduction in hemoglobin A1C in the medical management from 8.8 initially to 7.4 after one year, which represented a 1.4 percent drop. It is significant but unfortunately in medical management, it's just not long lasting, and I think from an internist, that's where the surgical outcomes are much more impressive for that.

Now if we look at the Medicare population specifically in the surgical outcomes, the average weight was 322 pounds, the average BMI is 53, the average age in our Medicare population was 51. The average weight loss was 86 pounds and losing minus 14 body mass indices. Out of the 713 surgeries that we've completed since 2001, 10 percent or 71 were from Medicare patients. 84 percent of the Medicare patients had hypertension, 68 percent had diabetes; as you recall, 38 percent in our medical management of all comers had it. 52 percent had high cholesterol, 40 percent had reflux and obstructive sleep apnea, and 14 percent
had depression.

As I showed you, the statistical differences between medical and surgical weight loss was about nine pounds versus 83 pounds. Surgical management of the resolution of the entire population, 84 percent had normal hemoglobin A1C after two years. After one year it went from 8.8 to 6.7, and then two years a 6.1 percent hemoglobin A1C. Hypertension was resolved 68 percent of the time. Obstructive sleep apnea, these are pre-and-post sleep studies, resolved or normalized in 84 percent of individuals. And fatty liver, steatohepatitis normalized in 70 percent of individuals.

We've also published data on monthly cost reduction in diabetic and hypertensive medications pre and post-surgery. This is in the Medicare population. The average cost for monthly medications for diabetes and hypertension was $192 per month preoperatively and post-surgical was $36.35, with a monthly savings of $156.

So in conclusion, I believe that bariatric surgery is a highly effective treatment for morbid obesity, and most importantly in resolving its comorbid medical problems, and it
should be offered to patients who fail conservative management. Compared to medical management, surgery results are more profound and long term than medical management.

However, to insure the optimal outcome, I think surgery needs to be performed in a multidisciplinary program for the best results. At least in our experience, the community or rural setting suggests that good outcomes can certainly be achieved both in the general and the Medicare population, and I believe that bariatric surgery is a key in the spectrum of treatments and modalities for the treatment of obesity. Thank you.

DR. DAVIS: Thank you. Dr. Schoelles.


I'm an internist and geriatrician. I am an employee of MetaWorks. We performed the meta-analysis, the systematic review of the literature and the meta-analysis that formed the basis of Dr. Buchwald's manuscript in JAMA. Our work was sponsored by Ethicon Endosurgery and my travel expenses for coming here today were supplied by Ethicon Endosurgery. I'm currently a student at the Harvard School of Public Health and
living on a grad student's budget again, so I accepted.

The key question we were asked to address in our, or in this particular part of a larger effort of looking at the bariatric surgery literature was on the question of how comorbidities are affected after bariatric surgery. We performed a search in the usual way that has become recognized in the systematic review process. Our company was founded by Dr. Thomas Chalmers and Dr. Susan Ross, and we have built upon the work of the Cochran Group as well as other EPCs doing work for AHRQ.

We did the search for this literature review beginning in 1990 and the cutoff date was June 5th of 2003. We were building an entire database catalog of all the bariatric surgery literature in that time period with the exclusions, the primary exclusions being studies that reported on fewer than ten patients or had less than 30 days of follow-up. Within that larger catalog we sought those studies that had some outcome pertinent to one of the comorbidities of interest. We initially were trying to also look at health care economics data and some of
those studies have some of the outcomes but not all.

There is a lot of difficulty with this literature and I think the presentations today made me think about how valuable registries are in this field. There are many issues with the way the number of patients at any given time point are reported. We didn't always know whether there was right censoring, in other words, patients who only recently were operated and in which cases there was attrition lost to follow-up.

What we settled on as our best compromise was to pick the latest time point at which at least 50 percent of the described cohort was being followed and for which there were outcomes. In this process we screened over 2,700 abstracts and this particular data set included 134 studies with 91 overlapping publications. We make an effort not to double count people. And in this set, again, we were choosing papers based on the reporting of some outcome pertinent to comorbidity.

As you can see, there were a large number of patients. The age range reported in the papers, in other words the range of the ranges,
went from age 11 to age 73. There were seven
studies that included enough older patients to
have a mean age over 50, and four of those studies
had a minimum age of 50. 25 of the studies in the
entire set included patients over 65 but did not
report separable outcomes.

These are some so-called forest plots
of the meta-analytic results. As you know from
hearing most of this through the day, the change
in weight either measured by BMI or absolute
weight loss in kilograms is significant. We were
able to capture some results on populations
specifically described as either diabetic or
glucose intolerant in some way, not always by the
specific definition that internists might use, but
the data is limited and yet, there were
significant decreases in hemoglobin A1C in the
diabetic population. Glucose results both overall
and within the diabetic population were quite
impressive as well. The decrease in total
cholesterol was less so but the change in
triglycerides was fairly significant.

You've heard these numbers throughout
the day today and these are the other overall
numbers for resolution or improvement in the
comorbidities and I won't belabor those again, but
again, they are high numbers.

DR. DAVIS: Thank you very much.

Dr. Rabkin.

DR. RABKIN: My name is Robert Rabkin,
I am speaking as a bariatric surgeon in private
practice in San Francisco. In the past I've
received funding from Tyco and Johnson & Johnson,
but my appearance here today is not paid for by
any other entity other than my patients.

I want to skip forward to question five
just to say that I'm highly confident that it's
very likely that results of bariatric surgery can
be generalized to the Medicare population as
practiced in a community-based, or by
community-based providers.

I want to address the construction of
question four. The most important concept I want
to convey today is that the duodenal switch or DS
procedure is a vastly different entity than other
weight loss procedures. The weight loss is
greater and more durable and due to the preserved
gastric anatomy, there's no dumping, gastritis or
ulceration. These elements distinguish the DS
from the Roux-en-Y gastric bypass, the lap band,
and notably from the biliopancreatic diversion or BPD procedure. As important, there are significant quality of life issues that are improved with the DS compared to the other procedures.

I have included in my slides some forerunners of the DS because they're sometimes confused with the modern DS procedure of Dr. Hess. Of historical interest only, the JIB was developed in the 1950s and is no longer performed. We've already heard about the other weight loss options so we can move on, and again, the vertical banded gastroplasty, we can move on. The lap band, like the vertical banded gastroplasty, is a restrictive procedure.

We all agree that the foundation of this is weight loss. The Roux-en-Y gastric bypass is the most popular procedure today, but it has limitations because it is primarily restrictive. Initial quality of life is compromised by extremely small meal volumes as well as a dumping syndrome, marginal ulceration and gastritis. Accommodation to the restrictive effect occurs in many patients, gradually allowing for larger meals, and can result in substantial weight
regain. There is a lifetime contraindication to ansates, which are among the most commonly used medications today, both prescribed and over the counter, and this problem is caused by the juxtaposition of acid producing mucosa to small bowel at the proximal anastomosis of the Roux-en-Y gastric bypass, which is avoided by the construction of the duodenal switch for the many formerly obese patients who continue to suffer joint problems of exclusion of ansates is a serious lifelong problem.

As I mentioned, the nomenclature can be confusing. The biliopancreatic diversion or BPD developed by Dr. Scopinaro in the 1970s is not the modern duodenal switch procedure. This is important and we will review the distinctions in a moment. This is a distal Roux-en-Y gastric bypass, which adds a malabsorption component to Roux-en-Y gastric bypass, but does not, has no effect on the disadvantages that we mentioned as far as the Roux-en-Y gastric bypass.

The modern duodenal switch constructs a two-shaped stomach for moderate restriction and limits the length of the common channel to reduce absorption. Reduced stomach capacity produces the
initial dramatic weight loss, and gradually the stomach size increases to permit larger meals, at which point malabsorption takes over to maintain weigh loss. As I mentioned at the outset, DS advantages include normal eating habits, no dumping and normally functioning stomach with no marginal ulcers. There's no blind pouch as seen in the Roux-En-Y gastric bypass. And upper GI x-rays and endoscopy and so forth can be done noninvasively to evaluate the entire stomach.

The disadvantages, while the duodenal switch is a more complex procedure, somewhat increased operative type, and the resected lateral portion of the stomach can't be reinserted.

Our practice primarily offers laparoscopic duodenal switch using techniques which I developed in 1999. To date we have performed more than 840 laparoscopic DS procedures, which is the largest such series, with one operative mortality. Among our initially published 345 patients, there were seven conversions to open laparotomy and 14 reoperations for infection, leak or stricture. The resolution of comorbidities is similar to the other presentations.
This demonstrates our two-year weight loss reported in our first published series, and within two years the average patient was within 10 percent of ideal body weight. Our heaviest laparoscopic duodenal switch patient weighed 656 pounds, another laparoscopic duodenal switch patient had a higher BMI of 118. Neither had surgical complications and both are enjoying a vastly improved quality of life.

Thank you very much for your time.

DR. DAVIS: Thank you. Sondra Albers.

MS. ALBERS: Hello. I am retired from the University of California San Diego, went out on disability, I'm no longer on disability because I'm no longer disabled. My travel here was paid for by INAMED. What they didn't know is I would have paid them or you for the opportunity to speak in the hopes of helping other seniors have the quality of life which I now enjoy.

I tried and succeeded at every diet that was made, I always got there, sometimes for a day, sometimes for a month. My pre-band weight which they left off there was 210 pounds. My comorbidities were hypertension, which I took three medications a day for, and still had high
cholesterol, asthma, one medication, to
inhalators, and lots of emergency room visits.
Heart disease on two medications, GERD, one
medication. They knew me at the ER, the doctors'
offices, the nurses, they all knew me, much beyond
my age.

I'm 70 years old now and I was 66 years
old when I had the band done. I had it done in
Mexico because this was pre-FDA approval and I was
not a candidate for gastric bypass due to risk
factors my doctors felt at the time. My initial
weight loss within one year was 100 pounds. I did
regain 17 pounds due to the band slippage, but I
have lost nine of those now that they were able to
put some fill in. I had other medical problems
and had to postpone fill. And since that was done
I've lost two more pounds, so I am seven pounds
from where I was and they've maintained that
for the entire time without a lot of effort,
by the way.

And I'm off all medication except for
two. I take one Avapro a day and one
Isosorbidemonote. I have not had an attack of
asthma since the day I woke up in the hospital. I
did not know what breathing was. I know now what
it is to breathe. My cholesterol levels are normal without medication. The GERD is gone with the exception of occasional bouts when I do eat spicy foods, when I know it's going to happen.

The band slippage appeared in January of '04. It was repaired laparoscopically the same day, the band was not compromised so they did not have to put another band in, and the treatment is continuing. I have had no other complications with the lap band.

There is always a risk to surgery and especially when you know that you're overweight, obese, morbidly obese, you know that you have a higher risk, but I'm still here and I want to tell you something. I wouldn't be here. My internist believes that, I believe it. If this hadn't been done to me, I wouldn't be here today. I would like to request of you that you do not forget that seniors not only can have a better quality of life, I dance, I skip through malls with 18 of my grandchildren, some of them are embarrassed by it, and I have a wonderful life. And there's a glint in my husband's eye that I didn't see for a while, and that's nice too by the way. So I'm asking, please think about this and do it. We give back.
We give it back in volunteer work, we give it back in quality of life, and not having our children or our grandchildren having to take care of as soon or as much. I thank you and I hope this helps.

DR. DAVIS: Thank you. Pamela Rogers.

MS. ROGERS: Good morning. My name is Pamela Rogers and I am here today to speak on behalf of myself as a person who has had bariatric surgery. I don't have any financial or other conflicts of interest and I've paid for this trip myself.

In response to the MCAC question one, the effectiveness of bariatric surgery as compared to nonsurgical treatment, I would like to tell you my story. As an obese person most of my life, I spent countless numbers of years and time trying to lose weight through dieting and nonsurgical treatments. While some efforts had been successful, I would always gain more weight back than I had lost, so in the short term they were successful but in the long term they were not. I would quickly regain the pounds and as I aged, these failures clearly outweighed the successes.

In early 2004 I was at my highest weight, around 275 pounds. My blood pressure had
become unstable and I was at risk for type 2 diabetes. Together with my primary physician, I decided something needed to be done. In an effort to make an informed decision regarding bariatric surgery, I reviewed most of the scientific literature that was available at that time and on April 6, 2004, I had the laparoscopic Roux-en-Y.

So to answer you question, if there's evidence that supports the effectiveness of obesity, and again, this is only anecdotal, but I determined through my readings that it did support bariatric surgery. Right now I'm seven months out from surgery and I have lost approximately 90 pounds and I'm confident that the weight loss will continue and eventually I'll get to what's considered a normal weight. I started out with a BMI of 43.3, considered morbidly obese, and today I have a BMI of 29, just overweight. I continuously maintain a normal blood pressure and am no longer taking previously prescribed hypertensive medications. I have a blood glucose reading of 80 and a total cholesterol of 139, well within normal readings. Not only have these changes contributed to my physical well being, I have developed a philosophy of liking myself.
These changes have also instilled a personal commitment to take care of myself by exercising, eating healthy foods, taking my vitamins, and making these changes permanent.

I’m going to address question two and question three together. Life is a calculated risk, all of the areas mentioned in the question, sustained weight loss, long-term survival, short-term mortality and resolution of comorbid conditions were all factors in my decision to have bariatric surgery. After reading the papers by Clements, Smith, Rashid, Buchwald and others, I was convinced of improvement in comorbid conditions, especially in hypertension and type 2 diabetes.

Investigating the mortality data showed that the short-term mortality rate of .5 percent for gastric bypass was an acceptable rate, a rate similar to gall bladder surgery and slightly higher than having an unruptured appendix removed. While research on long-term survival was limited, visiting obesity chat rooms, I often met people that had surgery in the 1970s and were doing marvelously, so that helped convince me that these people, it was a long-term thing, that these
people led healthy productive lives, and I could
do so too. Many of these people that I met in the
chat rooms also had comorbid conditions, all of
which were resolved or improved after surgery.
For those reasons I chose to pursue surgery as my
last resort, as my last hope for normalcy.

As we know, there are many different
bariatric surgeries and I have undergone a
laparoscopic Roux-en-Y, the only surgery that my
insurer covers. I just wanted to caution you that
while there are many different surgeries, I would
hope that CMS would come up with a list of
surgeries that they're going to cover. What
happened to me was that my insurer, after they
preapproved me, decided not to cover it because my
surgeon gave me a 150-centimeter y limb and the
insurer decided not to cover it after I had the
surgery, so I'm paying for it myself.

And I guess in summary, because my time
is up, I just want to thank you for having me here
today and as an individual who has had Roux-En-Y
surgery and researched all of the options, I
believe that laparoscopic Roux-en-Y surgery
affords morbidly obese individuals a sustained
weight loss, long-term survival and resolution of
comorbid conditions that they deserve. Thank you.

DR. DAVIS: Thank you very much.

Eldith Willis.

MR. WILLIS: My name is Willy Willis. I am a retired heavy equipment operator and grading superintendent for a grading contractor in Ventura, California. I have no -- I've got to read this because I'm talking to doctors. I'm used to talking to dirt workers where I can cuss at them and stuff, you know. Anyway, nobody owes me nothing, I don't owe anybody nothing, INAMED paid for my trip out here, okay? And they asked if I'd talk to you and I said yeah, I will give you my experiences.

My experience was, I'll give you a little bit of my medical background before I had this surgery. I woke up many mornings with my feet hurting, burning, tingling. A couple months later I go to the doctor, it was a neuropathy, had diabetes. He says get the weight off, good doctor, I talked to him like I would a construction worker and he talks back to me the same. He says I told you everything you've got to do, but you're not doing it. I have had a lifetime of not doing diets and I have been in a
lifetime of diets, and they all work, but they all
get right back on. So after my diabetes I still
wasn't losing the weight, the neuropathy was just
as bad, and my doctor told me to go see Dr. Billy
in Ventura.

I went to one of his meetings there
where they talked about the lap band and the
gastric bypass. My wife says you're not getting
any of them. So I took her back, we decided, she
decided on a lap band, because I wanted to lose
the weight fast, and the gastric bypass he says
you'll lose the weight faster. Well, I think I've
done as good as most gastric bypasses. I had the
lap band, and a year and a half later I have lost
180 pounds.

I was talking to one of the doctors
that talked up here and he said how do you do
that? I said, do what your doctor tells you, you
know, because I didn't know that Medicare was
going to this bill or not pay it. I know that I
had went as far as I could go and I didn't want to
live anymore. Let's see.

Before surgery I really didn't have a
life, I was over 425 pounds, now I'm 250. I got
up in the morning since I was retired. I couldn't
walk, I had a back surgery, a knee operation, I
have had all kinds of medical problems. The back
surgery helped but the doctor told me the same
thing, lose weight, you'll do better. I ended up
having the lap band from Dr. Billy. I feel great.
It has changed my life in every way you can think
of, and my wife can tell you some of those ways,
but I wish she wouldn't. It helped everything,
everything. And you know, that's without Viagra
or anything like that either.

All I did when I got up in the morning
was eat, watch television, walk by the
refrigerator, open the door and look at the same
food I had just seen ten minutes ago, so I'd get
another bite of it. And I ballooned. I mean, my
head looked like a giant bowling ball. After I
started losing weight, you feel better so you
start doing more. And now if you can find me in
front of a television for more than 20 minutes at
a time to watch news, you're doing good, because
I'm always working doing something.

Billy says do you exercise? I say no.
I don't lift weights, I don't do anything, but I
work all the time. Since then I have built a
little workshop in my garage and I'm making
furniture, I'm doing this, I'm doing that, I grow
a garden, I mow the grass, trim the grass, pull
the weeds. I do a little bit of everything. We
bought a Harley, which I always wanted but never
did. Now we go on Harley runs, me and the wife,
enjoy that thoroughly. I can't wait to get back
and hope it's sunny in California where I can ride
it this weekend, because I just got back from
Europe, Italy and Spain, two days before I come
here. And wish I hadn't told Medicare, or not
Medicare, but INAMED that I would come, because I
was so stinking tired when I got home I didn't
want to travel anymore.

But I'm glad I come, I've learned a lot
just from listening to these doctors talk. And
let's see. I really didn't have a quality of life
until I had this surgery. You can't imagine,
well, I guess you doctors can because you see guys
over 400 pounds, but my dad and everybody involved
around me, my family was worried, my wife was
worried, and she thanks INAMED, she told Vern back
there, I want to thank you, you saved my husband's
life.

And the only thing I really have to say
to people that need this surgery, Medicare, they
paid for my room, but they should pay more. For the simple reason they have saved more than they was paying on medicines for me in this last year and a half. I was taking 19 medicines a day, that's how bad of shape I was in, 19 medicines a day. I was so sick of taking pills and squirting stuff up my nose so I could breathe because I was too fat, everything. And I know in a year and a half, they made more than enough to pay for that hospital. So please add the wording so all these doctors, I've heard the same thing, if the wording was right, they would know who could get it, who couldn't get, and whatever.

Anyway, that's my story, I'm sticking to it. Thank you very much.

(Applause.)

DR. DAVIS: Thank you very much. When you're riding that Harley, are you wearing a helmet?

MR. WILLIS: I don't want to, but I've got to.

DR. DAVIS: Thank you very much to all those presenters, and here's the schedule. It's 20 after 11 on my watch, so we're a little bit behind schedule, but my plan would be to allow the
committee members to ask questions of those who have presented so far for about 15 minutes. Then we have six more people who have signed up for the open public speaker session. We're going to ask them to limit their remarks to three or four minutes, like those who have preceded them. So if we start with that at about 25 to noon, that should take us to noon when we'll take a break for lunch, and then we'll have plenty of time after lunch for the committee to ask more questions of the presenters and then to have open discussion and move toward voting on the questions that we have been asked to address. So, let me just open it up for questions. Yes please.

DR. OWEN: This question is actually posed to the professional presenters who declared a conflict of interest. I'm curious if your slides were developed or reviewed by any of the firms that supported your attendance.

(Negatives from all presenters from the floor.)

DR. DAVIS: Yes, Dr. Klein.

DR. KLEIN: This is a question for Dr. Pories and Dr. Flum. You had both mentioned, or one had mentioned that there is a learning
curve where you do fewer procedures at an increased rate of mortality, and Dr. Pories, you mentioned this idea of centers of excellence to really make sure proficiency is performed. Are you recommending that only centers of excellence or experienced surgeons be allowed to perform bariatric surgery.

DR. PORIES: I think that's a good recommendation. I think that surgeons must be adequately trained before you do it, this is difficult stuff. And I think you ought to look at it the way we look at cardiac surgery, where people have to have adequate training and proctoring before you get good results.

DR. KLEIN: And just along with that, then, how would you diagnose a competent surgeon, would it be number of procedures, clinical outcomes, or they have to be within a center of excellence?

DR. PORIES: Well, the centers of excellence have developed some tough standards, and one of the standards is that a surgeon must have a minimum number of 50 cases before he's considered part of the center of excellence, and the center of excellence must perform a minimum of
125 cases per year.

DR. DAVIS: If I could just pick up on that, this gets to the generalizability question, generalizability to community physicians, and perhaps for someone like me who is not in the field of bariatric medicine or surgery, perhaps somebody could give some background on who is doing bariatric surgery today in the United States, what is the training now being used and what should the training be. I presume a lot of this training is in general surgery residencies, there may be some fellowships involved. If somebody could give some general background, I think that would be useful.

DR. PORIES: We have a spectrum, I will just make a brief comment, because actually Dr. Buchwald has better information about that because he did a survey. But initially of course, most of us were self trained. Then there was a series of courses. But I think the standard today is either a mini-residency of about three months, but most of the new young people are now being trained in fellowships, and the number of these fellowships, the American College is very interested in developing standards for these
fellowships just as we have for residencies. But
Dr. Buchwald has the actual data on who's doing
what.

DR. BUCHWALD: I could comment on that.

At the moment, over 73 percent of American
teaching programs, residency programs, and about
89 percent of fellowship programs are teaching
bariatric surgery.

DR. DAVIS: Yes.

DR. ABECASSIS: I guess we've had
representatives of three different groups talk
about this issue and it does apply to this
question about how generalizable the procedure
might be in the community, and I'm just wondering
if the American Society of Bariatric Surgery and
the SRC and the American College of Surgeons are
working together on this, because I'm not sure
that I understand, and it may help my thought
process to understand how these groups are working
together to answer the question that you've just
asked.

DR. FISCHER: I think I can shed some
light on some of the things that have gone on and
they are very much in flux. Recently there was an
attempt by the Society of Surgery of the
Alimentary Tract, of which I was chairman of the board at that time, and SAGES, which is the Society of American Gastroendoscopic Surgeons, and then some other groups to develop a fellowship which would follow residency.

For various reasons there was a group that put together some fairly rigid standards and then the splinter groups went off and did something on their own which unfortunately sabotaged it. I think to a certain extent, although there is a match, my guess is the American Board of Surgery, of which I was chairman about five or six years ago, will be taking over all of these areas very much as they've had sub-boards in pediatric surgery, vascular surgery, and finally that will come under the American Board of Medical Specialties and the ACGME, the Accreditation Council for Graduate Medical Education.

The College will be doing verification of bariatric programs as part of its verification process in which there is long experience. This is now a quite large division of the College, the Division of Research and Optimal Patient Care. We've done -- and in general when we do
verification processes we do this in collaboration
and cooperation with other groups.

For example, the College now does the
Level I, Level II, Level III verification of
trauma centers throughout the country. These are
recognized by the state emergency systems. We do
that in conjunction with the American Association
of Studied Trauma. The cancer programs in various
hospitals are also verified by the College and we
do that in cooperation with the American Cancer
Society.

The Division of Research and Optimal
Patient Care has large programs in quality and
safety, team training, evidence-based surgery, and
for your information, we do very much support
improved performance and have programs and so in
this area we would welcome working with a whole
variety of different groups, bariatric surgeons,
whatever organizations they wish, SAGES, the
Society of American Gastroenterologic Surgeons,
the SSAT, and we've had informal discussions on
this issue with the ACGME and with the American
Board of Surgery.

So there are, it's a long-winded answer
to a very simple question. Yes, there are
fellowships. Are the fellowships standardized,
probably not. Will they be standardized in the
future, probably. And there are a number of
organizations working on that.

DR. DAVIS: Dr. Phurrough?

DR. PHURROUGH: Dr. Fischer, let me ask
this as the CMS person here. If CMS were to
readdress its policy on bariatric surgery, then
would the College be supportive of our restricting
this surgery to facilities that went through some
kind of accreditation process that certified that
the physicians were competent and that the
hospital had some program that insured quality
outcomes?

DR. FISCHER: I can't answer on behalf
of the College because that would have to be
discussed starting with the committee and going
through the board of regents and all of that. But
my guess is that the College would like to work
with CMS in an effort, and all other interested
people to develop guidelines for quality and
safety, and we really would like to track patient
outcomes. I think I can say that. How it would
happen, how long it would take, I don't know.

DR. DAVIS: Dr. O'Connell.
DR. O'CONNELL: Perhaps Dr. Fischer would, maybe I can put this question to you. In the data that has been presented, the morbidity rates seem to have been, they are fairly acceptable on the low range, some have been high. That is in dramatic distinction to what I'm experiencing in clinical practice where I get a chance to look at complications of morbid obesity surgery. What I'm finding is patients who have complications are, first, not admitted to the same hospital where they had their morbid obesity surgery, and the complications are then classified in terms of the medical diagnosis, so you never know the complications of morbid obesity surgery because you can't capture all the data. And my question is, how reliable is that morbidity data that we're hearing today?

DR. FISCHER: I don't know the answer to that but I can tell you the experience at our hospital. At Beth Israel Deaconess we now have a database of every single patient that's ever been operated on, and we track that actively. And the purpose of the database is to say okay, who got readmitted, who had a complication, who had a death that wasn't reported at the mortality and
morbidity conference.

I'm sad to say that there were a number of such events that have happened, and this is in all surgery, this is, you know, we do about 28,000 operations a year. So my, as chair of the department what I have said is I want every single complication which is increasing length of stay, reported at mortality and morbidity conference, every return to the operating room, you know, every readmission within 30 days reported. They're not.

Now, it depends on how you set up the study. If you set up the study with an independent nurse practitioner or somebody like that tracking the patients as the College is now doing in a hundred beta sites with NSQIP, you're likely to get reasonable data. The other way, I don't know.

DR. O'CONNELL: Do you pick up data from other institutions?

DR. FISCHER: We try, yeah.

DR. DAVIS: Dr. Weiner?

DR. HESS: Could I speak?

DR. DAVIS: Yeah, and introduce yourself.
DR. HESS: I'm Dr. Hess, in private practice. I wanted to speak to this bariatric surgery situation. Any good general surgeon should be able to do bariatric surgery, the problem is not are you technically able to do the surgery. The problem is, are you able to recognize complications and do you see your patients afterwards frequently? Many times patients are sent home one or two, or even three days, four days after surgery, to come into the office in two or three weeks. I want to tell you that some of the worse complications occur after a week or so, and if they are out in the country and if they end up in another hospital, as was mentioned here before, this poor person is in trouble. And it happens over and over again and these are the things that we need to put our focus on. I don't think it's so important about the technical part; every general surgeon should be technically able to do this operation, but not everybody knows or understands. Now after they have a few deaths in the early time, they get a little smarter and worried, but unfortunately, you shouldn't have to have someone die to learn. You ought to remember, Harry Truman said one time, the
only thing that's new is the history you haven't
read, and we're not teaching these things, and
they don't occur in other things anymore like they
used to. Thank you.

DR. DAVIS: Dr. Weiner.

DR. WEINER: I have a slightly
different line of questioning for the two
nonsurgeons that spoke with us as part of a larger
organization, specifically Dr. Stiles from Kaiser
and Dr. Still from Geisinger, both internists.
Although we're focusing on the surgery, part of
maximizing the benefit is getting the right
people, you know, avoiding type one or type two
error, that is, people that need a surgery get it,
and people who don't need the surgery don't get
it.

From your experience, again, as primary
care physicians working closely with surgeons,
what payers out there have gotten it right in
terms of criteria, particularly morbidities, BMI,
you know, based on the evidence and based on your
experience, would you like to recommend to us?

DR. STILL: Well, in central
Pennsylvania there is a whole host of different
insurers with differing criteria. I think that I
will just say the most common ones are a body mass index of 40 alone without any comorbid medical problems, or between 35 and 40 with comorbid medical problems. Initially when we started our program, our own health plan only reimbursed for a BMI of 45 and higher with two uncontrolled medical problems. I think that was too high for a new program starting out, as we've talked about today, so I think the NIH guidelines, I think from a risk stratification from internal medicine is appropriate, for a BMI of 40.

I would just like to comment with regards to ACGME with regards to the care of these bariatric patients. We do have a bariatric medicine fellowship for internists for special training in bariatric medicine. It is nonfunded, a non-ACGME-funded fellowship. And I think like the fellowships for minimally invasive surgery or bariatric surgery, bariatric medicine fellowships may be a great asset to come together to pull the centers of excellence together.

DR. WEINER: And more comments? I'm fairly convinced if you get good surgeons out there, they will find people to do the surgery on. But the issue of, as internists, if you can
comment on trying to see that only the right
patients are directed toward the surgeons. Again,
do you believe the criteria that you've expressed
will do that?

DR. STILES: As I see it, I'm a family
practitioner, is what I look at, I look at all
people who come for a potential surgery, and we
look at that them to make sure that they are, my
wording is, are you safe for surgery. We give
orientations to approximately a hundred patients
every month in small groups and we spend a whole
day doing that. At that time I give a pre-lecture
on what I mean by safety, because especially in a
managed care organization, so many people come in
feeling like they deserve the surgery, and indeed
they do, but I really feel that a safe patient is
the one we need to operate on, and I can say that
makes you have far less problems during the
surgery and after surgery.

And then what we do after that is we
make sure that that happens. I do, as I said in
my study, we look at the evidence and we look at
what the comorbidities are that could get our
patients in trouble, and we do every single thing
possible with many studies throughout our 30-plus
facilities in northern California to make sure
that the patients are safe.

And furthermore, the safety really has
to do with what you do with them afterwards, as my
distinguished colleagues have said. I think one
of my jobs at Kaiser is to meet with primary care
doctors throughout northern California to make
sure we have standards of care, to make sure that
not only are they followed at our center, which
they are able to be followed at all the time, but
also that doctors in the emergency rooms in the
primary care facilities have constant
communication with us so that when something is a
complication, they understand whether it's a
complication of the bariatric surgery, and I think
that's something that we're allowed to do.

DR. FISCHER: Could I just address your
question, just telling you how we reorganized our
bariatric surgery program, which is a big program.
In the newest program, in which we invited about
four internists to join the obesity center, every
patient who comes in will come in on the medical
side, and they will have the usual counseling and
interviews, so they will go for medical therapy
for six months and then if they don't make it in
six months they're referred for surgery.

We also have a tie-in with Jeff Flyer, who's probably the leading basic scientist in obesity in bench research and clinical studies.

DR. WEINER: Is that part of the criteria of the certification we heard about, or is that just what you folks do on your own?

DR. FISCHER: I don't know that it is yet, but I really think you have hit the nail on the head. There probably is a subset of people that can -- don't forget, we're next to the Joslin Diabetic Center and half of the patients we operate on are diabetics, so there is a strong tie-in between the two.

DR. ALLEN: Jeff Allen, University of Louisville. I'd just like to comment briefly on the question about the right people getting the operation and the wrong people not getting the operation. There are basic NIH criteria, BMI of 40 or above, BMI of 35 and above with comorbidities. That's very arbitrary. There are certainly people outside that realm that will benefit. For instance, there are studies being done in Australia, BMI 30 to 35 and diabetics, where a small amount of weight loss compared to
the 400 or 500-pounders can make a significant
difference.

I think it's a fundamental
philosophical question where if you believe that
obesity is a disease, and I do, and if you believe
that you have the treatment, which I think we do
in some form of surgery, then it seems unethical
to withhold it from patients who will benefit from
that. And like I said, the BMI 40 is an arbitrary
thing. Consider a schizophrenic patient, and I've
operated on schizophrenic patients. We send
people to -- many people will send patients to a
psychologist to screen them, but would you
withhold treatment from a schizophrenic patient
who has an abdominal aneurism or somebody who has
cancer, or would you withhold it from a patient
who is 17 for a lap band because it's FDA off
label?

So I think perhaps the answer is
perhaps more in outcomes, and as bariatric
surgeons we have to better define who will
benefit, but I think it's important to bear in
mind that the BMI of 40 or above, or 35 to 40 with
comorbidities is very arbitrary and there are
certainly people outside that population who will
We're going to take one more question -- well, go ahead and respond to that.

Barry Fisher. I just want to comment on trying to identify which patients will benefit and which will not. There have been several studies that have looked at preoperative predictors of poor outcomes, and none have come up with any conclusions. As I look retrospectively at my own practice, the only thing I can find is that patients who do poorly are patients who don't comply. And so the only criteria we've applied in our practice is patients who have a history of poor compliance with medication for treatment of medical conditions, we don't operate on. Other than that, I would second what has already been said.

We'll take one more question, Dr. Klein was going to ask a question, and then we'll get an answer to that and then we'll proceed with the other public presenters.

This is regarding the elderly issue specifically, and I think it should be addressed to maybe Dr. Flum and possibly
Dr. Wolfe as well. A lot was said about age increasing your risk of complications and mortality after surgery, which is true of all operations, and I know there's very little data, but could you review for us specifically the data that's available regarding the actual complication rates, mortality rates in older people 65 or older, versus younger people having this operation, and how that compares to older and younger people having other operations like colon cancer surgery or whatever is a similar type of morbid complication?

DR. FLUM: I'll start with some of the observational studies that are out there which we know of. Dr. Sugerman reported zero mortality in a cohort of patients over the age of 65 having a gastric bypass. We know in data from our own state, we clipped the cohort at 65 because of an a priori definition of what older was. But as you get to 60, 61, 62, 63, we see the mortality rate creeping up and creeping up higher than that 2 percent rate we talked about. Now that parallels very nicely to colorectal operations or the data on hip arthroplasties.

The real question here, and this now
broaches the last question, is the question of risk and reward. As you get older, the rewards shift from survival extension to quality of life and comorbidity improvement, and so that data is wholly unavailable.

DR. WOLFE: Bruce Wolfe. The data that the risk, mortality risk of obesity diminishes with advancing age is not new, so we have been aware of that for many years. It's been intuitive that operative risk would rise with advancing age, and now there is data to support that. Those two facts taken together have led many of us who have been doing bariatric surgery for many years to discourage patients from undergoing surgery, so the total number of patients over 65 who have actually undergone bariatric operations is obviously very small, and that is presumably the reason that there aren't more data published on the subject, there haven't been very many done.

In the public comment, the details of the Medicare experience and just what, who are the people covered by Medicare that have undergone bariatric surgery, in essence shows that 80 to 90 percent over the last three years have not been 65 years of age, so the vast majority of Medicare
beneficiaries have been in the disabled group who
are not qualified for Medicare on the basis of
age, so the total number of subjects to analyze is
not very great.

It's a reasonable hypothesis to pursue
and hopefully the expanded database that the NIH
consortium will address will be large enough to
address the issue more specifically, but we as
individual surgeons have to be cautious when we
see a patient that is over 65 in presenting the
outcomes data to them.

DR. DAVIS: Thank you. I hope most of
the presenters or all of them will be able to stay
until our afternoon session, because I'm sure the
committee members would like to continue this
dialogue, but in order to squeeze in the other
public presenters before the lunch break, let's
move to them now.

The first on the list is Morgan Downey.
And again, we will try to limit these, we will
limit these to three or four minutes and again,
ask the presenters to indicate any financial
conflict of interest and how they had their way
funded to come.

MR. DOWNEY: I'm going to withdraw. I
don't think I have anything to add at this point.

DR. DAVIS: Thanks for being with us.

Monica Ganz.

MS. GANZ: Good morning. Thank you all for allowing me to be here and addressing the panel and committee and everyone else. My name is Monica Ganz and I am from Woodland Hills, California and I represent Obesity Help, Inc., which is a supportive and resource group for morbidly obese people. We are on line face to face and we provide a place for morbidly obese people to come and get answers, information, resources, friendship, support and help.

I'm here to represent over a quarter of a million of our members who are all morbidly obese or who have gone through some form of weight loss surgery, myself included. This is me just three years ago, less than three years ago. It's a visual. I'm a visual teacher. I weighed over 450 pounds at the time and I'm only five-two. I could not walk or function as a normal human being, and as Dr. Wadden spoke of the psychosocial issues, I was a victim of all of those, ridicule, discrimination, I just wanted to be normal again. I had no other options. I suffered from sleep
apnea. Diabetes, my triglycerides were at 788. My cholesterol was at 358. And to say I was a walking time bomb was just, I couldn't walk, so that couldn't even be.

On January 14th, 2002, Dr. Edward Livingston saved my life by performing a Roux-en-Y gastric bypass at UCLA. Within one year, all my blood levels were back to normal, I'm no longer on the sleep apnea machine or CPAP. I went from being a nonproductive member of society to being a participating member of it again. If I had not been married, I would have been unemployed and on disability and a Medicare recipient myself. I am now down 266 pounds, paying taxes and supporting the system instead of living off of the system.

Obesity Help has approximately 4,800 members on Medicare, and that's what's in that box, a message to you from each of them. They are all concerned about what is being decided here and they wanted their voices to be heard. Of that, 255 of them are 65 years or older, which is about 5.3 percent, but let me say by being morbidly obese and being 65 and over is an oxymoron, as anyone who is morbidly obese doesn't have much chance of hitting 65.
And as many of the doctors and surgeons can confirm, as they did in some of the talks earlier, not only does the surgery need to be covered, but the support system pre and afterwards needs to be covered. In my travels because I set up support groups for Obesity Help, I talk to the patients all the time, pre and post, and the most successful ones are the ones that are in a supportive environment continually for years afterwards. We are no different than the alcoholic or the drug addiction, we just have a food addiction, and we continually need to be surrounded by people that understand what we are going through and battle those issues day to day. We ask that Medicare makes an educated and timely decision, and listen to the many silent morbidly obese people that I brought their voices with me in a box. I again thank you all for listening and making an educated decision.

DR. DAVIS: Thank you. Dr. William Denman, if I'm reading this correctly.

DR. DENMAN: Good morning, and thank you very much for having us be able to testify to you. I actually have two hats. I am the medical director for Tyco Health Care, but I'm also a
practicing anesthesiologist with a subspecialty in pediatrics. So to all my surgical colleagues, I want you to know that we are on the same side and there is an alignment here.

I would like to just address something to the panel not completely about morbid obesity surgery but about the things that we deal with in those patients who are morbidly obese who haven't had the weight loss procedure. Those of us who teach anesthesia certainly inform and try to impose upon our residents the issues that they're going to face when they're dealing with patients who are obese and particularly morbidly obese. Things that we deal with are positioning; it's very very hard to position patients who are morbidly obese or very heavy. The number of times that we put to sleep and have to deal with patients who are not coming for bypass surgery but are morbidly obese and having other types of surgery is obviously exploding at the moment.

Tremendous trouble with pulmonary function. Postoperatively I run a pain service in my hospital to try to deal with patients who are morbidly obese who can't breathe who have pulmonary dysfunction, and trying to manage their
pain acutely and chronically is incredibly difficult.

Cardiovascular problems obviously, hypertension and all the issues that we see here that we deal with in the morbidly obese are present in the patients that are obese coming for other types of surgery. Aspiration, difficult airways, et cetera.

So, I guess the point I'm trying to get across here is for those of us who are dealing with morbidly obese patients who are not coming for morbidly obese surgery, and the wonderful thing about those patients is if we're dealing with all those issues, is that there's light at the end of the tunnel for them. What I would suggest and what I would hope that we would continue to do and obviously I wear two hats, so I want everyone to understand that, is that as I see an explosion in the comorbidities that we're facing in the rest of my surgical patients that I deal with, the thought of being able to decrease that and to decrease the number of operations we may be dealing with because of morbid obesity is obviously something that this side of the blood-brain barrier is very keen on. Thank you
very much.

DR. DAVIS: Any conflicts of interest?

DR. DENHAM: I'm hoping Tyco is going
to pay my way, but obviously yes, my travel and my
appearance here is based on the fact that I am the
medical director for Tyco Health Care.

DR. DAVIS: Thank you. Henry Alder.

MR. ALDER: Good morning. My name is
Henry Alder, I am with Ethicon Endosurgery, a
Johnson & Johnson Company. In terms of conflict
of interest, Ethicon Endosurgery, J&J will be
paying my way.

I wanted to just add some perspective
to question number five on the questions, the
Medicare population aged 65-plus. We took the
liberty of looking at the MedPAR data, which is
CMS's own Medicare database, and looked at the
prevalence of bariatric gastric bypass surgery
under ICD 944.31 to look at the number of
procedures. In 2001, there were a total of 2,250
procedures done on the Medicare population. That
increased to 3,603 in 2002, and then up to 5,438
in 2003. But within the that population of
Medicare patients, going back to 2001, only 8
percent were over the age of 65, greater or equal
to age 64, that is 177 patients. In 2002, 329
patients were greater or equal to 65, which made
up 9 percent of the Medicare population. And in
2003, the total Medicare population over 65 was
672, or 12 percent. So that would probably
suggest that the Medicare population that is
benefitting, again, just from this one procedure,
gastric bypass, is probably going to be the
disabled or potentially those who are suffering
from kidney disease. I thank you very much for
your time and appreciate it.

DR. SUGERMAN: Henry, do you have the
mortality data, I think it was already alluded to,
in that MedPAR?

MR. ALDER: I had the mortality data
but I didn't make it available for public comments
today.

DR. DAVIS: Is it Mike Christeau?

Nick, sorry about that.

DR. CHRISTIAN: I'm Nick Christeau,
professor of surgery at McGill University in
Montreal, Canada, I am director of the bariatric
surgery program up there. You've heard people
mention my name here today and I rise to clarify,
because we were limited somewhat this morning, to
clarify a little bit the issue of comorbidity and
whether, because you have two of these sheets that
you have to vote on and you heard a lot of my
colleagues say this morning that the data on
patients without comorbidity really doesn't exist
because there are not that many people who don't
have comorbidities.

In our particular study, which you
heard parts about, on over a thousand patients
that underwent bariatric surgery at our center
compared to about 5,000 controls drawn from the
administrative database of the province of Quebec,
what I would like to point out is that this
particular database is a single payer system.
Therefore, anybody that dies in the province of
Quebec, some physician has to fill out a death
certificate and charge them the $12.50 fee that
he's entitled. Therefore, we capture all
treatments, mortalities, hospitalizations,
physician visits, prescription medications, and it
gives us an indirect access to the comorbidities.

So when we show that surgery reduces
the cancer visits for example, what we did with
the study is we excluded for the six months prior
to the entry in the study those who had already
seen a physician or had gone to a hospital for
either a cancer-related diagnosis, infectious
disease, or musculoskeletal. And even though it's
not perfect and clean and pure prospective
randomized trial, it does indicate that at least
for the six months prior to entering the study,
those people were not going to the hospital using
up health care for these conditions, but
afterwards there were marked differences between
the two groups.

Therefore, one can infer from this
data, and I know the statisticians in the group
may not like this, but one can infer that even if
you do not have comorbidities, over a five-year
follow-up with this particular study, the people
that did not have the operation in the red have
much higher incidence of these comorbidities as
reflected by them going to see a physician or
being hospitalized for their treatment. The same
thing goes for respiratory and mental disorders.
And the digestive disorders being higher serves as
an internal consistency control of our data.

Now prior to coming down here, I
reviewed our own database which has been kept
since 1964, our registry in paper form, and then
switched to electronic in 1995, and now we can
search it effectively. And unfortunately for us,
even though Medicare covers this procedure, we do
not get paid by the patient, there is a global
budget and within the global budget I have to
fight with the cardiac surgeons and with the
orthopedic surgeons for resources to perform these
surgeries. Therefore, the waiting list is up to
five years. My own personal waiting list right
now from the time somebody calls the office until
going in for surgery is about 5.2 years, and up in
Quebec City it is the same thing.

And I queried our database and we have
had three deaths within people waiting for that
period. One was a lung cancer that obviously
causethes patient's death, one was a patient from
a cardiovascular event, and one was a suicide from
a mental disorder, and I think we're
underestimating the mental disorders that you see
here.

The other good thing that came from
this study is that since the number of
hospitalizations and hospital days and physician
visits were markedly decreased in the bariatric
cohort, this translates to a very nice argument
that I could certainly make with our single payer system, and I think would apply to Medicare here. And that is, if the Minister of Health tomorrow in the province of Quebec, or in Ottawa more centrally, were to invest $8,500 Canadian for a patient to undergo this bariatric surgical procedure at times zero, and that gives us the first year that you see here on the left. And then we accrue the cost savings.

Mr. Willis indicated how much he who was paying for his medications. This is hard proof that indeed, there are cost savings. After about 3.2 years the color changes because now the ministry actually saves money, or the single payer system saves money by investing that $8,500 at times zero to have the patient operated, to have them look at some of the patients that we saw today. Thank you very much for your attention. I'd be happy to answer additional questions in the afternoon on this subject.


DR. KRAL: I'm John Kral, I'm a professor of surgery at SUNY Downstate in New York. I am employed by New York State and by New York City. Throughout my career since 1970 when I
started operating on people with obesity, I have been an employee of university hospitals. I've never derived any financial benefit, nor has my employment even been dependent upon my operating on obese people. You will not hear a commercial. I paid for my own trip.

The reason I am here is not to extend, and certainly not to stand between you and lunch, it's not to extend the tutorial that you have been subjected to this morning, I think everybody has done their best. I'm here to express my concern over some of the issues that you will of course, that are possibly clouding your interpretation of data and how you look at what has been presented today.

I think you have been perfectly apprised of the fact that you can tear up the sheet that says, that provides the questions about with no comorbidities, I think that has been made abundantly clear, that that's an unnecessary exercise to even consider that in people 65 or older, or those younger in Medicare who are already disabled.

As far as quality of data, though, I want to address that a little bit too. I do hope
that you have understood also that the standard, the human cry to see, as with drug studies, prospective randomized controlled trials is neither ethical, scientific, nor even feasible to perform. Not to cloud the issue of approach, I'm going to make a rather strong statement. If you were to have a show of hands here amongst the surgeons, let's do the following little experiment. Let's assume that the surgeons, that some of the surgeons here are severely obese and need an operation. I'd like for you to ask for a show of hands whether they would like the surgeon who's doing the approach laparoscopic who's done a thousand laparoscopic approaches, or to be randomized between that and having a surgeon who has done a thousand open approaches do their surgery. I would imagine that nobody would be asking in the year 2004, 2005, to have their surgery done openly, everything else equal.

Now, as far as publication bias is concerned, and that's something that you have to be concerned about, having heard so many advertisements here this morning, I think Dr. Christeau has the type of evidence and the type of material that is rather free from that. I
think the efforts being made by the Surgical Review Company, you heard Dr. Pories present the efforts that are being made, and Dr. Fischer from the American College of Surgeons. Registries and capturing is a good thing.

The experience from Canada, and I have personal experience from Sweden, where there is virtually no non-government paid surgery performed for obesity, all patients are there being captured, there is virtually no private sector there at all. You can trust that kind of data when it comes to outcome evaluation, and not fear the publication bias that you're always going to have when people are advertising their wares.

Thank you for the opportunity to be heard.

DR. DAVIS: Thank you. Dr. George Cowan. He's the one who stands between us and lunch.

DR. COWAN: Yes, I'm standing indeed.

I thank you very much for the opportunity to stand. I am past president of the American Society for Bariatric Surgery, founder and past president of the International Federation of Surgery for Obesity, co-founder of the Journal of Obesity Surgery, and a few other things. More
importantly, I became professor emeritus, got my honrable discharge at the University of Tennessee at age 66 this year, so I am free at last. However, I am currently very minimally part-time employed by Specialty Health Services, and I hope they will pay a little bit of my trip here.

I have three main points. One is as we heard, the vast majority of individuals receiving Medicare coverage are disabled, they are not over 65, so the age thing is relatively irrelevant right now, although we may be in the future looking at that because we hope more individuals if they survive that long, may indeed have the privilege of the surgery. My father died at 60, never got that far, morbidly obese. The average age is about 50 years. After the surgery, about a year later, the majority return to the work force, they return to the work force and two major things happen. One, they are no longer receiving money from the government on the dole to support them because they're disabled, and they in turn are making a salary and paying taxes to the government to support others who are disabled. It's a double benefit.
The study from Sweden in our first issue of Obesity Surgery 14 years ago showed clearly that in three years those who had the bariatric surgery paid sufficient taxes to recover the cost of the bariatric surgery, isn't that amazing, and you have 12 more years to go until you reach Medicare age in that sense if you're looking at the numbers. So there is a dramatic turnaround of not paying money for support for the disability, and people paying taxes in addition who are supporting others, it's a double benefit of the surgery.

Look at also at the competitive surgeries for the limited dollars of Medicare or limited support. It is competing with CABGs, it is competing with hip surgery, average age 70. These people do not return to the work force. They are in better shape to the love of their family and their grandchildren and such like, but they don't have that additional 15 years of actually paying taxes, the opportunity to pay taxes, the opportunity to make a living and come off the dole. And this is very important if you're looking at the limited slice. I'm not saying to withdraw CABGs or to limit them for
Medicare, but I'm just saying if you're looking at the benefits of bariatric surgery, it's way up there, it's the best bargain that Medicare has and offers, that it gets back to the American taxpayer.

Secondly, the comorbidities, I agree with Dr. Kral, that's basically in the tank from the point of view that most Medicare individuals that are disabled and are disabled by the comorbidities, therefore why are we worried about comorbidities versus none when somebody is morbidly obese. However, those few percent that I've maintained in my experience of 4,000 bariatric surgeries, that the people who have no true comorbidities are those in the ages of about 16 to about 25. They have psychosocial comorbidities of sorts, but physically they are pretty limited, I will agree. However, that's not what we're dealing with or talking about today, but those same 16-to-25-year olds, give them five or ten years and they're all going to have comorbidities, they're there. And therefore this is a non-issue, because I ask the panel to look at the potential for development of comorbidities, what is the percentage of development of
comorbidities? It's 95 to 98 percent. Why?
Because these individuals will not succeed with
voluntarily weight loss, they are failures. And
when they fail, they get bigger and bigger and
bigger after perhaps having lost vast amounts of
weight, but they get bigger, develop the
comorbidities, and then the potential for
comorbidities is important to consider the same as
comorbidities, it's virtually 100 percent of those
who come to surgery.

Third, we should indeed with Medicare
insist on standards. Should we insist on a
particular purveyor of standards who says you are
okay, you are not? I don't know that Medicare
really wants to go that far, but I would suggest
that there's an excellent set of standards that
have come through the American College of Surgeons
that Dr. Buchwald has helped to write from the
American Society for Bariatric Surgery, and these
are also in part some of the basis for the SRC
standards, which I would certainly ask the
panelists to look at from the point of view of
valuable standards themselves, not necessarily the
organizations, but the standards, although the
organization is pretty good too, but the standards
are something to look at and certainly could be
made available.

   Last, I would like to give you
something some of you might see as humorous.
People have called obesity a political disease,
morbid obesity a political disease. You can argue
about that. You can't argue with the people who
have testified today that they were diseased and
that they were fat and they are smaller and they
are no longer diseased.

   Now, nine out of ten of all the cases
of diabetes mellitus would not exist if we had no
obesity or overweight. Think about that. Which
is true? Is diabetes the disease or is obesity
the disease? I would maintain that in nine out of
ten of those individuals who are large, that
indeed diabetes mellitus type 2 is a secondary
condition to the disease of obesity. So maybe we
ought to downplay diabetes mellitus to a condition
and admit that obesity is the disease. Just a fun
think point, but thank you very much for the
opportunity. I am also the historian for the
American Society for Bariatric Surgery and I'm
looking forward to seeing the results of history
being made today and having the privilege to
report that for the future in some of our work.

Thank you.

DR. DAVIS: Thank you very much. A lot

of food for thought for the lunch hour. We'll

break for 60 minutes. It's ten after 12 on my

watch, so 1:10, we will reconvene.

(Luncheon recess.)

DR. DAVIS: I think we'll get started.

Some people might have gotten stuck in the

restaurant because they obviously weren't ready

for the large crowd given the bad weather outside,

but we're scheduled to go from now until 4:15 or

so, including discussion and voting. That's not

to say that we have to use up all of the time if

we don't need it, but we did have a lot of useful

dialogue and Q&A in the morning, and I think we

might as well just pick up where we left off

before lunch and open it up for questions from

committee members after Dr. Phurrough makes a

point.

DR. PHURROUGH: I would just like to

clarify CMS's current issues around bariatric

surgery. First of all, we are well aware that

there are very few Medicare beneficiaries over the

age of 65 who are currently getting this surgery,
we understand that. However, 90 percent of our population falls into this over 65 age group, and as the numbers Dr. Alder presented right before lunch, even though those are small numbers, they represent a 2 or 300 percent increase in the number of patients who are getting this procedure who are over the age of 65, and that number is obviously going to grow as our population grows. We add just about a million new beneficiaries every year over the age of 65, that's the population of our country that's reaching the age of 65 annually, and there's going to be a spike in that in the next couple of years.

So we're aware that it's not a big issue currently in the 65-plus population, but if we are in fact going to change our policy at all, we obviously have to address whether we are going to change that policy and how it affects the vast majority of our population, those who are over age 65. And in fact, we may need to have different policies based upon age or different indications or different criteria based upon age. So that's the reason why we want to know and we've asked the question such that, what's the benefit of this particular surgical procedure in the literature,
and then can you apply those results to the 65-plus population.

Secondly, there has been the question of why are we asking about patients who don't have comorbidities. Everybody who's morbidly obese has comorbidities. Everybody who's over age 65 and who's obese has comorbidities. Well, the reason we're asking that question is we've been asked to ask that question. The public is interested in why we have a procedure limited to patients with comorbidities when in fact patients who don't have comorbidities might benefit. So because we already have a decision around patients who have comorbidities, we need to ask the question around patients who don't have comorbidities, and if the answer is those patients don't exist, that's fine. Though, in spite of some of the comments we've heard today, we have been concerned in reviewing some of the literature that if you add up all the comorbidities that are listed in the patient populations in the trials, it doesn't end up being the entire population that was treated in the trial, so they are obviously either not asking the question, not asking the question extensively enough in identifying all the comorbidities, or
there are patients who don't have the
comorbidities. So, we think it's a legitimate
question even though the population may again, may
not exist.

Also, I just want to clarify, we
understand that our questions sometimes appear
outside current practice or outside current
populations in which we are providing
reimbursement, but they are in fact we think
appropriate questions based upon our current
policies and the potential to change that policy
in the future. So, I hope I have not confused
that more, I just wanted to clarify. We do
recognize some of the difficulties in the
questions.

DR. DAVIS: Dr. Weissberg had his hand
up.

DR. ABECASSIS: I just wanted to
clarify the clarification.

DR. PHURROUGH: I must be a good
bureaucrat, I've confused you more.

DR. ABECASSIS: I just have a very
specific question about the whole sheet on
patients without comorbidities, and one of the
questions asks how we expect these procedures to
affect comorbidities. In the patients that have no comorbidities, am I to assume that that means prevent comorbidities?

DR. PHURROUGH: Yes.

DR. DAVIS: Yeah, Bill.

DR. OWEN: I have a question and I don't know if this is the appropriate time to pose it.

DR. DAVIS: Yeah, go for it. That's fine.

DR. OWEN: This has to do with the issue of comorbidities. Unencumbered by any knowledge, I was likewise impressed that there was some sort of, I will presume ascertainment bias in the papers that were submitted to us, because it's exactly as you say, it doesn't add up to 100 percent of the patients that have comorbid conditions. So my query is, does anyone here know if there are any longitudinal cohort studies that are ongoing of patients who have BMIs of 35 or above, a natural history study, so that we know if this is true, I have to take the data as it is, and there are patients who are listed who don't have any, so do we know if that group behaves like an equivalent group that does not, or should I say
who does have it.

    DR. DAVIS: Please. And if you could
mention your name again, that would help.

    DR. KRAL: I'm John Kral, from
Downstate. The Swedish study is a longitudinal
study looking at the natural history of obesity,
and their inclusion criteria actually noted a body
mass index of 34.7, and that is ongoing for many
years and should be able to answer that query as
far as prognosis is concerned. That's probably
the best available data.

    DR. SUGERMAN: Did it show that there
are progressive increases in the comorbidities,
all of them that are listed?

    DR. KRAL: Yeah, there's a progressive
weight increase and there's a progressive
deterioration in all of the -- they develop
comorbidities that weren't there to begin with,
and the ones they have are aggravated, even though
they're trying to control them.

    DR. OWEN: I'm aware of the ones who
already have coexisting disease worsening, but
they have a subgroup that they follow that we will
ultimately have access to that will have no
comorbidities that we can do a natural history on?
DR. KRAL: Yes, because the whole population is captured and it's a national data bank.

DR. MARGOLIS: There are also studies ongoing in this country, NIH sponsored studies usually looking at educational interventions or medical therapies or individuals over time to see how effective or ineffective they are. Although they're not directly answering your question, they are looking for those sorts of things, so that either exists now or could exist as a secondary analysis from those studies, and I'm aware of two of them and I'm sure there's more.

There's studies usually sponsored by NIDDK looking at long-term effects of educational interventions in obese populations, some within minority groups, some within the general population, and they are usually looking at interventions and weight loss, but certainly they're looking for other illnesses as well and those answers could be there. Now whether or not there is morbidly obese, as some of the patients we're talking about here, I don't the answer to that, but I know they exist.

DR. DAVIS: I was interested in looking
a little more carefully at the Swedish study and
that's why I asked CMS staff if they could
distribute copies of the paper to you, which I
think they did earlier in the day, although you
don't have the complete article unfortunately, at
least my version only goes through page 6 of 16.
And of course the study was referenced in a lot of
the technology assessments that we have been
given, but one question I had about this ties into
the question that was just raised, and that is,
what happened with the control group in the
Swedish study? Were they subjected to any sort of
nonsurgical intervention? And the pages that we
have do reference at the beginning of the results
section that the control group was conventionally
treated, but I don't have any more information
than that. I don't know if anybody else has any
more information on what happened to the control
group in the Swedish study.

DR. PORIES: Dr. Kral can answer it
better than I can, but just very quickly, the most
disturbing evidence of what you want, Dr. Owen, is
what's happened with children. As we now see this
epidemic of adolescent obesity, we're now seeing
adult onset of type 2 diabetes and every one of
the complications coming on earlier, and I think
that shows that along with the obesity, this comes
with it.

DR. KRAL: John Kral. Medicine in
Sweden is subsidized, so it is not out-of-pocket
expenses. All the subjects who are entered into
this are receiving what is called conventional
treatment, meaning whatever is offered by their
general practitioners, and it includes anything
from diet, diet and exercise, behavioral, and
cohorts with drugs, so anything but surgery is
what they consider to be part of the control
group, and it is simply a community practice as it
is provided, and it is provided.

DR. DAVIS: Dr. Weissberg.

DR. WEISSBERG: Let's shake it up a
little bit after lunch here. The panel has to
make decisions about the different types of
surgery and we've heard a lot about the fact that
all of these variety of surgery can be done safely
and well. The question, though, is for this
increasing segment of the American population,
neither commercial or eventually Medicare, only a
tiny fraction of whom are currently accessing any
of these approaches, where should the locus of
control be for determining which patient gets
which operation? Should there be a web site that
helps the patient work through if there are
trade-offs between more gradual but continued
weight loss with lower risk of immediate
complications for a lap band, or more profound
weight loss for a duodenal switch at the expense
of a longer operating time and a higher number of
reoperations? Where are those decisions supposed
to get made, and are the centers of excellence
that we vaguely referred to going to be set up so
that different operations are all available in
each one of these centers?

DR. PORIES: My name is Pories and I'm
rising again, sorry. That's probably one of the
most fundamental reasons for setting up the
centers of excellence, is to develop a database on
standardized operations in well-described
patients, and then at the same time make sure that
these databases are coordinated with the ones from
the NIDDK lab study. And as you probably know,
we've just finished developing the databases for
the lap study, it took us about a year. So I
think you almost have to sort of look at these
operations in the same way we look at antibiotics.
There is no one ideal antibiotic for all infections, there is no one ideal antidepressant, and I don't think there is one ideal operation for all patients.

DR. WEISSBERG: But an internist has the option and the facility to prescribe one of 20 different antibiotics equally well. I get the impression that surgeons specialize in their procedure of choice.

DR. PORIES: I think in most centers now, taking some time with some, certainly the bands and the gastric bypasses aren't being offered, the duodenal switch is coming in a little bit more slowly but is also being considered. We didn't feel in the centers that we could prescribe what operations a surgeon should do, they have to choose that themselves and then tell us exactly what we're doing, and then promise to do it in a standardized fashion long enough that we can gather the data.

DR. DAVIS: Dr. Sugerman, you had your hand up a few moments ago.

DR. SUGERMAN: I did, and I just want to go over one more time some of the concerns that have been mentioned here, not as a question but as
a statement. And again, I'm here on the panel but
I'm also the president of the American Society for
Bariatric Surgery. I think you have heard over
and over again that there is a really major
problem with the unequal distribution of coverage
for Medicare patients from region to region in the
country regarding both the types of eligible
comorbidities and the types of bariatric surgical
procedures, and whereas some places will support
this operation or that operation, it's variable.
And that surgeons in hospitals are performing the
procedure without a guarantee of reimbursement, so
there is a risk to operating on one of these
patients if you're not going to get paid for it.
And then each of cases requires additional
bureaucratic review of every case as to whether
there is an adequate comorbidity or not.
In terms of comorbidities, I like to
say that this disease starts at the top of the
head and ends up in the toes, and it hits every
single organ in between. And the problem with the
manuscripts is they don't look at every single
comorbidity. For example, Dr. Buchwald's paper in
JAMA looked at four. And you know, that's why you
don't see 100 percent comorbidities perhaps in
these manuscripts.
So from my point of view, it seems to me that the Medicare system, and it would require a new decision and coverage decision, should use the 1991 NIH criteria. It would then increase uniformity of access and assure surgeons and hospitals of appropriate reimbursement and improve bureaucratic efficiency. So, I'm just making it as a statement and throwing it for discussion, even though I know that's not the questions we're being asked.

DR. DAVIS: I have Doctors McNeil, Raab and Buchwald on my list. Barbara?

DR. MCNEIL: I'd like to ask Dr. Alder a question. Is he still here? You mentioned before lunch that you had done an analysis of the MedPAR file and gave us the figures of the increase in percentage of Medicare individuals over 65 who were having bariatric surgery between '01 and '03. And then somebody asked you a question about the mortality results and you said you didn't have them, you had them but you didn't have them. Could you say a little more about that?

MR. ALDER: Sure. First of all, it's
not Dr. Alder, it's Henry Alder.

DR. MCNEIL: Okay.

MR. ALDER: And we did have mortality rates, but they were in the computer, so over lunch I was able to download it, and I have mortality rates for the Medicare population.

DR. MCNEIL: Oh, good. What are they?

MR. ALDER: This is for all Medicare, and for 2001 was 1.2 percent; 2002, 0.9 percent; and 2003, 0.8 percent. And this is for all Medicare beneficiaries.

DR. WEINER: Over what period, one-year mortality?

MR. ALDER: 30 days. Now we also have average length of stay.

DR. MCNEIL: How about, though, for the over 65, that was my real question.

MR. ALDER: We don't have it segregated by age.

DR. MCNEIL: But you could, right?

MR. ALDER: It's evidently an opportunity to do that, and going back to our vendor to get that segregated, right.

DR. MCNEIL: Oh, a vendor did this for you?
MR. ALDER: A vendor did this for us, that's correct.

DR. MCNEIL: It would probably be very useful to have that information; as a matter of fact, it might be essential.

MR. ALDER: Yeah. Just some added information. This compares very favorably with some other procedures that are performed.

DR. MCNEIL: I actually understand that. I guess what I'm -- I was very impressed actually by the similarity of these mortality rates, however the procedure is done, with CABGs and hips and whatever. But I'm a little concerned that I don't fully understand the mortality rates and the complication rates for the over 65, and I understand that getting complications from the MedPAR file is probably impossible because we don't know what preceded the patients admission versus what occurred at the time of the admission, so I'm willing to write that off as an impossibility. But getting mortality data would really be pretty important.

MR. ALDER: And I would agree.

DR. DAVIS: Greg.

DR. RAAB: A few moments ago, Dr.
Sugerman, I think you referenced a differential access of Medicare beneficiaries according to where they lived, the different types of procedures. Is that due to the local coverage policies, is that it? And I'm curious, maybe Steve knows, what's the range of access? Is it that a certain procedure is prohibited or permitted in certain areas and not others, is that it? I'd be curious, we're talking about the Medicare population having access to bariatric surgery, and I'm curious how much access there is under the current system, what local review policies are.

DR. PHURROUGH: I don't know what all the 51 policies are for 51 different contractors, but in general, my impression is none of them non-cover, they don't have that option. Their options are we have coverage, we don't define except for diabetes and cardiovascular disease, I believe. We don't define comorbidities other than those two.

DR. RAAB: Are they restricting it to banding versus bypass, or are they that specific?

DR. PHURROUGH: They do have the option for defining some of the other procedures other
than bypass where we have a specific decision that bypass is covered using the same comorbidity issues. The other procedures, contractors do have discretion to determine we're not going to pay for that, and I don't know what the range of that is.

DR. DAVIS: Just to follow up on this line of questioning, Dr. Barry Fisher mentioned that some of the cases that he was involved in were denied for coverage by the local carrier even when comorbidity was present. I wonder if you could explain what the situation was there.

DR. FISHER: Over the course of time, as I said, we decided not to take on the Medicare patient population. We were told to code the patients with a 250.00, which is diabetes if they had diabetes, as their primary diagnosis and we would get paid. We were denied. We were told to code them as 278.01, which is morbid obesity, and put the 250.00, and every single case was denied and had to be appealed. And frankly, for the amount of time involved and the amount of compensation, it isn't worth it. So we made a business decision not to do Medicare patients under the Medicare program until that situation changes. That's why I argued for removing the
capability of a medical director for making a
decision based on medical necessity. The criteria
should be clear, should be unencumbered by any
conditionality, and that way if you want the
people to be covered, you want them to get the
surgery, that way you remove any judgment
decision.

DR. FLUM: David Flum. If I could just
echo one point there, it gets down to the issue of
they'll cover the procedure but it's the type of
procedure that they will allow. In Noridian,
which is the northwest regional coverage for 11
states, does not cover for the adjustable gastric
band. So you're asking where the data is for
patients over 65, and we simply can't provide it
to you because we can't do the procedure.

DR. RAAB: In those situations where
carriers have, they have medical directors for
each state but they're making all the decisions
for the entire geography, not state by state?

DR. FLUM: Well the Noridian medical
director, the director of the regional carriers
can make those calls. And just so you know, we're
waiting for this panel to help them make decisions
about coverage, because it really is a decision
that's made on that medical director level.

DR. RAAB: But doesn't that require local carrier advisory committee input state by state, geography by geography?

DR. FLUM: Yeah, but the message that I've gotten is that they take the regional carrier's lead. So for example, if the medical director of Noridian said that adjustable gastric bands seems like something we should cover, then the states would follow.

DR. DAVIS: Is this an answer on this same question.

MR. GARVER: Yes.

DR. DAVIS: Please.

MR. GARVER: Jim Garver, INAMED Health. To answer your question specifically, because we have looked at this on a carrier-by-carrier basis, Noridian, Blue Cross of Kansas, and I just drew a blank on the carrier for Florida, it is principally a Part B issue where the physician services are not being covered where many of the Part A's are covering the hospital stay. So there is a discrepancy, particularly when you have two different intermediaries in a given state coming up with separate policies.
DR. RAAB:  Steve, would that go away under the MMA provisions where the carriers have to coordinate?  No?

DR. PHURROUGH:  We're probably getting a bit far out of the evidence issue, but there are MMA provisions that say we're going to have a new contracting system in which the contractor for a region will have the same Part A Part B, they will not be separate Part A Part B contractors for the same region anymore, but that's some time in the future.

DR. RAAB:  But for a given geography, I thought it had a provision where fiscal intermediaries and carriers have to coordinate.

DR. PHURROUGH:  That is for new policies, it's not retroactive to old policies.

DR. RAAB:  Thank you.

DR. DAVIS:  Dr. Buchwald was next on my list.

DR. BUCHWALD:  Thank you.  I would like to make a few remarks.  I have been trying to figure out what my role is as a guest panelist.  I have a vote, but my vote doesn't count, so I guess that defines my role, and maybe it affords me the privilege of making a few comments.
First of all, I wasn't sure when we were saying our conflicts of interest if our affiliations should be mentioned and I left a few things out, such as I chair the Obesity Coalition, which is a group of essentially every major group in this country, like American Heart, American Medical Association, American Dietetic, over ten groups in this country that are all interested in the treatment of obesity, and on this Obesity Coalition I represent the American College of Surgeons, and I have represented the American College of Surgeons in an annual course on bariatric surgery, putting out a CD-ROM, and as the chair of the National Bariatric Surgery faculty, so I wanted to put that into the record.

Now, a few remarks, if I may. Really, what should a guest panelist do in terms of helping fellow panelists? We should listen to what we have heard, we should take a lifelong experience, and the three guest panelists up here have had a lifelong experience in this field, and try to make it into some sort of a focus on where we would think the situation should go, and I made a few points for myself.

Number one is, we've heard that we need
more data, and there is no physician, there is no scientist in this world that would deny that we need more data probably in every field, and certainly in this field. And having made that statement, the question is where do we go from there. It would be wrong to say we don't have the data, therefore, we cannot make any decisions, or we should deny coverage so that we will never get the data. On the contrary, we should say we should focus on demonstrations, on maybe a Medicare demonstration program that will bring out the data that is currently missing.

So the fact that we have no data on many of these aspects, people over 65 and so on, is not a negative comment, it's a progressive comment looking to the future, and we must obtain these data, and to obtain these data we have to extend coverage and record what happens to these groups that we don't know that much about.

Another point that has been made before but it probably should be reemphasized, that there are probably no patients, especially over the age of 65 who do not have comorbidities, so I know why the question has to be asked, but it's being asked about a population that generally does not exist.
Because if you talk to any person who is morbidly obese, they will have a comorbidity.

The other thing I want to make a comment on is, it is the standard of care in our society to treat disease and to treat it as soon as possible. We don't wait for colonic polyps to become colonic cancers. We don't wait for little breast masses to become big breast masses. We treat a chemical abnormality of the blood, hypercholesterolemia, to prevent the inevitable death that will ensue if it is not treated. We treat the physiologic abnormality of high blood pressure to treat the inevitable death if it is not treated. And therefore, asking the question of patients, even if they existed, who have minimal or no comorbidities, should one treat them, goes against the entire spectrum of our standard of care. We know that the morbid obesity is going to kill them so why shouldn't we treat it as soon as possible, rather than say let's wait until they get a comorbidity, let's wait until this happens.

I'm honored that our meta-analysis paper has been mentioned so many times. What does that show in one sense in terms of the
comorbidities? If you take a patient who comes to you as a physician who has diabetes, type 2 diabetes, hypertension, hyperlipidemia and obstructive sleep apnea, and you treat all of these conditions, you're going to end up giving that patient a whole lot of pills, putting him on an instrument to sleep at night, and you're not going to treat any of those diseases really. You're going to mitigate them, you're going to make the patient feel better for a period of time, but the diseases continue insidiously to work towards a fatal conclusion.

If you treat the morbid obesity, which is the primary disease that causes all these other diseases, you're going to get rid of not only the morbid obesity but you're going to get rid of these fatal diseases.

I listened to a comment talking about prevention and how important it is to prevent. Nobody in the world would deny that it is essential to prevent morbid obesity if we possibly can, but that begs the question, what are we going to do with the people who are morbidly obese? Nobody today would stay we shouldn't treat AIDS, we should only concentrate on preventing it. We
shouldn't treat diabetes, hypertension, we should only concentrate on preventing it. We have to treat the people who have the disease in addition to preventing.

The question of which is the best operation. There is no answer to that question, because it is a non-question. Which is the best operation for what? Which is the best operation in terms of engendering weight loss? Well, you've seen those things, they're up there. Which is the best operation for risk? Those data have been presented and it's a different answer. Which is the best operation for comorbidities? Probably all of them. And then which is the best operation for patient satisfaction, which we haven't really even talked about today, quality of life, patient satisfaction. So how does one make this decision? I think this is a decision that's best left to the patient and to the surgeon and it should not be left to a panel, it should not be left to any sort of set of instructions. Nowhere when any insurance body, Medicare governs fixing a hernia, do they say we want you only to do a Kugel repair, or we want you only to do a Lichtenstein repair. I think this belongs in another spectrum of
discussion.

And I guess that's more or less what I have to say. I think we're only here for a certain reason today, that the morbidly obese are a segment of our population that is still subjected to a great deal of bias and prejudice, and therefore the treatment of the morbidly obese is subjected to a certain amount of bias and prejudice. If we were talking about other diseases, there wouldn't be this conflict, or should we extend to it to people with early disease and so on. I think we have to get beyond the bias. Obesity is the last permitted prejudice in our society, and we must not permit it anymore. We have to say that obesity and morbid obesity in particular is a disease and that today the treatment of choice is bariatric surgery. And I'm sorry I was long winded.

DR. DAVIS: I appreciate your comments.

(Appplause.)

DR. DAVIS: Dr. Buchwald, I just want to interject here that I don't think it's only a matter of maybe a double standard between obesity and other issues. There is a double standard between treatment and prevention, and we struggle
with getting Medicare to pay for a lot of preventive services. Medicare doesn't pay for smoking cessation treatment today although it is now looking at that issue, although of course it pays for treatment of lung cancer and heart disease and stroke, and everything else caused by cigarette smoking. So you have to figure out a way to allow Medicare to pay for something that's preventive by figuring out how to consider it to be a treatment. Well, it's a treatment of tobacco dependence, which is then ICD-9 and DSM-IV. And similarly, it's the comorbid condition that allows CMS to pay for this under existing law. So, I think that certainly there are issues relating to obesity, but there are also vagaries of the law that authorizes Medicare that I think also come into play.

DR. BUCHWALD: And fortunately the law has been amended, so that obesity is a disease, or at least in terms of the strict law, obesity can no longer not be considered a disease.

DR. DAVIS: That's it, yeah, the rule was changed so it doesn't say that it's not a disease.

DR. BUCHWALD: They spoke in a double
negative, but if I can eliminate the double
negative, obesity is a disease.

DR. DAVIS: I think Dr. Sugerman was
next. No, Dr. McNeil.

DR. MCNEIL: I would like to go back to
one of the earlier questions. I must say that on
average as I look at all of the data, it's very
impressive, and I am quite taken by the results.
But I am really still disturbed by one thing, and
it's the following: It goes back to Jed's
question. I had the feeling from listening to
some of the individuals in the audience that many
of the speakers did a particular procedure and
that was their procedure, though they might do
others, but they really really liked whichever one
it was.

So then I was trying to decide if a
patient came to, even if it's a center of
excellence in a hospital with, say, 3 or 400 beds,
what is the chance that a patient would have
access to a surgeon who did all, say six, open and
laparoscopic procedures at a number greater than
50 a year, and how would the internist know which
physician to send that patient to?

That's the thing I'm totally confused
about, because I understand the data in the aggregate, I'm totally convinced, I understand the reduction in comorbidities post-treatment, I have all that, so I don't want to talk about that aspect of it at all. I'm much more interested in understanding from a real quantitative viewpoint, what are the risk selection criteria that are involved in sending a patient to procedure one versus procedure two, and I can't find it in any of these articles and it's got to be there, with all of this writing, someone's got to have done that. So I don't want a qualitative answer, just to be clear.

DR. BLACKSTONE: Let me first say that when you're beginning to develop a program in bariatric surgery, which we've had experience with, you I think need to start with a procedure around which you can build a comprehensive approach where your understanding of the data, if you're going to do evidence-based and data-driven medicine to the extent that that's possible allows you. And so in our view at the time that we started our program in 2001, that pretty much meant gastric bypass Roux-en-Y, we had the most data, we had the best system of care, and we knew
what the benchmarks would be for outcomes from
what had been published.

Patients seeking surgery do extensive
research on the Internet, to your point. Most
patients will come in with a year or more of
research, they have been to many different
presentations by different centers, they spend a
lot of time and energy themselves selecting and
trying to discern from the information that they
have what the best procedure they think is for
themselves.

When laparoscopic banding became
available through the FDA, we actually waited
about six months to adapt it, because we had to
adapt our entire system to it. It's a little
different training, a little different education
about nutrition because you don't interrupt the GI
tract, and these issues have significant clinical
implications for how you care for patients.

So when a patient comes now and they
say Dr. Blackstone, I have been reading about this
for a year and I really want a lap band or a
gastric bypass, we then look at the food journal
they've submitted, we get the data from the
nutritional consult they've just had, we look at
their psychological profile, and together with the patient we make a decision, and to my knowledge that is not actually quantified anywhere, that process.

We do not do the duodenal switch right now, it's a malabsorptive procedure primarily and because of that it requires, again, an entirely different strategy among your supporting allied health team. And in your clinical pathway of care, it's a whole different clinical pathway, and so to adapt that, which we may do, we really need to be convinced that we have a population of patients to whom it will be most applicable, and in my judgment the evidence was that it was less applicable in my population. I could get very good resolution of comorbidities with the bypass and the band, and so we haven't offered it. However, if we were to see a patient who we thought would be best served by it based on what we know, we would refer them to a surgeon who does a significant number of switches or BPDs, so that they could be evaluated for that procedure there.

DR. MCNEIL: Could I just ask a follow-up question, Ron? Could you just give me a little scenario of how that patient that you just
referred somewhere else, what would be the
characteristics of that patient that would be
different from the patient that you kept in house?

DR. BLACKSTONE: Primarily it would be
someone who, A, had a strong bias themselves to
the procedure. Again, you know, as you know, in
real life when you're working with a patient and
they come in with a year and a half of duodenal
research data and say this is what I want, then
even if you think they may be able to achieve
those results with bypass, I think you owe it to
them to allow them to be evaluated by someone who
is very good and has a system that supports the
switch.

DR. MCNEIL: Would you be saying, then,
I just want to be absolutely clear I get this
because I still don't have it, would you be
saying, then, that in the vast majority of cases,
the patient should be the decision maker as to the
type of surgery, and the results will be
essentially the same in terms of short and
long-term mortality, major complications, and
approximate weight loss?

DR. BLACKSTONE: I think that their
preference for the type of procedure has a role to
play. I think that we see patients that we don't think are appropriate for one or the other, and then we work with them and talk with them about why we think that is.

DR. MCNEIL: Could you just give me an example of that, because I really still, I'm not a surgeon and I don't see how this works.

DR. BLACKSTONE: I can tell you in my particular bias right now, based on our results and what I've observed, if we have a patient who is diabetic, we will often suggest to them that we think that the bypass gives better long-term results for diabetes right now, based on what we know. And that might be a more concrete example. Some patients' behavior patterns may not be as good for the band. Again, you're weighing that against their profile. And this is one of the things that I wanted to mention about our population. Obviously if you have a procedure that is less risky that you can offer to an older group of patients who you wouldn't maybe think were good patients for the bypass, for instance, then there is a way to differentiate. You know, you want to be able to offer some less risky procedure to those patients if they can get a
reasonable amount of resolution of their comorbidities and improved quality of life for less risk. So you know, I don't know if I'm being -- you know, it's not as straightforward perhaps as that.

DR. MCNEIL: Well, just if I could push this just one little second more.

DR. BLACKSTONE: I'm not sure I'm glad I got up here.

DR. MCNEIL: It sounds as if you run a fabulous service and are extremely generous and altruistic in sending patients out, so that if a patient came in and your particular service didn't offer the switch procedure, for example, you would send them out. Do you think that happens everywhere, and if it doesn't, then is it possible that a patient is really going to get a suboptimal procedure? And now I'll stop.

DR. BLACKSTONE: It would be arguable among my colleagues whether a bypass could ever be considered suboptimal to a switch. The differences in who would be good for one or the other might be a little bit, you know, that might be hard, so I'm not sure if you couldn't send someone out would be. But the truth is, there are
very good people doing switches in the U.S. that we could send the patient out to, and we would argue and lobby for that if it we felt that was the right procedure for them. You know, I think that it's important when you're a responsible surgeon to grow up to the point that you realize that perhaps you're not the person who should do a Whipple if there's someone down the street who does 50 of them a year who might be really really good at them. And I think that it's important when you're thinking about patient outcomes and quality to always go there so that that's your primary driver.

DR. BUCHWALD: Could I take a crack at that?

DR. MCNEIL: Well, I wish you would because I'm still very confused.

DR. BUCHWALD: You still look skeptical.

DR. MCNEIL: Well, I'm not skeptical, but I guess I don't have enough trust, to be perfectly honest, in the system as a whole to know that a physician, that a primary care -- not enough knowledge, trust and knowledge about this as a whole, to know that an internist would know
what kind of bariatric surgeon to send a patient
to and to be sure that that bariatric surgeon
would say no, I'm not the right one for you, you
need another procedure, please go across town to
the Mass General and leave the Brigham, just for
instance.

DR. BUCHWALD: I don't know if I can
remove your mistrust, but let me try a few things.
First of all, in my own community, Minnesota, in
my own center, we do them all, so that answers one
question. We do the whole range. We have
seminars with the patients and we let the patients
decide, and that maybe answers another question,
who should be the ultimate decision maker, the
patient. We might guide them but the ultimate
decision maker should be the patient, just as the
patient is the ultimate decision maker on what to
do for prostate cancer, what to do for atrial
fibrillation, should they be put on Coumadin or
should they try to be defibrillated and their rate
controlled. These are decisions that the
physician has to make together with the patient.
All right.

The second thing is, so what happens in
our own community when somebody comes in to
another surgeon or to another group of surgeons who do not do the duodenal switch? They send them to us. And then to give you a little trust in the system, there are today at least two million people that would qualify under the NIH standards for bariatric surgery. We're doing about 140,000 cases annually, so we are serving 1 to 2 percent of the population. Where would this be accepted if we would be saying we're only going to serve 1 to 2 percent of the diabetic population or the hypertensive population, but we're really only serving 1 or 2 percent. So if there is anything but an altruistic feeling like the patient is mine, the patient is mine, I don't think it exists. All of us who are in the field have waiting lists for a year, or two years, and therefore, if a patient wants a particular operation and it's not something that's being done in that center, it's no hardship to say you go over there, because they do it well.

DR. DAVIS: Dr. Klein.

DR. KLEIN: This is changing track completely. I wanted to get to the issue of comorbidities and what that means in the elderly population, because the term has been bandied
around but I'm not clear we understand what exactly is being meant by the term comorbidities and how that will be defined in the population over the age of 65. Because in that group, BMIs even of 30 to 35 range can potentially impair quality of life and be a comorbid condition. In fact in our own experience, a BMI of 35 to 40 results in practically 100 percent of elderly people being frail according to the standard criteria of frailty in older people.

So if we could get to some kind of decision about what comorbidity means in the older population, it may be different in the younger population, and if that's the case, then there is no reason to have this meeting, because all we're doing is talking about considering this procedure in people who don't have comorbid conditions.

DR. COWAN: George Cowan. I have talked and I have not had anybody state otherwise, that there are five main classes of comorbidities. One is medical, and that's what most people focus on, the diabetes, the sleep apnea, the swollen ankles, the shortness of breath with exertion. It goes on over a hundred items.

The second one is social. Yes, social,
the prejudice that people have alluded to and such
like, which can be an extremely strong comorbidity
in and of itself that people live under. They are
down to their last two friends. Dr. Wadden
covered that.

Thirdly is psychological or psychiatric
and again, that has been addressed.

Fourth is physical. Where do you find
a size 60 panties? How do you get a 500-pound
person into a small Volkswagen? Those are the
various things where people just don't fit into
the movie theaters, the planes, the trains,
et cetera.

And fifth is economic. Some people
argue, is this a comorbidity? Well, if you can't
get a job, I maintain it is, just because you're
fat, but you're better than anybody else at doing
what you do. And when you don't have the bread,
you don't keep the family together, you have
psychosocial dynamics that are extremely
dysfunctional, and again, it becomes a significant
comorbidity.

So when you talk about comorbidities,
yes, for big people you can find a comorbidity for
everybody if you want to go along those five major
groups. What you maybe saying is, what is a
significant comorbidity and how do you define that
particular comorbidity? But it's out there. When
you weigh a hundred pounds or more overweight, you
are subject to all of the nastiness that the
American population can provide, and I'm sure you
will agree, there is a lot of it out there in
addition to the medical, social, psychological,
and physical comorbidities.

DR. KLEIN: I'd like to know, what does
Medicare consider a comorbidity for this
procedure? I couldn't find it in the documents.
I may have missed it.

DR. PHURROUGH: We don't define it, we
give two examples, and I don't suspect we will
ever define it. We may give more examples based
on some of the information here, but it would be
very unlike Medicare to try and define it. One
reason we took out the comment, obesity is not an
illness, is that we in general are not in the
habit of telling the medical world what is and
isn't a disease.

DR. KLEIN: Would it be under the
purview of this panel to say for the elderly
population, a reasonable comorbidity is poor
functioning, poor physical function of life, and that's it?

DR. PHURROUGH: The panel has a lot of freedom to do what it wants to outside of answering the questions, but if you would like to advise us what you think comorbidities are, then we'll take that into account as we look at your recommendations.

DR. DAVIS: Do the NIH guidelines define comorbidity.

DR. KLEIN: Very vaguely, and physical function is one of the comorbidities that they define, but not one that's accepted by any insurer.

DR. SUGERMAN: They don't define it for a BMI of 40 or greater, but there are no examples of comorbidities, but I think that's the issue, that there are so many of them. I mean, there are so many of these comorbidities, BMI of 40 or greater, and then they do define it for the 35 to 39 in terms of sleep apnea, degenerative joint disease, obesity, hyperventilation, and so forth.

DR. DAVIS: Does anybody want to continue on this point? I have a list of people who want to get off into other areas, I presume,
but if people want to speak to this issue, we can take them out of order.

DR. PHURROUGH: Let me make one more comment about comorbidities. Anytime we define something with a list, then there's always a problem, because something is left off the list or something that's on the list suddenly shouldn't be on the list. Obesity isn't a disease. Well, it shouldn't be on the list of what isn't a disease, and it takes an act of CMS to change that. So creating lists are always problematic, so our preference is not to do that, though we have chosen in some cases to do that.

DR. DAVIS: Dr. O'Connell.

DR. O'CONNELL: Well, my observation here is that we started off with NIH guidelines of 35 plus comorbidities and 40 and no comorbidities. And we've learned from at least one of the speakers earlier today that even below 35 there may be comorbidities that would make some kind of intervention necessary. And to me this is like a fuzzy moving cloud; when is in fact bariatric surgery necessary, and we as a panel are sitting here and the thoughts are going through our minds, but I see a big void in the bariatric community
not coming forward and being actually proactive
and saying wait a minute, you should do it here,
whether that be 32, 38 or 48, but I don't see
that. What I see is you arguing back and forth
whether you should do a lap band, or a duodenal
switch, or representing one company or another,
and it makes it very difficult for panel members
to try and decide something like this.

DR. DAVIS: Dr. Margolis, did you want
to chime in on this issue?

DR. MARGOLIS: I guess my question is
somewhat along that line, although from a
different point of view. I can either wait or ask
it now.

DR. DAVIS: Is it on the issue of how
to define comorbidity?

DR. MARGOLIS: No, no, not comorbidity,
who the procedure should be done on.

DR. DAVIS: Then if you could hold off.

DR. MARGOLIS: Which is what I think
he's addressing. He's not really addressing
comorbidity anymore, he's addressing who should
get it.

DR. DAVIS: I want to be fair to Steve
Phurrough, who got on my list, and Mike as well.
DR. PHURROUG: That was earlier and I don't remember what my question was.

DR. DAVIS: Mike, do you remember what your question was?

DR. ABECASSIS: Well, I wanted to follow up on Dr. McNeil's comments, because I'm a surgeon and when I was training I did more vertical banded gastroplasties than I care to remember. And you know, that was the panacea at the time, and now there are other procedures, and we're hearing about the benefits and the merits of each procedure. And I just read a paper that came out last month where, I think it came out of Minnesota, but it was actually the other institution in Minnesota, that said that they had a large series of patients that they were now doing a second procedure on where they had failed years after the first procedure, and the first procedure in this series was the VBG and now they were doing Roux-en-Y. So I'm kind of wondering along the same lines. Are there patients that the surgeons in the audience think are going to get a banding procedure, for example now, and then if they plateau or regain weight on that, are then going to be candidates for either a Roux-en-Y
procedure or duodenal switch procedure? Are these procedures mutually exclusive or is this a spectrum of procedures, because I'm also confused as to who would get what procedure right now.

DR. KRAL: John Kral again. I would like to take this opportunity to address really rather related questions. Patient selection is really what you're talking about, Dr. McNeil, and you alluded to that again. And you, Dr. O'Connell, asked for criteria, do we have a moving target here or what's going on.

It all begins with the extraordinary biases out of which this whole field sprang, and our current understanding of obesity is rather different than it used to be. It's not many years ago we learned that it has to be treated like a chronic disease. It is no longer suggested that one provide treatment for 10 weeks, 15 weeks, and that is the end of it. Nobody would ever have suggested that about hypertension or diabetes, but that's actually what was suggested just until a few years ago. So it is a moving target and the standard has evolved and it has evolved from a rather, I would say hazardous type of surgery before we had learned how to operate on very heavy
people. So that's why the border has been shifting, it has been moving downwards.

I predict that we're going to see those hard and fast body mass index levels, and I can tell you that I was the initiator of the consensus conference in '91 and one of the people who led putting together that program at that time. It was a panel, an independent panel that reached the conclusions. And that was based on the practicality of what was feasible and possible to get any kind of acceptance for.

Since then we've had the advent of laparoscopic approaches, which is a real change in our ability to provide safer care, at the same time as the field has been evolving. And with that has our understanding of, number one, our ability to provide a more effective treatment at lower levels of body mass index.

And abstracts have been presented on the study done in Australia using a laparoscopic banded approach in a prospective randomized, and I'm the enemy of randomized trials, but here it was done for ethical reasons in patients with a body mass index 30 to 35, because it was considered unethical to randomize above that level
because you didn't have an alternative equipoising in the nonsurgical arm. And it of course wasn't ethical to go below 30 where you couldn't be certain that the disease mandated that level of intervention.

And that's a significant change and it's not addressing the issue, but it's just explaining why you're not getting hard and fast criteria because no one has even dared to enunciate them. So it's very nice to have this study of 30 to 35 body mass index where it actually provided carefully and safely, and doing a better job than anything else has been able to do.

Back to the crucial issue, who are you going to refer to whom, why and how, and what criteria can you use? Dr. Buchwald and I are probably those who go furthest back in time in performing surgery for obesity, the early '70s. I have, as Dr. Buchwald implied that they had done in their center, have performed and provided all of the modalities available up until the laparoscopic approaches became available, and I have not learned and not provided myself complex laparoscopic procedures because I was not willing
at my stage in life to overcome that level of the learning curve.

In providing all of those modalities, let me first say, there is not one shred of evidence that there are selection criteria for predicting, and I've wanted to do this my whole career, I've spent my whole life trying to figure out what is an optimal method of treatment, of surgical treatment among the various wrinkles and facets of technical variance of surgery. There is no hard data on this.

However, let me address with you, Dr. Abecasis, since you just brought it up, already at the NIH consensus conference, I proposed and had proposed earlier that one probably needs to take the same approach to this disease of severe obesity as one does in some other diseases, and that's to have a staged approach, and that staged approach includes surgical modalities. Where I think it is fair to say that a laparoscopically placed band might, if nothing else, succeed in selecting patients who with failure of that procedure would be eligible and reasonable to provide a more aggressive, possibly more dangerous, but over the long term more effective
procedure. So a staged approach is not unreasonable. It's not a failure of the whole field that people are seriously considering that revisional surgery might be necessary. Because we do not have those criteria doesn't mean it's all bad. But we do not have hard data and I have a perspective, a little more than the one you heard about from before from 2001.

DR. WOLFE: Bruce Wolfe. I would just like to offer a couple of quick comments that might perhaps help understanding of a couple of the issues.

Number one, the potential confusion over the issue of the patients who do or do not have comorbidities is presumably impacted by the fact that a given population of patients with a BMI of 45 and a certain age who seek surgery has declared in their own mind that the risk of the surgery is worth it if they don't have the metabolic comorbidities, but they have self selected their psychosocial impact, whereas a patient who doesn't seek surgery has a lesser psychological or psychosocial impact. That isn't really studied because at surgical centers we don't see that whole population of people who
doesn't come seeking the treatment.

I mean, personally, if the patient doesn't have diabetes or the more common comorbidities, I say to the patient well, what is it about being overweight that leads you to seek a life threatening treatment? I mean, there's got to be something bad about being 300 pounds that you would be willing to take on this risk. And if they don't understand the risk, then you've got to start over and make sure that they do.

And if you go through that process then there probably is some self selection of who these patients are, and if you go that route, then you can say yes, they all have comorbidities because we don't operate on people that don't have comorbidity.

Now, this question of how do you decide which operation is best for which patient is a very good question. Dr. Buchwald and Dr. Pories have both already alluded to the fact that we don't actually have clear data with criteria on how to make such a selection. You go back just a step and say well, what are the mechanisms by which these operations actually work? I mean, coming up with a treatment, it's nice to know the
details of the pathophysiology and what the
mechanism of action is of the intervention that
one proposes.

As it turns out, we don't actually know
how these operations work in detail, we don't
really know exactly why are there successes and
there are failures. For example, there are so far
ten gut peptides that have been identified, from
Agrelin in the stomach to PPY-3 in the colon, that
are regulators of appetite and satiety and when
they go up to the brain and affect the CNS
centers. How those interactions related to the
receptors in the brain and affect appetite is not
known, but certainly is involved in the
determination of how a given operation works.

The idea that the stomach is made small
and that that's how they lose weight or the idea
that they malabsorb is hopefully oversimplified
and in fact not correct, and it is beyond the
scope of today's meeting to get onto those issues.
But until those matters are better defined, it's
going to be difficult for us to come up with
better predictors of exactly which procedure will
be best for which patient. Now we're going with
some pretty crude associations, for example, a
more severely obese patient is less likely to achieve a satisfactory or healthy BMI as we call it, but that, there is no data at this time that says one procedure or another should be done because of that circumstance.

If we knew that they had some different secretion of Agrelin and PYY, then perhaps there would be a basis. So it's premature for us to really be able to develop clear guidelines on which procedure is best. Hopefully, more research will help us to identify those factors.

DR. DAVIS: Thank you.

DR. SUGERMAN: If I could just add one last comment, I think the best procedure is the one that the surgeon really knows how to do well and safely, and the worst would be that there be some demand that every surgeon perform every procedure. I think the clear-cut issue is that the surgeon does a quality operation with quality care of the patient, and any of the procedures seem to be effective in the right hands.

DR. DAVIS: Dr. Fisher.

DR. FISHER: I will try to be brief. I think what you should take away from this is that there is no one operation that is better or
perhaps no one operation that is better for a
specific identifiable group of patient subgroup,
because I don't think any of the data that has
come forth has demonstrated that. So you
shouldn't concern yourselves with that, you should
concern yourselves with whether patients should be
covered or not.

And just as you don't concern
yourselves with whether an internist prescribes a
calcium channel blocker or a beta blocker as the
first line of defense against hypertension, that
you leave to the doctor. And here again, I think
you have to leave to the surgeon the choice of
surgery that works well in their hands, just as
internists use specific medications.

Don't look back. We no longer use
Rauwolfia alkaloids because things have changed
and gotten better. So don't look back and compare
to years ago. Today we have laparoscopic surgery
that is being provided and all of the operations
can be performed in appropriate settings that way.

We designed, and the reason I have the
data that I presented to you today is that in 2001
when the band became available, I asked the
question and we're testing it, that if we use the
same preoperative training and same postoperative
program, is the program more important than which
operation is performed. And I don't have data
that goes out five years yet, but in another three
I will have valid data that I will be able to
present and answer that question. Right now I
don't have that question, but that's the
long-range study that we've been doing in our
community program.

So I ask you, don't concern yourselves
with things that we don't have answers to, like
the best procedure. We have accepted standards by
which we've been performing bariatric surgery
which have not been overtly challenged. The BMI
of 40 was accepted since 1991, it's been accepted
not only and recommended by the NIH, but also by
the American Obesity Association, and even appears
in the guidelines of InterQual and Mill &
Associates, and if it's widely accepted, that is a
good baseline place to start. If that population
becomes well served we will be doing a tremendous
boon to our society.

DR. PORIES: I think Dr. O'Connell
deserves a straight answer, and I think the
straight answer is there are some clearly defined,
it's not a moving target. The NIH guidelines of
35 plus comorbidities and 40, the age from 18 to
65, the business that if you have someone with
alcohol abuse or substance abuse or uncontrolled
depression is contraindications, those things are
excellent standard good guidelines that virtually
everyone follows. They are hard, they are fast.

Now obviously we're testing the edge of
the bubble because there are problems. We have
morbidly obese adolescents, we have people over 65
who are morbidly obese, and so on, and in many
cases those are being tested under IRBs under an
appropriate setting in a controlled setting.

One of the main reasons for setting up
the centers of excellence is to collect large
controlled databases, perhaps on a practical
basis, but at least that will allow us in a year
or two or three to see how effective these things
are. But I don't want you to walk away and say
there aren't any guidelines because there really
are.

DR. DAVIS: Let me go back to Dr.
Phurrough and then Dr. Margolis, and we'll pick up
where we were.

DR. PHURROUGH: I think Dr. Wolfe
finally answered the question that we've been looking for, there are no criteria by which you can define which procedure is a better procedure.

MS. ALBERS: May I as a patient say something quickly about that?

DR. DAVIS: Sure.

MS. ALBERS: Every senior I know, and I'm talking about in different socioeconomics, we're pretty computer savvy today. We either own computers, we go to libraries, we research. We don't just walk into a doctor and say I'm fat, I want surgery. I'm overweight, I want surgery. And we don't, if a doctor says you need surgery, just walk away and have surgery. We research, we go on line. There are groups that you can go to where you belong because you're thinking of it, for all the types of surgery. We are entitled to have a good input in the final decision because we're the ones that are going to live with this.

DR. DAVIS: Thank you. Dr. Margolis.

DR. MARGOLIS: My question is a little bit different although somewhat associated with what's been going on. The data that's been presented is very nice, and it has certainly been well presented in both qualitative and
quantitative ways in the packets that we received, and well reviewed over the last several years.
I guess my concern gets to some of the points that have recently been made that there's both a lot of patient self selection in terms of having surgery, but the amount of people who could have bariatric surgery is basically underserved, and that the patients who have been studied so far or have been reported on so far are really a very small select group that have both had, it sounds like very good pre-care and very good post-care as has been described here, but it's a very small percentage of everybody who could have surgery, that they have to be very self motivated to find the people and find the insurance companies to actually pay for it. So I guess my question is how do we know that what's been presented and what's been so well summarized is really going to be what we find in four or five years when more and more people are having the surgery?

DR. DAVIS: Dr. Goodman, did you want to answer that?

DR. GOODMAN: I wanted to support the question before it's answered, I have a corollary to that so as not to waste time. To the extent
that these procedures are regarded widely as safe
and effective and they are accorded more public
attention as they are today, demand is bound to
increase. And this demand is bound to stretch the
definition of comorbidities, it's bound to lower
the BMI, the threshold BMI. And with an aging
more obese population and the financial and
professional incentives which always prevail,
we're going to experience some kind of indication
creep, sometimes called the woodwork effect. And
so therefore, isn't it likely that some
significant new population distribution is going
to emerge as indicated for these procedures,
regardless of which one you happen to prefer, for
whom we know that we have precious few data, let
alone rigorously generated data. I'm talking not
much data, let alone the good stuff.

And so, this is potentially some shaky
ground. And this isn't confined to this type of
surgery, this condition, it's seen throughout
various procedures, interventions with which
Medicare has to deal. So therefore, we have to
give Medicare, as well as the patients and their
doctors an evidence base and clear criteria that
will enable them to respond to this anticipated
emerging patient population that's going to come forth with these procedures. So I'm consistent, I hope with Dr. Margolis, what's the basis upon which we can be ready for this change in distribution if it's going to be some people with whom we're not quite familiar?

DR. DAVIS: With the whole flu vaccine debacle, we've been dealing with this question of prioritization and poor access to diminishing supplies, so your question kind of rings loudly in my ear, having dealt with the flu vaccine situation over the last couple of weeks. Yes, Dr. Sugerman.

DR. SUGERMAN: Well, I want to answer that from at least our society's point of view because we wholeheartedly agree with both of you and with Mr. Phurrough that we really do need data, much more data than selected series. We need broad population-based data, and I think we're going at it in a step-wise manner, starting with the NIH-funded labs project where they are now collecting and developing plans on how to rank severity of illness so that the results can be risk adjusted just like it is for coronary artery bypass surgery. And then to the centers of
excellence in which as part of being a center of excellence, you plus submit your outcomes data, and furthermore it's submit but verify, so there will be site visits of all of these centers of excellence for which they are paying to be a center of excellence. And from that step, we're hoping to go forward with mandatory data submission and this is a hope, for membership in the society, that if you want to be a clinical member of the society you must submit your data, which is the next step where we would like to go.

And in having been with you at the AHRQ meeting, we would want to work with Carolyn Clancy and want to develop this, and with Medicare to push forward and to get these data, because we need these data desperately for all of the reasons that everybody here has mentioned, whether it be adolescents, whether it be 65 and over, or whether it be the entire population, whether it be this procedure, that procedure, or what procedure, we need more data. We have a lot of data, we never can get enough. And so that's where I think we would be supportive of where you would like to go.

DR. DAVIS: Yes, please.

DR. KRAL: I want to draw the attention
to two studies that are directly pertinent to what you're asking. First of all, in the SOS study where access is not an issue, access is equal for everybody more or less, the patients electing, and they're electing to have surgery, have worse disease than the controls, and everything is being done to try to match them and it has been matched, but the patients electing to have surgery are worse off than those, at the same body mass index, who elect not to have the surgery.

In other words, it is a step for somebody to say I'm going to have surgery, it sounds like the easy way out, as if there's going to be a mission creep downward, the woodwork effect, so there is data of that kind showing that it's the more ill people who are going to elect to have and request the surgery.

The other piece of data that I want to give you is a paper by Fitzgibbons and coworkers from the early '80s. I started to interest myself in the selection process very early, as I mentioned before. That demonstrates that people wanting treatment for their obesity have different personality characteristics among other things, and different characteristics than the population,
everything else equal, not seeking treatment. So sure, is there a selection bias in that? Yes, there is a self selection bias in that, but I'm not so sure that it's a hazardous one.

DR. DAVIS: Dr. Weissberg.

DR. WEISSBERG: I just wanted to mention in terms of the social networks that are promoting perhaps new populations coming into this consideration for surgery, in our technology committee we were looking at one of the edges of the bubble that was referred to, doing these procedures in adolescents. Not that many people reported on it, but one of the most amazing facts was that of the adolescents in one survey, fully 25 percent of them had a family member who had had a similar procedure. And I think that in addition to going to anonymous sources on the Internet, people are going to be developing more and more actual contact and experience with how it has been life transforming and/or hazardous in people around them.

DR. DAVIS: Dr. Buchwald.

DR. BUCHWALD: If I could just get back to that point that Dr. Goodman made, you're absolutely correct. This is the way of life.
When people start, and having lived long enough I have some sense of history, when people started doing angioplasties, they said the same thing, where is this going to go. And before then when they did CABGs, where is this going to end up. And pacemakers, and defibrillators, and nontechnical things such as drugs for hypercholesterolemia, there was tremendous debate. Where is this going to go? Half of the population is going to be taking drugs, and they do at this moment.

And the standards have been lowered, again as you correctly stated, the standards for what is hypercholesterolemia keep being lowered and the data support that the lowering is justified. So this is a way of life in anything in medicine. But I think what is unique is that the group representing the bariatric surgical community, the American Society of Bariatric Surgeons that has now formed the centers of excellence project and the testing organization to do this says we're going to police this, and we're going to provide more and more data. I think that is different about the bariatric community than some of the other communities that have come forth
with new procedures, or several procedures and so on.

DR. DAVIS: Dr. Goodman.

DR. GOODMAN: And in all cases, Dr. Buchwald, that you mentioned about the wide use of technologies, and you picked some very good ones, to my knowledge they were all supported by rigorous studies, randomized controlled trials. I'm thinking of coronary artery stents, defibrillators, pacemakers, the treatments for hypercholesterolemia, the legion of RCTs supporting expansion indications for those is well known. And my concern is in trying to help support Medicare be a prudent decision maker, and doctors and patients to make those decisions, will they have that type of data to support their decisions when they are faced with an opportunity to do a procedure with some indications that are a little bit different. And we know that.

It sounds like we've stopped doing RCTs in this area for quite some time now, and we know precious little about the elderly Medicare population and that's who we're going to see in this what I referred to as indication creep. So I agree with the phenomenon. I'm suggesting that we
help support Medicare and patients and doctors to
get the data to make these decisions.

DR. BUCHWALD: Unfortunately, we're not
going to have too many opportunities to do
randomized clinical trials using a real control
group, namely obese patients who are not going to
be treated. We're just not going to be able to do
that. We've tried it. We've tried it for 30
years. The patients don't stay in the control
group, they cross over. We're going to have to
come to our conclusions in another manner.

We all agree randomized controlled
trials is a wonderful thing and has been put forth
as a gold standard, which in a sense it is. And
because of that, if you look in our meta-analysis
paper, there's table nine, I believe, that takes
the five randomized trials in this field and says
are they any different than the 22,000 patients
that we looked at, and the 134 studies that we
looked at, and the answer is no. In other words,
the few randomized trials, the small handful we
have, gave the same data as the overall
meta-analytical assessment.

DR. GOODMAN: Let's get some data.

Let's set up some systematic fashion to get some
data for this emerging population.

   DR. DAVIS: Dr. Weiner.

   DR. WEINER: I have a question and comment, one that wouldn't have been possible until Barbara's question. You know, in reading the literature very carefully as I did as a non-physician, but trying to take the evidence base as well as the public health perspective, I too wondered about, you know, which of the now six different classes, and it's actually more than six, as you know, there are even more subvariants out there, and the literature didn't suggest one was better. You experts have also suggested that it's not clear cut that one is better. All right, that's the output side, the outcomes in terms of mortality and morbidity, and granted, there's some preference. But what about the inputs, the costs, the training? Dr. Buchwald has convinced me that we do have a public health problem and I would like to back up and look at the whole issue of obesity and prevention, et cetera, but that's out of our sphere, so I won't do that. I'll just focus on the issue, what did you say, two million people potentially needed the surgery and we're doing 140,000 a year?
DR. BUCHWALD: Conservative, two million are eligible.

DR. WEINER: Well, are there not great implications of which of the six or 12 different procedures we pick in terms of ramping up and cost benefit? Now we're not allowed to look at cost in terms of does the evidence suggest this procedure has a positive impact, and I'm prepared to vote as many will on that question in a moment. But here we have several that may lead to very similar if not identical outcomes. So therefore, you know, we're not going to be in a position to ask for what is the cost of this procedure versus that procedure, not just for the surgeon, but the entire market basket of services as well as output.

But obviously the field needs to address that if we're ever going to hope to answer the types of questions, the woodwork effect questions as well as Medicare as a prudent buyer. And I'm sure that Kaiser and some of the international settings that do ask these questions probably have begun to address it, but I encourage all of you, particularly as we ramp up these databases, to ask these hard questions. The
trainers, you know, which is easier to train if we're going to double, triple output of training. Some are harder than others. The outputs may be the same, but difficult questions, and perhaps we can address a few of them today, but I think we're really talking more into the future.

There are differences in costs, correct, and training implications of these six different classes? And if the outputs -- was that not really? All about the same?

DR. FISCHER: I think the key to many of the questions that have been raised here lies in programs. If you're going to train people for a certain period of time, let's say for a year, and most of the time in a well set-up situation they are going to have the ability to do four, five, sometimes six. I think the exception may be that in certain parts of the country, in certain institutions, that the duodenal switch is not often performed, and that may be the procedure which is not as often performed, but for the others it should be possible to train people well and then have follow-on with proctoring and I think the training will be taken care of.

DR. WEINER: How about the issue of
similar outputs but different input costs? I don't know if you're the right one to answer that question.

DR. FISCHER: Do you want to translate that?

DR. WEINER: In other words, the number of days in the hospital, the types of level of staff that you need for the different procedures, inpatient days.

DR. FISCHER: Well, I think there are a number of different criteria. I think with clinical pathways, I think if the clinical pathways are well worked out and people meet the criteria of what a program should look like, they're probably not terribly different between for example the lap Roux-En-Y gastric bypass, a little shorter length of stay than the open. The lap band is one day, all's well the next morning and home you go.

So there really is a difference in length of stay, there may be a trade-off as far as the rapidity of weight loss. I think one thing that nobody has mentioned today, and I thought the anesthesiologists that got up was going to mention it, is that my own feeling is that just as we have
for example an anesthesia team for cardiac surgery, we have an anesthesia team for transplants, we have an anesthesia team for neurosurgical oncology.

I think one of the things people ought to start looking at, I think we need an anesthesia team, and I'm trying to get this in our institution for the very obese patients who are sick. I mean, you wouldn't take somebody who does pilonidal sinuses all week and send them into a room for anesthesia to put to sleep somebody who weighs 450 pounds. I mean, they have terrible airway problems, and the problems we've had have not been with the surgery, it's been with the airway. So whatever you decide to do, I think whatever standards there have to be for programs really ought to take that into account, which in my experience is part of a source of a problem or potential problem.

DR. KRAL: May I make a quick one? Many of put together anesthesia teams who are highly specialized on taking care of the severely obese patients. That is the hallmark of any good program. Dr. Weiner, one issue that has to be mentioned, I don't think we should belabor the
approach question, laparoscopic versus non, as I
indicated earlier when I spoke, forget that.

DR. WEINER: Even with my issue of one
being more cost effective or a better value for
patient or society, with that issue you believe
that --

DR. KRAL: That's not an issue, the
surgery should be provided laparoscopically in the
year 2005, primary procedures. But the thing that
you didn't consider that I want to make a plea for
is to understand that the outcome for the patient
is dramatically different for having a purely
restrictive procedure like the laparoscopic band
and any of the bypass type operations. They are
significantly different. And I have provided
these types of operations throughout my career and
I have done my utmost to try to educate and get
the patients to be educated about the differences
between those procedures. And when the patient
has a choice, they must have a choice, and they
will choose, and they will choose differently, and
one size does not fit all. We cannot with a
mechanistic technocrat attitude say we're going to
choose an air-cooled four-cylinder car. We can't
do that.
DR. DAVIS: I have a question about waiting lists. Dr. Flum this morning, I don't know if he's still here, maybe somebody else can help me with this. Dr. Flum presented data showing, I believe, that people who had bariatric surgery had a lower mortality rate than people who were on the waiting list for bariatric surgery. And I think Dr. Buchwald also referred to people being put on waiting lists and the access problem that that represents. So for comparing people who have the surgery versus those who are on the waiting lists for the surgery, one wonders how comparable those two groups are, and then that raises the question, well, how are people chosen to get the surgery versus being put on the waiting list? Is this first come first served, or is there some sort of priority scheme that would move people over others and they would jump over others because either they're more sick or less sick? How is that done?

DR. PORIES: Well, there are two studies. Our own study is one where we followed the patients who were scheduled for surgery, in other words, they not only met the standards for surgery but were actually scheduled and then were
turned down, primarily for insurance reasons. There were a few that were turned down because they changed their mind. The mortality difference was in the group that was operated on, the mortality was 1 percent per year over nine years. In the group that was not operated on, the mortality was 4.5 percent per year, so people do die on the waiting list and the mortality is higher.

DR. DAVIS: And you're saying these two groups were probably similar?

DR. PORIES: We thought so. Now admittedly, those who got the insurance paid probably may be more adept, may be more nimble, may be more quick in getting insurance coverage, whatever, but that's what we got, it's as good as proof as we could get.

DR. DAVIS: Dr. Buchwald, you referred to people on waiting lists. Has this been an issue in your practice, or across the field, how is this prioritization done? If the demand or the number of people who are candidates for the surgery overwhelm the resources to deliver the procedure, how is that dealt with?

DR. BUCHWALD: I think the speaker you
referred to is Dr. Christeau from Canada. They have about a four-year waiting list. In the United States most of us have one-and-a-half year waiting lists. As a result it's done first come first served with certain exceptions. In our own institution we've done about four or five people who were on the cardiac transplant list and they had bariatric surgery instead of a cardiac transplant, and they survived and they're off the cardiac transplant list. We've had some people with pseudotumor cerebri who were going blind, and we pushed them up on the list.

DR. DAVIS: Thank you. Dr. Phurrough.

DR. PHURROUGH: If there is this access problem that causes waiting lists around the country and there is an increasing demand that's going to happen, and if the bariatric surgery society is recommending only centers of excellence do the surgery, how do we get rid of the waiting lists? Who is going to do the surgery in Hagerstown, Maryland?

DR. PORIES: I'm glad you brought that up, because you know, it's quite different from transplant centers where we have a limited number of organs, and certainly at East Carolina we could
do more kidneys if there were more kidneys. In this situation I think we have to be aware that we need to be able to provide the service but provide it with great care. So it's our job to define the centers of excellence with great rigor, but then also help centers achieve that level of rigor by education, better training, putting people there. So we now already have 250 applications that are being processed across the United States and I hope that we can probably double that number to get that work done. But we're not going to identify centers of mediocrity, we're going to be pretty tough about it.

DR. SUGERMAN: Walter, how many surgeons are in those 250 centers, do you think?

DR. PORIES: Just off the top of my head, about 700.

DR. DAVIS: Again, just to interject, another example from my sphere of work in immunization, I remember this situation came up when the CDC was considering recommending varicella vaccination universally for children and they made the recommendation well before Congress had appropriated funds to support the vaccination across the country for public sector immunization
programs. But you needed the CDC to make the
recommendation in order for Congress to provide
the appropriations. So in this case you might
need a coverage decision and the increase in
demand in order to motivate the training and the
multiplicity of centers of excellence in order to
accommodate that demand.

DR. SUGERMAN: I might add, and maybe
Walter, you might address this issue in terms of
the private insurance carriers out there are
demanding that this be developed, some of them are
doing it on their own. I know that you can
address Blue Cross Blue Shield of North Carolina,
but another issue with regards to access that
clearly is out of the purview of what we're
talking about today is the growing tendency of
private insurance carriers to block access to this

DR. PORIES: We have had very good
support from the Blues in North Carolina, partly
because their CEO sits on the board of governors.
But he has been very helpful and has said they
will delegate their centers of excellence program
to us as soon as we're really functioning. We're
having similar discussions with four other Blues,
we're meeting with the medical director of one of
the Big Five in two weeks, so we're getting quite
a bit of support, and of course we have to do it
right and do it well, but I think this is the way
to go.

DR. PHURROUGH: How many bariatric
surgeons belong to your society now and how many
hospitals does that represent?

DR. SUGERMAN: I can't answer the
second question, but the first question is that
there are 1,200 members of the society who are
surgeons who are full members of the society.
There are an additional group of what are called
associate members who haven't achieved the
criteria to become full members, and there are an
additional 700 allied health members, who are
nurses, dietitians, nutritionists, so forth.

DR. DAVIS: Yes, please.

DR. KNAPP: Just from the standpoint of
the question of doing clinical medicine, my
question with these waiting lists, and this may be
becoming a two-part question, the first part is
how much of this waiting list is economic?

DR. DAVIS: Versus not big enough
supply sort of --
DR. KNAPP: Versus shortage of access problem.

DR. ALLEN: I can maybe answer that. People on our waiting are people who have come in and established themselves as good surgical candidates and we are waiting to get them on the OR schedule. At my hospital, we have taken a number of measures to streamline, so once the people come in, we weigh them, we make sure they clearly are NIH qualifiers and make sure they're acceptable operative risks. And we also do an insurance verification at that point; if for instance they have Blue Cross of Kentucky, and after listening to the information about the procedures, giving the patient the choice, they may say I want nothing but a band. We say that's going to be a real problem because Blue Cross of Kentucky doesn't cover a band and if you want to go through with the process you have the options of changing your allegiances, trying to appeal this, or paying for it out of your pocket.

So I think the short answer to your question is there's a very limited number that are economic. There's not people lined up who just can't wait to get in the operating room, it's
really I think in most institutions a problem of
getting in for initial visit and before the whole
deciding process occurs.

The other thing that's important, I
think to differentiate, to make sure the panel
members know, is that it's not like -- I do a fair
amount of general surgery as well. If somebody
comes into me and they have I gallstones and they
have problems and they need their gall bladder
out, you know, if they say I really need it now, I
say let's do it tomorrow morning. You can't do
this with a bariatric operation. This is the
ultimate elective operation; you need to go
through a number of processes, psychologic
evaluation, nutritional evaluation, as well as
getting insurance preapproval prior to doing to
ensure payment, not necessarily even to the
doctor, just to make sure the patient doesn't get
hit with a $30,000 bill at the end of this because
for whatever reason the T wasn't crossed or the I
wasn't dotted.

DR. STILES: I'd like to follow up in
terms of access in terms of economics, and a
little bit different slant on it coming from a
major payer which is an HMO called Kaiser
Permanente. There's a lot of things that I see as the doctor who sees all the patients and knows of all the patients that are referred from northern California to our referral center, and we get at least 200 referrals a month for bariatric surgery. And I would say that certainly we do probably within our region maybe 100 a month. And if you do the math, that means 100 people that we are reviewing and often seeing are not ending up getting the surgery. And you might say, some of our patients might say that's an access problem. But I because of being the person that sees most of them, I will say it's because they are not yet ready. There are stringent things that we make our patients do that is similar to what these other fine surgeons are doing as well in terms of making our patients really healthier for surgery, in terms of their medical comorbidities. Our patients walk before surgery, there's a big thing that we make people do. Before a lot of them will come in on their scooters and I will do everything I can, and I'm called the cheerleader for all the patients, and that's because I believe that we can get them healthier and we can get them safer before
surgery.

It's not meant as a roadblock, but yet people sometimes will be on their own trajectory. Sometimes they will come in and hear our orientation, they will be ready for surgery in three months even if they have significant comorbidities. Sometimes it takes them a year and a half. Sometimes they come in on their scooters and if at all possible, I'll get them to physical therapy to learn upper body extremity exercises. I'm not going to belabor you with all the different things that are possible to do out there, but a lot of us are doing these things to get our patients healthy for surgery.

So that the access time may be a year and a half for one patient, but you know what my patients say, and this is the honest truth, is that when they are ready, they know that they are ready, and that's because they understand what they need to do, and they understand we have done everything possible to insure their loved ones that they are going to be safe for surgery, and we have an extremely very very good record in that as well.

And the last thing I'll say is that
postoperatively, it's not a simple thing. Luckily
at Kaiser, if we want to see a patient or a
patient wants to see us, we don't have any problem
with that, and we will go to -- sometimes I go out
to different centers that are farther away in
order to see the patients there postoperatively,
and we actively have them back for many different
kinds of programs. And I think that having access
postoperatively insures you that the surgery that
you do will be done to the best way possible and
that even if they decide they need another surgery
down the line, that that's because that's the
appropriate treatment for their severe obesity
because really, we're taking care of more than
just the surgery, as we have all been talking
about. Thank you.

DR. DAVIS: I think the intensity of
the questioning and the discussion is ebbing a
little bit, which probably means that people are
going ready to vote. Dr. Phurrough and I were
just whispering to each other a little while ago
that if the panel believes that we really don't
need to go laboriously through the set of
questions for people who are morbidly obese but
without comorbidities, we could probably just
dispense with that.

     DR. PHURROUGH: We could probably vote
on the first question, and if there isn't a good
response, then we wouldn't have to do the rest.

     DR. MCNEIL: I agree with that. I
think we should vote on the first question on the
second page and then not vote on the rest of the
questions on the second page, depending on the
answer.

     DR. DAVIS: Let's just take any final
comments before we do that. Dr. Sugerman, did you
want to chime in?

     DR. SUGERMAN: I was going to vote to
dispense with the second page, so that answered my
question.

     DR. DAVIS: Yes, Dr. Weiner.

     DR. WEINER: I fully agree that
dispensing with the second page times 25 is a good
idea. However, are there not still some
instances, particularly I heard about young
Medicaid recipients that really have no other
morbidities at that time, even if you look real
hard, they don't? Therefore, by not voting, have
we excluded them for consideration?

     DR. PHURROUGH: You're going to vote on
the first question, my assumption is, on the second page, which says we could not find any evidence with which to answer the rest of the questions, which is not necessarily relevant to what we eventually do with patients who may not have comorbidities.

DR. WEINER: So we can't vote on the evidence if there isn't any.

DR. PHURROUGH: Yeah.

DR. DAVIS: Yes, Mike.

DR. ABECASSIS: I wanted to echo your concern, because I think it we answer the first question, and let's say the vote is that the evidence is not overwhelming, you know, if you look at some of the subsequent questions, it asks our judgments as to how likely a good outcome is to be in this setting. So I think that by answering the first question, we may actually be disadvantaging potentially a patient like the one that you just brought up, a younger person that we know is going to get into trouble shortly and that might potentially benefit from the procedure. I just want to make sure, Steve, that we're not doing that by taking this vote.

DR. PHURROUGH: The purpose for which
we have you here is to tell us what the evidence shows. If in fact the evidence is not there for us to arrive at a conclusion, then there are alternatives that we have as an agency to hopefully insure that that patient population is in fact not disadvantaged. It may be that they are not disadvantaged by continuing our current coverage because there is no evidence to change that. Or it may be as we've had the discussion that we're never going to get that information in the current clinical trial setting and so we may do as we have done in other decisions recently, say coverage in this particular entity is only reimbursable if we're collecting data at the same time. And so we can define criteria by which someone who "has no comorbidities" may in fact be able to have surgery but to protect that patient we are only going to do it in the context of some kind of trial to obtain clinical data.

DR. DAVIS: Any other final requests or comments before we move to vote? If not, Kim, I think has some instructions that she will provide about voting.

MS. LONG: For the record, the voting members present for today's meeting are
Dr. Barbara McNeil, Dr. David Margolis, Dr. Cliff Goodman, Dr. Brent O'Connell, Dr. Jonathan Weiner, Dr. Jed Weissberg, Dr. Michael Abecassis, Dr. Kieren Knapp, and Dr. William Owen. A quorum is present and no one has been recused because of conflicts of interest, and at this time Dr. Davis can call for a motion to vote.

DR. DAVIS: Is there a motion to vote?

DR. GOODMAN: So move.

DR. DAVIS: Second?

DR. MCNEIL: Second.

DR. DAVIS: Any objection to voting?

(No response.)

DR. DAVIS: If not, we will proceed with voting. Now, we probably need to talk about the cards and how we're going to do this.

DR. PHURROUGH: Everyone has a pack of cards.

DR. DAVIS: Right. So the request is that everybody vote whether they're a voting member or not, and we don't want to disenfranchise anybody at the table.

The first set of questions pertains to obesity patients with one or more comorbidities, and question number one is: How well does the
evidence address the effectiveness of bariatric
surgery in the treatment of obesity in patients
with one or more comorbidities compared with
nonsurgical medical management? And the response
choices range from one for poorly up to five for
very well. And so, we'll ask each person to pull
out their number and hold it up so that Kim can
record them.

(Dr. McNeil, Dr. Weissberg, Dr.
Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr.
Klein, Dr. Buchwald and Dr. Sugerman voted five;
Dr. Margolis, Dr. Goodman, Dr. O'Connell and Dr.
Weiner voted four.)

DR. DAVIS: Thank you. Question number
two is: How confident are you in the validity of
the scientific data on the following outcomes?
And we will have four votes for this question, and
the answers from one for no confidence up to five
for high confidence, and first is for sustained
weight loss.

(Dr. McNeil, Dr. Weissberg, Dr.
Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr.
Klein, Dr. Buchwald and Dr. Sugerman voted five;
Dr. Margolis, Dr. Goodman, Dr. O'Connell and Dr.
Weiner voted four.)
DR. DAVIS: Kim was just reminding me that we will post the results at the end of the meeting on the screen. The next is long-term survival.

(Dr. Raab, Dr. Buchwald and Dr. Sugerman voted five; Dr. McNeil, Dr. O'Connell, Dr. Weissberg, Dr. Abecassis, Dr. Knapp, Dr. Owen and Dr. Klein voted four; Dr. Margolis, Dr. Goodman and Dr. Weiner voted three.)

DR. DAVIS: Got it. The next is short-term mortality.

(Dr. McNeil, Dr. Raab, Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis, Dr. Weiner, Dr. Weissberg, Dr. Knapp and Dr. Owen voted four; Dr. Goodman, Dr. O'Connell and Dr. Abecassis voted three.)

DR. DAVIS: The next is comorbidities.

(Dr. Abecassis, Dr. Knapp, Dr. Raab, Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis, Dr. Goodman, Dr. O'Connell, Dr. Weiner, Dr. Weissberg and Dr. Owen voted four; Dr. McNeil voted three.)

DR. DAVIS: Got it, thank you.

Question number three, how likely is it that bariatric surgery, including RYGBP, banding, and
BPD, will positively affect the following outcomes in obese patients with one or more comorbidities compared to nonsurgical medical management, with the response choices ranging from one, not likely, to five, very likely. First for weight loss.

(Dr. McNeil, Dr. Goodman, Dr. O'Connell, Dr. Weiner, Dr. Weissberg, Dr. Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis voted four.)

DR. DAVIS: Next, long-term survival.

(Dr. Abecaassis, Dr. Raab, Dr. Buchwald and Dr. Sugerman voted five; Dr. McNeil, Dr. O'Connell, Dr. Weissberg, Dr. Knapp, Dr. Owen and Dr. Klein voted four; Dr. Margolis and Dr. Goodman voted three.)

DR. DAVIS: Next is short-term mortality.

(Dr. McNeil, Dr. Raab, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis, Dr. Weiner, Dr. Weissberg, Dr. Owen and Dr. Klein voted four; Dr. Goodman, Dr. O'Connell, Dr. Abecaassis and Dr. Knapp voted three.)

DR. DAVIS: Next is comorbidities.

(Dr. McNeil, Dr. Goodman, Dr.
O'Connell, Dr. Weiner, Dr. Abecaassis, Dr. Knapp, Dr. Raab, Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis and Dr. Weissberg voted four; Dr. Owen voted three.)

DR. DAVIS: Thank you. Question four: How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients with one or comorbidities? And there is a definition of net health benefit in the glossary at the bottom of the page as a reminder, balance between risks and benefits, including complications of surgery. Response choices range from one for no confidence up to five for high confidence, and we'll have six votes for question four. The first one is for RYGBP open.

(Dr. McNeil, Dr. O'Connell, Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis, Dr. Goodman, Dr. Weiner, Dr. Weissberg, Dr. Abecaassis, Dr. Knapp, Dr. Owen and Dr. Raab voted four.)

DR. DAVIS: Okay. Why don't we go row by row, and we'll do RYGBP lap next.

(Dr. McNeil, Dr. O'Connell, Dr. Weissberg, Dr. Abecaassis, Dr. Knapp, Dr. Raab,
Dr. Klein, Dr. Buchwald and Dr. Sugerman voted five; Dr. Margolis, Dr. Goodman, Dr. Weiner and
Dr. Owen voted four.)

DR. DAVIS: Next is BPD open.

(Dr. Klein, Dr. Buchwald and Dr.
Sugerman voted five; Dr. McNeil, Dr. Margolis, Dr.
Goodman, Dr. O'Connell, Dr. Knapp, Dr. Owen and
Dr. Raab voted four; Dr. Weiner, Dr. Weissberg and
Dr. Abecaassis voted three.)

DR. DAVIS: Next is BPD lap.

(Dr. Abecaassis, Dr. Knapp, Dr. Raab,
Dr. Klein, Dr. Buchwald and Dr. Sugerman voted
five; Dr. McNeil, Dr. Margolis, Dr. Goodman, Dr.
O'Connell, Dr. Weiner and Dr. Weissberg voted
four.)

DR. DAVIS: Next is banding open.

(Dr. Klein, Dr. Buchwald and Dr.
Sugerman voted five; Dr. Margolis, Dr. O'Connell,
Dr. Weiner, Dr. Owen and Dr. Raab voted four; Dr.
McNeil, Dr. Goodman, Dr. Weissberg and Dr. Dr.
Knapp voted three; Dr. Abecaassis voted two.)

DR. DAVIS: Last is banding lap.

(Dr. Abecaassis, Dr. Raab, Dr. Klein,
Dr. Buchwald and Dr. Sugerman voted five; Dr.
Margolis, Dr. O'Connell, Dr. Weissberg, Dr. Knapp
and Dr. Owen voted four; Dr. McNeil, Dr. Goodman
and Dr. Weiner voted three.)

DR. DAVIS: Thank you. Question five:

Based on the scientific evidence presented, how
likely is it that the results of bariatric surgery
in obese patients with one or more comorbidities
can be generalized to the Medicare population aged
65 and older? The response choices ranging from
one, not likely, to five, very likely.

(Dr. Klein, Dr. Buchwald and Dr.
Sugerman voted five; Dr. Weissberg, Dr.
Abecaassis, Dr. Knapp and Dr. Raab voted four; Dr.
Margolis and Dr. Owen voted three; Dr. McNeil, Dr.
Goodman, Dr. O'Connell and Dr. Weiner voted two.)

DR. DAVIS: And 5.B, the same question,
can be generalized to providers (facilities/
physicians) in community practice.

(Dr. Buchwald and Dr. Sugerman voted
five; Dr. Klein voted four; Dr. McNeil, Dr.
Margolis, Dr. Goodman, Dr. O'Connell, Dr. Weiner,
Dr. Weissberg, Dr. Abecaassis, Dr. Knapp and Dr.
Raab voted three; Dr. Owen voted two.)

DR. DAVIS: Thank you. And we will
begin with the next set of questions and see how
far we get, depending on the outcome of number
one, which some might predict the outcome of. So, this next set of questions is for obese patients without comorbidities. Question number one: How well does the evidence address the effectiveness of bariatric surgery in the treatment of obesity in patients without comorbidities compared to nonsurgical medical management? The response choices range from one for poorly to five for very well.

(Dr. Margolis, Dr. Weiner, Dr. Weissberg, Dr. Abecassis, Dr. Knapp and Dr. Buchwald voted two; Dr. McNeil, Dr. Goodman, Dr. O'Connell, Dr. Owen, Dr. Raab, Dr. Klein and Dr. Sugarman voted one.)

DR. BUCHWALD: So as we were discussing before, if the panel is comfortable with this and if CMS is comfortable with this, based on the results from question number one for obese patients without comorbidities, we can dispense with the remainder of the questions. Is there general assent among the committee members? And Dr. Phurrough, on behalf of CMS, you're happy with that?

DR. PHURROUGH: The committee has spoken.
DR. WEINER: As long as the record shows our concern.

DR. DAVIS: That's right. And of course the full discussion has been transcribed, will be available to CMS, will be posted on the web, and so I think the committee's sentiments about this will be part of the record. Yes, Mike?

DR. ABECASSIS: You don't think it's worth restating the concern as a matter of public record?

DR. DAVIS: What we should do now is as is customary for MCAC, is to go around the table and allow each person to make whatever comments he or she would like to explain his or her votes. And that would provide an opportunity to express a concern like the one you were referring to. So why don't we proceed with that now, so Barbara, sorry to pick on you.

DR. MCNEIL: So, I guess I usually, I sometimes vote a little harder than I did this time, I am told, but I was really quite impressed with the data, so I thought that the outcomes were fairly clearly and effectively improved by the various kinds of surgeries. I was less, really less able to make decisions among the six
different types and that's why my votes went down. And I didn't see any data whatsoever that made me think that I could be absolutely certain that these very same results would apply to the Medicaid population over 65, or the providers at large without a significant amount of monitoring or training.

This looked to me like a good situation where the data looked pretty compelling for lots of situations, but to go forward whole hog, we really have to thing critically about what we're going to do about monitoring, how we're going to define the patient populations better, how we're going to define the sites better, and it seems to me there are a slew of ancillary questions that CMS will have to think about that go way beyond the specific questions that we voted on just now.

DR. MARGOLIS: I don't really have all that much more to add other than I think the data has been well summarized multiple times already. I mean, those summaries are available I guess publicly, and they were reviewed and discussed today. My one overriding concern is just how the patients were selected who had the current procedures, and how that's going to influence the
outcomes in the future, but there's really no
great way to answer that right now with the
exception of perhaps the Sweden study, so you will
need to evaluate as you go forward.

DR. GOODMAN: And for most of these
questions, the preponderance of the evidence
outweighed the lack of rigor by which the evidence
was generated, so historically a big body of
evidence was built up, it wasn't built up in a
very rigorous way. If we had to do it all over
again, there's probably a better way of doing it,
but at this point it built up to be largely
persuasive.

The second point is that we need to
establish the capacity to capture the data for the
emerging populations of indication creep, which is
inevitable.

DR. O'CONNELL: A couple of things. I
have some reservations about the short-term
morbidity and mortality, I think it's
significantly under reported and I think we'll
find as we go forward it's going to be a little
higher. I like the data but I, again, did not
find anything to suggest we could move this to the
Medicare age group. I'm also a bit worried that
the community is not ready to take on the load, as evidenced by the limited number of facilities, certainly in my state, that are capable of doing this major surgery. So, I'll just leave it at that.

DR. WEINER: Again, I too underscore everything that's been said, and just add a few things. The provider community seems to be very advanced in its thinking about quality and evidence base and data collection, and I urge you to continue in that way hopefully with some cajoling from CMS. And the vote, my vote and everyone's vote was very low on the over 65; that clearly must be a priority in terms of emphasize, because there was some suggestion in some of the literature that there could be some counterbalancing negatives for that population.

I also do believe that the focus here today and the focus of most of you is one procedure, a few clear set of outcomes on a patient who has clear-cut need, but we will need to step back, and two issues I raise. One is the broader, how this fits in with the broader preventive in medical, and again, that wasn't our charge today, but I know most of you focus on
that. It should be and will be Medicare's charge, I know the administration here for four years more makes that a high priority, and kudos to them for that.

And then also the issue of training. I think clearly the work force issues which I spent some time on, and surgery and bariatric surgery, I never quite put surgery and public health quite so closely together as perhaps in this case, and I think we must look at that from the broader perspective, again, not exactly Medicare's charge, but Medicare by far is the biggest payer for training in this country, so perhaps the two should go together.

DR. WEISSBERG: Sometimes when I walk into my office there's a manila envelope that's taped shut with a confidential stamp on it, and that represents a report of a serious adverse event from somewhere in our health care system that happened to one of our 8.2 million members. Five times in the past year there have been serious adverse events, including deaths, in bariatric surgery patients. Now given that we're doing between 1,000 and 2,000 a year, that's an acceptable level of short-term mortality as judged
by what our surgeons reported in the literature. But when I read the details of those cases, I see opportunities for improvement and for driving that level of mortality down even further. So, I'm very concerned about the profession rapidly getting up to gear in terms of policing itself, sharing its knowledge, and standardizing to the point of driving that short-term morbidity and mortality down even further, and I'm very confident that our government will be able to derive data as the population inevitably expands.

DR. ABECASSIS: I guess I just want to say sort of a cautionary note about -- and I understand that our job is to evaluate the data that exists, and make the best recommendations based on the data, but I just want to go on the record by saying that just because the data are not there does not mean that some of these things don't make a lot of sense. And the perfect two examples of that are patients who are truly obese, especially younger patients who are headed towards terrible morbidities that, you know, under the data that exist now, would not be candidates for the procedure.

And the second is the population over
65. Again, just because there aren't a lot of data on those patients, probably as a result of lack of coverage for certain procedures, we should not take that as meaning that the procedures don't make sense. And the reason that I'm concerned about this is that being in transplantation, I know what it's like to deal with intermediaries who decide on their own what the rules should be. And unless it's clearly stated by CMS, you have tremendous discrepancies in coverage on a geographic basis, and I think that that's wrong.

DR. DAVIS: Mike, just to clarify, you might be talking about a young person with a BMI of 36 but no comorbidities?

DR. ABECASSIS: Yeah, that would be it.

DR. DAVIS: Thank you.

DR. KNAPP: As a practicing rural family doc, the thing important to me is not necessarily all the reams and reams of data that we were given to read, but the overall picture and actually what works for the patients. We've been presented with a number of procedures today, they all seem to work, they all seem to decrease the morbidities and mortalities. I don't think they
will resemble anything compared to what we're seeing ten years from now as far as procedures, these may not even exist, but the idea is that it does provide some hope for that. I'm the guy who walks in and has to look at 30 people that are grossly overweight every day in my office.

I think one of the problems with the data on the Medicare patients who are over age 65 may be because of the morbidities associated with that size and age group, we may have already thinned the herd by the time they've gotten to age 65, to use a farm term. I think you're going to see survivability go up remarkably in that age group and I think you will have the data within a number of years for the over age 65 group.

DR. OWEN: The area that I want to comment about specifically is external validity of the data. In many ways I have an ongoing concern that we're seeing center-specific effects in terms of what's presented here. I'm often reminded when you go to national meetings and you ask about performance measures like those in the search, you ask the audience, how many doctors prescribe beta blockers for their patients after an MI? Everyone's hand goes up. And I'm fearful that of
course you're seeing the same thing in terms of reporting bias in the literature and what's being seen here. In other words, you're seeing best experiences and best clinical practices. As this unrolls, I am fearful we will see exactly what has been seen in every other subspecialty when a new procedure is introduced, and that is the experience in the larger community differs quite substantially from what has occurred in the past and what has been reported, so that's the area of greatest concern.

And I recognize that the centers of excellence program is in place, it is admirable, it is wonderful. But I also remind you that there is a wonderful paradigm of quality monitoring and quality improvement which was actually mandated by Congress and CMS in the Medicare program, and that's the end-stage renal disease network program which has been in place now for about 15 years. When data collection began in terms of looking at performance of something as simple as dialyzing someone, 75 percent of the patients were found to have inadequate dialysis. So caution is urged, and likewise, I urge a lot of rigor in terms of making certain your participants adhere to best
clinical practices.

DR. RAAB: I don't want to repeat what everyone's said about the evidence. I found it compelling that the procedures had real impact compared to nonsurgical interventions, nonsurgical management, but I want to highlight that I was most attentive during Barbara McNeil's queries as to which procedure should be chosen for which patient. I think that's fairly troublesome, and it calls for the need for more long-term information, perhaps registries.

DR. KLEIN: I have recently become a geriatrician at my hospital and you know, our population is getting older, and the prevalence of obesity in the elderly population 65 and over is increasing dramatically. Now obesity has become the most important cause of frailty in the elderly and it's a leading cause for nursing home admissions. And so I think having a procedure that's low risk like potentially the gastric banding procedure, that will improve functionality, is critically important, and one of our end points should be not just looking at weight loss and the typical comorbidities in the elderly population, but really their ability to
function, which requires a different paradigm completely in looking at outcome measures.

        DR. BUCHWALD: First of all, I would like to plead that we all work together to provide the missing data, and I think we shall. And then I just want to thank Medicare for having this conference, for giving a voice to the bariatric surgical community, and for even having some of us sit up here. Thank you.

        DR. SUGERMAN: I too want to express my thanks and say how impressed I have been with this process, and I hope that the discussions that we have had amongst ourselves and the people who presented will be weighed very carefully by Medicare, and consideration be given to how best to equalize access for all of our patients who need this surgery so desperately across the country.

        DR DAVIS: Yes, please.

        DR. RABKIN: Dr. Davis, I want to tell you how impressed I am by the panel, but I did want to do one little pesky thing, which is to clarify for the record the nomenclature, which I believe one of the questions referred to BPD, and the data today that was given referred to the
duodenal switch, and it's my belief that the panel members felt that what they were talking about labeled BPD included the duodenal switch.

DR. DAVIS: Is there general agreement with that? I see a lot of nodding of heads around the table. Thank you for that clarification.

I would just like to extend kudos to members of the committee, CMS staff, and all of the presenters for their outstanding participation in today's proceedings and in the preparation for it, and I will now turn things over to Kim Long and Dr. Phurrough to close off the meeting.

DR. PHURROUGH: I want to add my thanks both to committee members who do -- this is not a simple task. We sent you lots of stuff and it was obvious that you spent some time on it, and we appreciate that. I thank the guest panelists for agreeing to be part of this. Our goal is to have good quality clinicians to provide advice to our panelists who in many cases are good methodologists but may not have specific clinical knowledge of the specific process, though we give them enough stuff to learn a good bit about it. So we have a history of doing this and we will continue it.
Thanks to all those who showed up to present, both those who were formal presenters and those who chose to present today. I want to specifically thank Dr. Pories for his comment about Mama Michelle here.

MS. LONG: Kim.

DR. PHURROUGH: Kim, excuse me. Dr. Pories wanted about a couple of hours, in fact he'd like to have had all day, and we just couldn't do it. So there was this back and forth to get down to what we thought was an adequate amount of time, about an hour, 45 minutes to an hour, and you did a superb job in coming down to that. So I think the panel was well served by this interaction that went on to get this down to a small amount of time. But we do appreciate all of those who spent their time and the effort to come and assist us today.

Now we have had the question and folks have asked, what's the next step? Well, we have several options. First, it's do nothing. Every Medicare beneficiary today who has any comorbidity and is obese can have surgery, nothing prevents that from happening in our current policy. You meet all the indications, surgeons are competent
in doing it, you can do that surgery.

Now, we do have various levels of rules
that are established by our various contractors
and so we could open an NCD and become more
specific in our details around who is and isn't
covered, more specific around what are the
appropriate comorbidities and so forth.

We could open a coverage decision and
say we're going to cover less, based upon some of
the discussions that we've had today, and we could
open a coverage decision that says we're going to
cover more.

So those are all options. So what our
expectation internally is that we're going to take
the recommendations and the information that has
been provided to us today and internally discuss
whether in fact we should have some change in our
current coverage decision.

Now, we in general do coverage
decisions, or we initiate coverage decisions in
two manners. One is, we decide internally to
readdress coverage decisions. The most common way
that we change our coverage decisions or have new
coverage decisions is someone asks us to do that,
and we have a fairly well defined process, you
find that on our web site, www.cms.gov/coverage. And anyone, and I mean anyone, from a beneficiary to a provider to a company to an organization, in fact it was CDC who had us remove the obesity language, or who asked us to remove the obesity language, can request that we modify our current coverage process to something else. And so we would certainly be interested in hearing from someone who is interested in us changing our policy. We in fact think that's the best way to do it, because then we have some public interest in having that done and it's always helpful that the public is interested in what we're doing rather than our deciding on our own to do things. That always goes over better with the public.

So those are our next processes, and so we will be reviewing this information, though we certainly encourage folks who are interested in us having a different policy to request that we change that.

So with that, thank you again for your time, and Kim, you have some final, or Michelle, you have some final comments? I can't even remember who I'm talking to.

MS. LONG: I want to thank everyone
also, and if somebody would move to adjourn, we can end the meeting.

     DR. WEISSBERG:  Move to adjourn.
     MS. LONG:  Second?
     DR. O'CONNELL:  Second.
     MS. LONG:  We are adjourned.

     (Whereupon, the meeting adjourned at 3:45 p.m.)