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CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Coverage Advisory Committee

November 30, 2006

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland

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1 Panelists
2
3 Chairperson
4 Alexander H. Krist, M.D.
5
6 Voting Members
7 Mark V. Boswell, M.D., Ph.D.
8 Barbara D. Boyan, Ph.D.
9 Kim J. Burchiel, M.D.
10 A. Mark Fendrick, M.D.
11 David R. Flum, M.D., M.P.H., F.A.C.S.
12 Jeffrey G. Jarvick, M.D., M.P.H.
13 Stephen L. Ondra, M.D.
14 Laxmaiah Manchikanti, M.D.
15 John S. Kirkpatrick, M.D.
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17 HCFA Liaison
18 Steve Phurrough, M.D., M.P.A.
19
20 Consumer Representative
21 Charles J. Queenan, III
22
23 Industry Representative
24 Kim K. Kuebler, M.N., R.N.
25

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1 Panelists (Continued)
2

3 Guests
 4 Tom Faciszewski, M.D.
 5 Jon D. Lurie, M.D., M.S.
 6
 7 Executive Secretary
 8 Michelle Atkinson
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1 PANEL PROCEEDINGS
2 (The meeting was called to order at
3 8:05 a.m., Thursday, November 30, 2006.)
4 DR. PHURROUGH: Good morning, folks.
5 We're getting ourselves ready here in just a
6 minute, so if folks will take their seat, we'll
7 get started here. I yell pretty well, so I'll
8 start. I am Steve Phurrough, I am the director of
9 the coverage and analysis group and the
10 representative, CMS representative to this
11 particular panel. Welcome today.
12 I'm going to repeat this over and over
13 and over again. I have been repeating this for
14 the last three months and no one seems to believe
15 me. We are not doing a national coverage
16 determination on spinal fusion. We are not doing
17 a national coverage determination on spinal
18 fusion.
19 (Laughter.)
20 The purpose of the Medicare Coverage
21 Advisory Committee is to provide recommendations
22 to CMS as to the strength of evidence around a
23 particular technology that we ask them to review.
24 The purpose of the advisory committee is not to
25 tell us whether we should or should not cover

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1 something. It's not their role, it's not a role
2 that we allow them to assume, because even if we
3 are having the, this particular committee meet
4 during a national coverage determination where we
5 may in fact be asking them what's the evidence
6 around the particular issue that we are addressing
7 in that NCD, we're still not asking them to tell
8 us whether we should cover it or not. We never

9 ask them that. In fact, they are prohibited by
10 their charter from doing that. I just wanted to
11 clarify that. I have had this interview now for
12 12 to 15 times, and not always accurately -- well,
13 I should say that it's usually accurately quoted,
14 it's just not believed. We're not doing a
15 national coverage determination.
16 Now the reason we have these kinds of
17 meetings is to stimulate many of you who are
18 involved in the treatment of patients, in the
19 development of evidence or in the development of
20 technologies to recognize what this particular
21 group and what CMS believe about the state of
22 evidence around a particular technology and to
23 stimulate you to do something about those gaps, if
24 those gaps are present. We think we have done
25 that successfully in some other MCAC's, or at

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1 least that has begun, and that is their role here
2 today, is the evidence sufficient for us to be
3 comfortable as a community, health care community
4 in the use of spinal fusion in degenerative disc
5 disease, or are there some gaps that need to be
6 filled, and if there are some gaps that need to be
7 filled, we will be encouraging you to help fill
8 those gaps over the ensuing months to years.
9 So that's the goal here today. We
10 expect a lively discussion. It would be a
11 different MCAC if the discussion was not lively.
12 There are time lines to be met. Those time lines
13 will be met. If you are a speaker, you have a
14 specific of time to speak and when that time is
15 up, your speaking is up. So you may be cut off.
16 There are a lot of people who want to talk, you
17 have your time, and you need to finish within that
18 particular period of time.
19 There are some specific formal things
20 that we need to get done to begin with, the
21 microphones are now on, so I can quit yelling, and
22 I will turn this over to Michelle Atkinson, the
23 executive secretary, and let her start with the
24 official business.
25 MS. ATKINSON: Thank you, Steve. Good

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1 morning and welcome, committee chairperson,
2 members and guests. I'm Michelle Atkinson, the
3 executive secretary for the Medicare Coverage
4 Advisory Committee. The committee is here today
5 to discuss spinal fusion for the treatment of low
6 back pain secondary to lumbar degenerative disc
7 disease.
8 The following announcement addresses
9 conflict of interest issues associated with this
10 meeting and is made part of the record. The
11 conflict of interest statutes prohibit special

12 government employees from participating in matters
13 that could affect their or their employers'
14 financial interest. Each member will be asked to
15 disclose any financial conflicts of interest
16 during their introduction. We ask in the interest
17 of fairness that all persons making statements or
18 presentations also disclose any current or
19 previous financial involvement in any company that
20 manufactures tools used for the diagnosis or
21 treatment of spinal problems. This includes
22 direct financial investments, consulting fees, and
23 significant institutional support. If you haven't
24 already received a disclosure statement, they are
25 available on the table outside of this room.

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1 We ask that all presenters please
2 adhere to their time limits. We have numerous
3 presenters to hear from today and a very tight
4 agenda, and therefore cannot allow for extra time.
5 There is a timer at the podium that you should
6 follow. The light will begin flashing when there
7 is two minutes remaining and then turn red when
8 your time is up. Please note that there is a
9 chair for the next speaker, and please proceed to
10 the chair when it is your turn.
11 For the record, the voting members
12 present for today's meeting are Mark Boswell,
13 Barbara Boyan, Kim Burchiel, Mark Fendrick, David
14 Flum, Jeffrey Jarvick, Stephen Ondra, Laxmaiah
15 Manchikanti, John Kirkpatrick. A quorum is
16 present and no one has been recused because of
17 conflicts of interest.
18 The entire panel, including non-voting
19 members, will participate in the voting. The
20 voting scores will be available on our web site
21 following the meeting. Two averages will be
22 calculated, one for the voting members and one for
23 the entire panel.
24 I ask that all panel members please
25 speak directly into the mike. You may need to

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1 move the mikes and share them. And lastly, please
2 remember to discard your trash in the trash cans
3 located outside. Thank you very much, and I will
4 turn it back over to Steve.
5 DR. PHURROUGH: One last introduction
6 before the rest of the panel is introduced.
7 Unfortunately, I will need to be stepping out of
8 the meeting for brief periods of time during the
9 day. Dr. Marcel Salive, who is the division
10 director for issues to include spinal surgery,
11 will be filling in on those occasions to provide
12 CMS input. I have no other issues, so we'll turn
13 it over to Dr. Krist.
14 DR. KRIST: Thank you all for coming

15 here today. I want to start by thanking you for
16 the work you have done to get here today, and CMS
17 for putting this together, for the technology
18 assessment, for all the presenters today, as well
19 as the panel members.
20 As Michelle was saying, we have a tight
21 schedule, and one of my jobs is going to be to
22 keep us on schedule, so I apologize if I end up
23 cutting you off. If you could pay attention to
24 those lights and try to stick to the time lines,
25 that would be good, because I'd like to make sure

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1 that the panel has enough time to ask questions,
2 to clarify the evidence issues that they have, as
3 well as have time to discuss all the topics that
4 you lay down for us.
5 For speakers, when you get up to the
6 podium, if you would introduce yourself, where
7 you're from, and also the conflicts of interest to
8 begin with, and we'll start actually with doing
9 the same thing for our panel here, so starting at
10 the end with Tom, and introduce yourself and say
11 if you have any conflicts of interest.
12 DR. FACISZEWSKI: Tom Faciszewski, with
13 the Marshfield Clinic, and I have nothing to
14 disclose, no conflicts.
15 DR. LURIE: Jon Lurie (inaudible).
16 MR. QUEENAN: I'm Charlie Queenan, a
17 management consultant, and I have no conflicts of
18 interest.
19 MS. KUEBLER: My name is Kim Kuebler,
20 I'm associate director of the medical publication
21 Respiratory, and am the industry representative.
22 I have spoken on (inaudible) and received grants
23 from PhRMA, Abbott Laboratories and the Michigan
24 Department of Community Health. I have also been
25 a contact point for the Advancement of Medical

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1 Technology Association, which included
2 representatives of Avinet, Abilene Health, Des
3 Plaines Spine, Innovative Spinal Technologies,
4 Medtronic and Zimmer.
5 DR. KIRKPATRICK: I'm John Kirkpatrick,
6 I'm from the University of Florida, an orthopedic
7 spine surgeon, and I have to beg ignorance. My
8 conflicts were reviewed as far as stock holdings
9 and they were close to threshold, but I have not
10 been informed whether they have to be disclosed.
11 Michelle?
12 MS. ATKINSON: No.
13 DR. KIRKPATRICK: So I'm fine, thanks.
14 DR. MANCHIKANTI: Laxmaiah Manchikanti,
15 Pain Management Center of Paducah, Kentucky. I'm
16 an interventional pain physician. I'm also CEO of
17 a group of pain physicians. I do not have any

18 conflicts of interest.
19 DR. ONDRA: Steve Ondra, from
20 Northwestern University in Chicago, I am a spine
21 surgeon. I have grant and support, as well as
22 consulting.
23 DR. JARVICK: I'm Jeffrey Jarvick, a
24 radiologist at the University of Washington, and
25 I'm a co-founder and stockholder of a company

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1 called (inaudible).
2 DR. FLUM: I'm Dave Flum from the
3 University of Washington, and am a general surgeon
4 and researcher. I have NIH support for research
5 but no conflicts.
6 DR. FENDRICK: Mark Fendrick, general
7 internal medicine at the University of Michigan.
8 No conflicts.
9 DR. BURCHIEL: Kim Burchiel, Oregon
10 Health and Science University neurosurgery, and I
11 have nothing to disclose, no conflicts.
12 DR. BOYAN: I'm Barbara Boyan, from
13 Georgia Tech and Emory, I'm a tissue engineering
14 faculty member, and I am totally conflicted as far
15 as being a consultant for MTF, BioMed, Medtronic,
16 Zimmer, and I'm on the board of directors of two
17 companies, both of which have spine products.
18 DR. BOSWELL: Mark Boswell, Texas State
19 University Health Sciences pain management. No
20 conflicts.
21 DR. KRIST: I'm Alex Krist. I'm at
22 Virginia Commonwealth University in the department
23 of family medicine, and I have no conflicts to
24 disclose.
25 And I think at this point we'll turn it

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1 offer to Dr. Feinglass to do the CMS presentation
2 of the background topics and the voting questions
3 for discussion.
4 DR. FEINGLASS: Good morning. I want
5 to thank you all again for coming out very early
6 to Baltimore. To reiterate what Dr. Phurrough
7 said, we are not doing an NCD on spinal fusion,
8 just so you hear it again. As many of you know,
9 surgical intervention for degenerative disc
10 disease is really a very controversial issue on
11 many levels. Because of this controversy, we have
12 brought you all here today to hopefully evaluate
13 the impact of this treatment, to target this
14 benefit to the Medicare population and shed some
15 light on the current state of the evidence in the
16 field.
17 I also would just at the outset of this
18 meeting like to acknowledge the long awaited SPORT
19 trial which was published last week in JAMA. You
20 will notice that SPORT will not be debated in much

21 of the evidence presented today because the data
22 published thus far deals with information in an
23 area not addressed by the MCAC today. And also,
24 the data that is available publicly was just
25 published last week. We commend the SPORT

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1 researchers for their work and encourage others in
2 the field to look at doing large scale RCTs, and
3 look forward to the rest of the data that will
4 come from the SPORT trials.
5 So to begin with the official reading
6 of the questions. Today's hearing is to consider
7 spinal fusion for the treatment of low back pain
8 secondary to degenerative disc disease.
9 The first question: What level of
10 confidence does the evidence provide in addressing
11 the outcomes needed to determine the effectiveness
12 of lumbar spinal fusion for low back pain due to
13 lumbar degenerative disc disease? Rate it from
14 low to high. Discussion questions: Is the relief
15 of pain the appropriate primary outcome, or should
16 it be restoration of function, return to work, or
17 something else?
18 Question 2: What level of confidence
19 does the evidence provide for characterizing the
20 complications, adverse events and other harms from
21 lumbar spinal fusion for degenerative disc
22 disease, both short term and long term?
23 Discussion questions: What does the variability
24 in surgical risk depend on? As this procedure is
25 permanent, are there other potential long-term

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1 harms that have not been discussed?
2 Third question: Based on the evidence
3 presented, how likely is it that lumbar spinal
4 fusion for lumbar degenerative disc disease
5 improves clinical outcomes as compared to
6 conservative treatment, both in the short term and
7 long term? Discussion questions: What are the
8 causes of low back pain? Is patient selection
9 important, and if so, what are the clinical and/or
10 patient characteristics that are reliable
11 predictors of satisfactory outcomes? If there is
12 an absence of evidence of long-term benefit, would
13 evidence of short-term benefit be sufficient to
14 justify a fusion procedure? If one clinical trial
15 were to be done, what should it be?
16 Question 4: Based on the evidence
17 presented, how likely is it that the various
18 fusion procedures improve health outcomes for
19 lumbar degenerative disc disease? Consider these
20 procedures both with and without instrumentation,
21 short term, long term, and then with
22 instrumentation and without instrumentation, and
23 then we ask about specific procedures.

24 Discussion: How important is patient selection
25 relative to the type of procedure? What criteria

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1 are used to select the type of fusion procedure?
2 Question 5: What level of confidence
3 does the evidence provide that radiographic
4 interpretations are correlated with clinical
5 outcomes for lumbar spinal fusion due to lumbar
6 degenerative disc disease? Is there uniform
7 agreement regarding terminology for radiographic
8 interpretations?
9 Question 6: Based on the evidence
10 presented, how likely is it that the results
11 generalize to the Medicare population for, A,
12 relief of pain, and B, complications, adverse
13 events and other harms? Discussion questions: Do
14 studies need to be done in the Medicare population
15 to strengthen the conclusions? Discuss the impact
16 of age and comorbidities.
17 Those are the official questions.
18 DR. KRIST: Okay. Next we'll hear the
19 technology presentation from Dr. McCrory.
20 DR. MCCRORY: Good morning. I'm Doug
21 McCrory, assistant professor of medicine at Duke
22 University. Oh, I need to speak into the mike.
23 There we go. Well, while we are waiting, I'd like
24 to acknowledge my co-authors, two of whom are here
25 today, Dr. Turner, a neurosurgeon who does a lot

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1 of work with spine surgery, who is on faculty at
2 Duke, and Dr. William Richardson, who (inaudible)
3 today, who provided an invaluable amount of
4 evidence to this project. Here we go.
5 I'm on the medical staff at Duke
6 University and my co-authors' conflicts are listed
7 there.
8 I want to start by, first of all, I
9 think my remarks today are going to try to
10 summarize the report. I'm not going to be able to
11 provide all the details of the technology
12 assessment, as it's rather lengthy and detailed.
13 I want to go through a few slides, I hope it's not
14 too repetitious for many members of the audience
15 here today, and then get into the questions that
16 we addressed.
17 So you know, first of all, we were
18 concerned with lumbar spine disc disease. I
19 reviewed this with members of our own staff who
20 were not very well versed in this and go into it
21 in some detail. I wanted to draw a (inaudible)
22 facet joint, and we were interested not only in
23 the (inaudible) disc, but also the disease that
24 occurs from early (inaudible) spondylosis.
25 The rationale for lumbar spine fusion

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1 really relates to relief of back pain or
2 radiculopathy. It has been typically considered
3 after conservative measures have not provided
4 symptomatic relief. The fusion risks are fairly
5 well described in the literature. They include
6 risk of anesthesia, perioperative risks, as well
7 as short and long-term risks associated with the
8 spinal nerves.
9 Just to review the range of procedures
10 that we're considering as part of the spinal
11 fusion, anterior fusion or ALIF is a procedure
12 often used in middle-aged patients who have
13 symptoms, usually disc degeneration at a single
14 level. They are often posterolateral fusion,
15 which can be single or multiple levels, often
16 utilizing bone grafts or metal instrumentation.
17 And sometimes it's combined with lumbar
18 decompression or laminectomy.
19 Circumferential fusion combines
20 anterior and posterior, including interbody fusion
21 done posteriorly, PLIF, and the particular choice
22 among all these procedures varies as the degree of
23 variety that is used, depending on comorbidities,
24 symptoms, and the optimal approach to the lumbar
25 spine is made on a case-by-case basis.

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1 The final slide, just part of the
2 motivation for the technology assessment I believe
3 was the increase in spinal fusion surgery that had
4 been seen, and this slide from Dr. Cowan's
5 presentation compares the thoracolumbar fusion
6 rates, the cervical fusion rates and the lumbar
7 rates. Now this is data from all ages, but the
8 subgroups have shown that the increase in the rate
9 of fusion has occurred not only in middle-aged
10 patients but also in those over 65 years of age,
11 which is the target population here.
12 So more specifically, the background
13 for this report was that there was no systematic
14 evaluation on the efficacy or safety of lumbar
15 spinal fusion in the elderly population, and
16 elderly patients may be clinically different
17 because age-related changes in the spine may mean
18 that they have a different disease, it may include
19 diffuse disc and facet degeneration. And as
20 people age, they generally get more comorbid
21 conditions that could affect the procedure's
22 efficacy and safety.
23 So, that brings us to the key question
24 that we were charged to address with the
25 technology assessment. In patients at least 65

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1 years of age with degenerative disc disease and/or
2 degenerative joint disease of the lumbar spine,

3 what is the evidence regarding indications and
4 outcomes, including the adverse events and overall
5 net health benefit, of lumbar spinal fusion as
6 compared to non-surgical conservative treatment or
7 other surgical strategies? So you know, we wanted
8 to pay attention to the age range of the patients
9 which we were particularly interested in,
10 primarily we were interested in outcomes, and the
11 fact that we're interested specifically in how
12 well they did and whether there were adverse
13 events, compared with conservative management or
14 other surgical procedures.
15 So, a few slides on methods. The way
16 we decided to approach this question was to look
17 at a variety of sources. We did look to web sites
18 for professional society guidelines or preexisting
19 systematic reviews. We wanted to look at the most
20 recent data, so we also looked at news articles,
21 data from the FDA, and solicited advice from
22 several experts. We did a comprehensive search
23 relying on MEDLINE, but we limited that to a
24 primary search of literature since 2002; we relied
25 on systematic reviews and other data to fill in

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1 for previous data previous to 2002.
2 So the purpose of the MEDLINE search
3 was to identify the recent trials or recent series
4 of cohorts. We did limit it to groups with more
5 than 50 patients, and based on conservative
6 treatments.
7 Our inclusion criteria was guided by
8 the question. We were considering any lumbar
9 spine fusion surgery, so regardless of the
10 approach, anterior, posterior or both, and we
11 looked at data on the use of instrumentation as
12 well as non-instrumented fusions. Comparisons
13 were nonsurgical management, which would include
14 pain medication, treatment, injections, and
15 rehabilitation strategy. We specifically did not
16 include chiropractic treatment. We were also
17 interested in comparisons with lumbar
18 arthroplasty.
19 The set of outcomes that we were
20 considering is also enumerated right here. We
21 looked at two time frames, early and late, as
22 defined in the questions. We were particularly
23 interested in patient outcomes such as quality of
24 life, disability measures, pain and pain
25 medication use, in particular narcotic use. We

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1 looked also at adverse events including
2 perioperative complications, later reoperation,
3 and longer term outcomes such as adjacent segment
4 disease. We considered radiographic fusion as an
5 outcome, but only if it was ancillary to one of

6 the other two sets of outcomes, either the
7 efficacy outcome or one of the adverse event
8 outcomes in bullet three.
9 The Oswestry Disability Index, we
10 looked at the disability as it is currently. We
11 named this specifically in our methods as an item
12 we were going to look for, specifically looking at
13 the 10-item instrument that looks at activities of
14 daily living, and each of the 10 items is scored
15 with six response choices. Those scores are then
16 standardized on a 0 to 100 scale. There has been
17 a bit of background psychometric work on the scale
18 with standard error measurements, that's about
19 four points, but the minimal point and important
20 difference, that is the difference in score that
21 would correlate with the change in how the patient
22 perceives this disability level on a global scale
23 is in the range of 10 to 15. And indeed, the
24 level of 15 was selected by the FDA for use in
25 the, I believe the arthroplasty versus (inaudible)

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1 as being a clinical significant difference, in
2 contrast to the change on visual and pain scales
3 (inaudible) on a 0 to 100 scale, and for the RDI,
4 somewhere in the range of 2.5 to 5.5.
5 In general, these sort of clinically
6 meaningful global measures, where patients
7 describe being much improved or very satisfied,
8 can be seen from these satisfaction scales, and
9 just incidentally, the minimal clinically
10 meaningful changes in conservatively treated back
11 pain is generally less smaller than those who are
12 referred for fusion to treat their back pain.
13 So, we also had an organizing principle
14 just in terms of our approach to the literature.
15 We felt that the clinical rationale for selecting
16 a procedure depended very much on the clinical
17 presenting symptoms as well as the subjective
18 degree of pain, as well as the patient's interest
19 in surgery. We organized it according to the
20 syndrome of axial back pain and spondylolisthesis.
21 We weren't really able to be as fine in our
22 gradations of the clinical syndrome as we would
23 like, pretty much because of the limitations both
24 ways, the information we had at hand, and it's not
25 well described in the literature.

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1 I apologize that this slide is not
2 terribly readable, but let me go through the
3 results of our literature search. So just
4 considering the Ovid MEDLINE searches, we had
5 several independent subsearches, we did some
6 supplemental searching that resulted in 125. And
7 then we had about 273 review articles. Also, we
8 looked at references from Cochrane's reviews and

9 other sources.
10 The total number of articles that we
11 ended up looking at was 1,391. We excluded about
12 a thousand of those because they weren't focusing
13 on one of the areas of our key questions, but
14 detailed (inaudible) many were excluded. The
15 final evidence report includes citations of about
16 82, and granted, this is not an exhaustive list of
17 all the literature, but the articles that
18 (inaudible) these topics in order.
19 The first is dealing with the axial
20 back pain, and what we did is look at comparisons
21 of lumbar spinal fusion without surgery, and then
22 data on anterior lumbar interbody fusion,
23 posterior procedures, and arthroplasty. What we
24 will do is look first at spondylolisthesis and
25 then deal with some of the other areas, such as

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1 incidence of adjacent segment disease, look at
2 other complications, and then we'll look at the
3 difference between instrumented versus
4 non-instrumented fusion from previous reviews.
5 We'll look specifically at a group of studies that
6 were performed in patients over 65 years of age
7 and deal with a little bit of complications in
8 that context. And then finally, we'll look at
9 techniques to augment fusion.
10 So here are the results. Studies of
11 lumbar fusion for axial back pain, I want to
12 emphasize that there is no randomized clinical
13 trial that has a direct comparison of lumbar
14 spinal fusion with non-surgical treatments in the
15 population of those greater than 65 years of age.
16 We did identify four random studies of fusion that
17 were not done in the U.S., for axial pain versus
18 rehab, and all of these were done with a posterior
19 or mixed fusion. Most of this data for this
20 procedure are coming from other series of cohort
21 studies.
22 I'll show you this graphic on the four
23 randomized trials. For each trial, I'm showing
24 both arms of the study. The open circle on the
25 right represents the Oswestry score

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1 preoperatively, the closed circle on the left
2 shows the Oswestry score postoperatively, so the
3 arrow indicates a change in the Oswestry pre to
4 post surgery. And then looking at both of the
5 arms, you can get an idea what the difference is
6 between those arms.
7 Looking at the Oswestry, you can see
8 the reduction in the Oswestry score was between 10
9 and 15 for both the rehab arms and the fusion
10 arms, and this difference between the length of
11 that arrow and the length of that arrow would be

12 the difference in efficacy between those two
13 procedures. As you can see for the four studies,
14 the differences between the effects were somewhat
15 different. The Fritzell study was statistically
16 significant but the others did not show
17 statistically significant differences, with the
18 exception of Fairbank. Fairbank, I do want to
19 note, was powered to detect a difference of about
20 four points on the scale, and in fact the
21 difference reported was 4.1, which is less than
22 that which is usually recognized as a clinically
23 significant difference.
24 And I just wanted to discuss for a
25 moment, there are different ways of approaching

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1 the clinically significant, this was greater than
2 10, it's not quite 15, so you might argue that it
3 doesn't matter clinically, but there was variation
4 in the way a lot of the studies were validated.
5 But if you're looking at a clinically important
6 difference as to whether surgery significantly
7 exceeded the effect of rehabilitation, then
8 clearly a four-point difference doesn't get near
9 that level required to be a clinically meaningful
10 difference. So although the Fairbank study does
11 show a statistically significant difference, we're
12 not clear that it is a clinically significant
13 difference between the pre and post surgery
14 scores, compared with rehabilitation.
15 So with that framework in mind, the
16 Fritzell study also did not achieve that 15-point
17 difference between the fusion and the rehab arm.
18 Now, these studies (inaudible) and why
19 is that? There were some differences in the
20 patient population in terms of how long the
21 patients had undergone conservative management and
22 there were also differences in the degree of
23 intensity of the rehabilitation therapy. For
24 example, the Brox trial had one of the more
25 intensive rehabilitation regimens, (inaudible)

00030

1 involving those components, and like Fritzell,
2 seemed to be the most intense rehabilitation
3 intervention. Now, that said as a hypothesis, the
4 details were not terribly well described, and I'm
5 not trying to pretend that's a conclusion that you
6 can reach from these studies.
7 So in summary, you know, we believe
8 that these do provide evidence of before and after
9 clinically meaningful change in the stability
10 index and shows a difference between fusion
11 surgery and conservative treatment, but I don't
12 know that we would necessarily call that
13 important.
14 So moving on to the ALIF studies, as I

15 said before, we used an isolated single-level disc
16 degeneration in adults with a positive discogram.
17 The one theoretical advantage of (inaudible), show
18 you data from a number of uncontrolled series as
19 well as trials that compare ALIF with
20 arthroplasty. These were primarily designed to
21 show that ALIF are, that arthroplasty was better
22 or worse than other possibilities such as
23 posterior.
24 One of the first things I wanted to
25 notice about these studies is that the change from

00031

1 before and after surgery on the ALIF arms was of a
2 greater magnitude than we saw with lumbar fusion.
3 So in every case here, it exceeded a change of 15
4 on the disability index, so from before and after,
5 by frequency and disability. However, you know,
6 there were no trials here that compared ALIF to
7 conservative non-surgical approach. Some of these
8 did compare to the arthroplasty arm but are not
9 shown on this slide. So despite the fact that the
10 change in the disability rating is of greater
11 magnitude, the lack of a comparison may make it
12 difficult to draw a conclusion about how effective
13 ALIF is, as a particular procedure is considered
14 to be conservative therapy.
15 So again, looking at posterior lumbar
16 fusion, you'll see direct comparisons between
17 different types of posterior fusions. Those
18 include the (inaudible) separately to posterior
19 fusions, (inaudible) or a circumferential fusion
20 which was done as either an ALIF or -- I'm sorry,
21 an anterior -- sorry -- a circumferential fusion
22 which was done either anteriorly or entirely
23 posterior.
24 You can see from this slide, the --
25 there was a reduction in scores, and what I showed

00032

1 you before was 24-month outcomes, and that was a
2 reduction of about 13 points. And the point of
3 this slide was to illustrate that the changes in
4 visual and pain scale between these procedures,
5 the experience was actually fairly similar, so
6 these are not significantly different from one
7 another. These groups aren't huge, but the power
8 (inaudible) clinically important.
9 Last but not least, the RCT comparison,
10 this was not a random controlled trial, these were
11 patients who had initial observational studies
12 looking at outcomes for different populations, but
13 it did allow one fairly large sample sizes, a
14 comparison of the pre-op to one year post-op, and
15 could be randomized by the type of procedure. And
16 as you can see visually, I apologize for the
17 reproduction of the slide, the slides are in

18 order, so this is ALIF, PLIF and/or TLIF,
19 posterior fusion, and 360-degree fusion, and
20 they're on the same order over here. As you can
21 see, the before and after here were all somewhat
22 similar, there were some slight differences in
23 that the PLIF and TLIF were, reductions were a
24 little less than the others, and the posterior
25 fusion was a little more than the others, but the

00033

1 differences were not very large. They didn't
2 exceed that clinically significant threshold.
3 To look at some additional data from
4 the circumferential fusion, going with the
5 anterior-posterior or entirely posterior two-level
6 approach, we saw that these, the changes in the
7 Oswestry were somewhat more variable, in a few
8 cases the differences were large and exceeded 15,
9 in many of the cases they were smaller and didn't.
10 Some of these data came from randomized controlled
11 trials but many had variations in technique, for
12 example, the (inaudible), but many of them were
13 just not controlled studies. So we didn't have
14 any other cases where there was a control
15 sufficient to reach conclusions about the efficacy
16 relative to the conservative therapy arm.
17 To show some data on the arthroplasty
18 trials. The arthroplasty trials were done in
19 specific indications in the study populations, so
20 in all of those studies I will show you that the
21 patients were single-level degenerative disc
22 disease with only axial pain, or not only axial,
23 but also a positive MRI or discogram measured
24 around that level. These studies were all done in
25 patients with an average age of around 40. But as

00034

1 I mentioned, they were inferior trials compared
2 with ALIF, and all of them give data of no more
3 than two years.
4 On this study, I want to point out that
5 the before and after Oswestry differences were
6 generally greater than 15, and that's in terms of
7 the mean change. I did want to illustrate, only
8 one of these studies showed the proportion of
9 patients who individually had a clinically
10 significant change from before and after that
11 exceeded 15 points. So here in this, you'll see
12 that 68 percent of patients had a change in
13 disability. Now prior to the study showing the
14 changes in disability, and that's obviously when
15 you're dealing with means, some patients have a
16 better outcome, some patients have a worse
17 outcome. We were looking for these sorts of
18 results (inaudible) little bit for clinically
19 important (inaudible) actually experience a large
20 disability. Again, the drawback in interpreting

21 those arthroplasty trials is that none of them
22 were compared to conservative treatment.
23 We're going to switch gears now and
24 leave the axial back pain studies and go on to the
25 spondylolisthesis studies. As compared to the

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1 axial back pain studies, these spondylolisthesis
2 studies, the goal is usually treatment of patient
3 complaints, radiculopathy or spinal stenosis. And
4 the, I wanted to primarily highlight the one
5 randomized controlled trial that not only compares
6 fusion to conservative treatment, and that is the
7 Moller and Hedlund in 2000, and followed up then
8 by Ekman in 2005 with long-term follow-up data.
9 I'm showing you data here on these two
10 panels on pain, and I must apologize, the original
11 Moller and Hedlund study describes this as being
12 measured with a disability index and then Ekman
13 describes them in further studies, so I'm not sure
14 whether we're (inaudible) identical correction to
15 try to present everything in numbers that relate
16 to, but these are, should be interpretable along
17 with the Oswestry.
18 So the Moller-Hedlund study showed
19 results in favor of surgery and compared to
20 exercise at one and two years in both pain and in
21 the disability rating index. And these
22 differences here at one to two years look like
23 they exceed 20 in terms of the pain scores and
24 were just about 15 in terms of the disability
25 rating index. One of the remarkable things about

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1 the Ekman study was it was one of the few that had
2 really long-term follow-up data about the effect
3 of, both the surgery, but also those patients who
4 were maintained on conservative therapy. And
5 remarkably, there didn't seem to be a great deal
6 of difference between the conservative patients
7 and those who had surgery. So the thing I wanted
8 to point out was the trajectory of the non-surgery
9 patients who didn't really worsen, they didn't get
10 clinically significantly better, but these two
11 groups' experience gets closer together as time
12 goes on as a consequence of the mild decrease
13 there and a mild increase in pain, and the same
14 thing with the disability there, and this result
15 is nonstatistically different for them.
16 I want to turn now to the instrumented
17 fusion. There has been a lot of data, a lot of
18 synthesis of this sort of data presented by
19 (inaudible) summary instruction, clinically shown
20 to increase the rate of radiographic fusion. The
21 relationship between a radiographic fusion and
22 outcome is only indirectly available and not
23 terribly strong.

24 I want to show you data from Gibson and
25 all, which compares randomized controlled trials

00037

1 looking at instrumented versus graft-only fusion.
2 So we didn't want to reinvent the wheel, this
3 seemed to be a pretty reliable analysis, and so
4 this is the fusion data in the seven studies.
5 Most of them had at least a trend for favoring
6 instrumentation in terms of creating a fusion.
7 The next slide shows poor clinical
8 outcome as a measure where patients are asked
9 whether they are better or worse than they were
10 after surgery. And when you combine the data from
11 all these randomized controlled trials, they favor
12 instrumented fusions.
13 Bono and Lee took a different approach,
14 in that they not only looked at random controlled
15 trials as the Cochrane review did, but looked at
16 uncontrolled series. The studies were combined,
17 but there were quite a few, and this shows the
18 total number of patients involved in all these
19 controlled studies and resulted in a large number
20 of patients, and indeed, they did show
21 statistically significant improvements here for
22 any fusion versus no fusion, or, I'm sorry,
23 instrument fusion versus no instrumentation,
24 semirigid or rigid versus none. The fusion rates
25 were not terribly impressive, but again, this is

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1 data from the 1980s and 1990s.
2 When we look at the clinical outcomes
3 as the Cochrane review did, there was a trend,
4 though not statistically significant, for what's
5 better, good or excellent results among
6 noninstrumented fusion. Again, which is
7 (inaudible) that we would not expect from the
8 (inaudible) associated with the instrumented
9 fusion. The only direct data we had from
10 randomized controlled trials that I want to
11 highlight was the Fritzell study. This was using
12 bone graft, the square group was using VSP, and as
13 you can see, the diagonals and the square is
14 (inaudible) but also very similar for disability
15 outcomes. The good fusion rates can be achieved
16 without instrumentation, there may be an effect
17 over time, and I think I'll hold it for the last
18 slide, that in terms of open fusion, that the
19 instrumentation, but the good fusion rates may be
20 obtained without instrumentation.
21 Okay. What I would like to highlight
22 for a moment, the adjacent segment disease data,
23 this required looking at long-term studies that
24 correlated disease at levels either above or below
25 fusion, and we looked at a bunch of uncontrolled

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1 studies that provided long-term outcome data at
2 specific levels of the spine, and we found that
3 when we were looking at this data relating to
4 adjacent segments, the definitions vary a great
5 deal in terms of how (inaudible) might be defined,
6 and how variability was (inaudible) and we didn't
7 analyze that data.
8 What we did feel was reliable was that
9 data on reoperation for adjacent level disease
10 which was more precisely measured or more reliably
11 measured. So we actually looked at ten studies
12 that had four to 14-year follow-up and calculated
13 an overall pooled rate that was around three
14 percent per year. We were not entirely
15 comfortable attributing that to the effect of
16 fusion, the original fusion causing increased
17 motion at the adjacent segments, so we tried to
18 figure out what would be an appropriate control
19 for that. We did look at several long-term
20 studies without fusion, which also gave us data on
21 the reoperation rate for symptomatic recurring
22 stenosis, and when we applied a similar
23 methodology, the only difference being that we
24 included reoperation at the same or different
25 levels, we found a reoperation rate of about 2.5

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1 percent per year.
2 Again, this is a crude way of sort of
3 trying to subtract out the background of
4 progression of spinal disease, but we feel like it
5 provided a little bit of additional information
6 helping us to interpret that three percent per
7 year figure.
8 We had a hard time addressing the issue
9 of the elderly population in the focus question.
10 One way we attempted to do that is we identified
11 studies that identified older populations, and the
12 populations in this group of studies weren't
13 precisely what we were interested in but they
14 seemed to be the best we could do, with over 55 as
15 being a representative population that might be
16 more generalizable to the Medicare population.
17 I want to highlight two studies that
18 provided within the same study a comparison of
19 older and younger patients. And the conclusion in
20 each one of these studies was that perioperative
21 complications may be increased in older patients,
22 with 12.5 percent complication rate in older
23 patients versus a 5 percent complication rate in
24 younger patients. While the sample sizes are not
25 very big and the result is not statistically

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1 significant, they do suggest that the
2 perioperative complications do increase. The

3 Kilincer and Carreon studies suggested that there
4 was a difference in the type of surgical procedure
5 that the older and younger patients were
6 undergoing, such that the younger patients were
7 more often receiving instrumentation, with the
8 older patients less frequently, so I think in
9 addition to the complication rate trend, there
10 also seems to be a trend to use procedures that
11 were expected to be slightly safer in the older
12 populations.
13 And, I have just a couple more slides,
14 I know I'm running out of time. We looked at a
15 variety of ancillary procedures used with fusion
16 to, as an enhancement. The only data that came
17 out of that as being clinically important was the
18 role of BMP as an alternative to autograft bone or
19 PLF. These data were summarized in the Journal of
20 Neurosurgery guideline. There was a little bit of
21 new data that reinforced that, and we basically
22 didn't have any additional findings beyond that.
23 (Inaudible) has to be contained as it can cause
24 problematic tissue spread out of where it's
25 supposed to be.

00042

1 I want to turn now to a couple of
2 slides just to highlight some of the
3 methodological issues we encountered in our
4 interpretation of this literature. The first set
5 here is taken from a systematic review from Bono
6 and Lee, 84 reports that they looked at. They
7 noted that the studies were nonspecified and, you
8 know, largely not random studies, and there were
9 other failures in the documentation of details of
10 the procedures. So there was some confusion on
11 what fusion criteria were used to determine
12 whether fusion had been observed as an outcome or
13 not, what the program source was, and what the
14 fusion rate was or at what rates fusion occurred.
15 Now we found that these deficiencies
16 were present in the studies we looked at and the
17 more recent studies that they looked at as well.
18 I wanted to highlight a few things that they
19 didn't comment on specifically. One of the
20 problems is that the lumbar spinal fusion studies
21 tend to be identified by a group of patients for
22 whom the inclusion criteria really is being driven
23 by the procedure, rather than being driven by the
24 patient's symptomatic multiple presentation. This
25 creates problems in interpretation of the

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1 literature because we're not quite sure under what
2 circumstances that procedure might be applied to
3 patients, so we favor more stringent
4 criteria-based approaches for defining patient
5 populations and selection of surgical procedures.

6 An obvious drawback for the purposes of
7 this panel is that the studies we found were
8 almost uniformly middle-aged people and not an
9 elderly population. One of the main goals of our
10 technology assessment was to try to focus on
11 patients who are (inaudible) such as the suit
12 index or the pain scales and in contrast to a lot
13 of the older (inaudible) global assessments for
14 patients of having to use their own judgment about
15 whether they're either better or worse or, you
16 know, measures that are utilized to determine
17 whether fusion has in fact occurred. We do
18 believe that this focus on more well measured
19 outcomes is important in assessing the current
20 literature and in evaluating going forward.
21 And finally, you know, also for this
22 technology assessment, we were interested in the
23 comparison between surgical therapy and
24 nonsurgical therapy. The nonsurgical controls
25 were really not terribly well standardized and

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1 described and could not be easily reproduced, at
2 least in the papers that we looked at. We noted
3 in more detail, and some of the other speakers
4 will comment on this later, that a greater
5 characterization of the disease needs to be done
6 in terms of the spinal anatomy in greater detail,
7 and also use of (inaudible), and finally after
8 looking at the previous treatments that the
9 patient had undergone, and that includes both
10 surgical treatments as well as other kinds, and it
11 should describe what the process was, and for what
12 type of herniated disc report or what type and
13 what duration of frequency.
14 My final slide is just kind of on the
15 SPORT study, it is ongoing with patients with
16 degenerative spondylolisthesis and who were
17 randomized for fusion or nonoperative treatment.
18 That data has not yet been published, but should
19 be forthcoming next year. And when we made the
20 slide, there were no other planned U.S. studies
21 that would compare fusion for axial back pain to
22 rehab. Actually, since then I have learned that
23 there was some material in a meeting, in fact
24 there may be a slide, and maybe it's getting
25 underway in December.

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1 Thank you. I believe that used up my
2 time and, if I'm not mistaken, the questions are
3 going to be saved until the question and answer
4 period.
5 DR. KRIST: Yeah, I think we will be
6 probably getting to that around 11 o'clock on our
7 schedule. Thank you, Dr. McCrory. I appreciate
8 your presentation. Next, Dr. Steven Garfin is

9 going to be presenting for us.
10 DR. GARFIN: Thank you. I'm Steve
11 Garfin, from the University of California San
12 Diego. My co-author was referenced extensively in
13 the tech report and earlier, Chris Bono, who is
14 here in the audience somewhere, from Harvard. I
15 in particular have a lot to disclose, it would
16 probably save time to tell you what I'm not
17 involved in, but as the chairman of the department
18 I also receive money from government and private
19 industry. Chris Bono is not a chair and doesn't
20 have to take any under the guise of the whole
21 department, any funding, nor a salary, I
22 understand.
23 (Laughter.)
24 The most important thing, number one,
25 we are both spine surgeons. Back pain is a

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1 significant problem. 75 to 80 lifetime
2 prevalence, annual incidence of 15 to 20 percent
3 per year, and it affects all of us at some time in
4 our life. It's the primary cause of disability in
5 patients less than 50 years old. It involves
6 500,000 workers' comp and personal injury cases.
7 I add that group, because many of those patients
8 become Medicare disability patients less than 65.
9 Chronic low back pain is defined as a
10 failure of nonoperative management. The time
11 period is not known, whether it's three months,
12 six months, one year, it varies. 10 to 25 of the
13 cases result in greater than 75 percent of the
14 cost. Again, high in workers' comp, this will
15 fall into the Medicare population if they don't
16 get back to work.
17 The natural history course is that they
18 do improve, 90 percent improve within two to six
19 weeks and get back to work with normal function.
20 There are 25 percent recurrences. There are only
21 11 percent of these that are chronic patients, and
22 few consider surgery. Unfortunately, though, the
23 percentages are small because the amount of people
24 who have back pain, the numbers are very large.
25 So, why is there confusion about

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1 fusion? There's a lot of reasons. The
2 pathophysiology of low back pain is unclear.
3 There's limited support diagnostic tools. There
4 is conflicting evidence and confusing evidence,
5 and I will try to go through these. Axial low
6 back pain symptoms are very vague. Normally there
7 is a normal neurologic, they may or may not have a
8 nonradicular sensory pattern, pain may extend from
9 the back or not, it may be localized, it may have
10 functional limitations or not.
11 The differential, there are a number of

12 significant medical problems, tumor, infection,
13 fracture, those are relatively easy to pick up on
14 x-ray or clinical exam. What we're talking about
15 today is axial low back pain, whether it's due to
16 the disc, stenosis which can cause back pain,
17 scoliosis which often does not cause pain, it's
18 there but can cause back pain. All of these taken
19 together above the word unknown can cause about 10
20 percent of what we know. 90 percent of the
21 patients come in with low back pain associated
22 with various sophisticated terms such as lumbago,
23 and we don't know what caused it.
24 It may be structural, it may be
25 microinstability, maybe some chemical irritation

00048

1 from the disc or nerves, abnormal loading,
2 sagittal balance. It may be hypotonic in that the
3 thoracic spine is hyperextended with low back
4 pain, or the low back pain may be functional, so
5 there's many reasons that we don't know.
6 Potential sources could relate to the discs, the
7 nerves, facets, muscles, ligaments, bone and
8 psyche, and we have very limited ability to
9 differentiate.
10 The disc, as you all know, has an
11 annulus on the outside and then the nucleus on the
12 inside. The big nerves we also know about, the
13 cauda equina and the spinal nerve that exits.
14 However, there are smaller nerves like the
15 sinuvertebral nerve, which goes across the
16 posterior annulus, and that annulus is often left
17 in place during kyphoplasty in the lateral side of
18 the disc. There's also the nerve (inaudible)
19 which runs a couple layers within the disc across
20 the longitudinal ligament and into the
21 intravertebral space. So there's a lot of
22 intrinsic sources that can sense pain, none of
23 which do we know or can pinpoint.
24 There's bones, ligaments, joints,
25 muscles all around the spine. It's a very complex

00049

1 anatomy, any one of these can cause pain, and we
2 don't have the ability, unfortunately, to localize
3 them to one area or another, which adds to the
4 confusion.
5 The diagnostic tools also are fairly
6 nonspecific. History tells us nothing except my
7 back hurts, maybe except for tumors or infections.
8 The physical exam is often normal. X-rays show
9 standard things in everybody over 25 or 35, narrow
10 disc space, some osteophytes. CT is good for
11 looking at bone but usually not the area we're
12 interested in. MRI is good for disc disease,
13 stenosis, herniated disc, so 30 percent of the
14 population who are asymptomatic has the same

15 findings. And discogram is what many of us use to
16 pinpoint the location of pain, but it is only 70
17 percent reliable. It's just not specific as a
18 diagnostic tool.
19 Outcome of assessment depends on the
20 diagnosis. It could be pain, it often is pain.
21 It could be the outcomes of function, are they
22 back to work, are they getting out of bed, do they
23 hurt much, do they take less narcotics, what's
24 their walking tolerance, what's their activity
25 level with the back involved, what do the x-rays

00050

1 look like. Seek and ye shall find. There's
2 multiple outcome measurements, and to make this
3 list I just took some selected references, they
4 focus on function, they focus on quality of life,
5 they focus on pain, walking tolerance, timed
6 functional tests, VAS has an outcome, NASS has an
7 outcome, every specialty society has an outcome,
8 and there is no consistent use of any or all of
9 them.
10 There are challenges to low back fusion
11 with the diagnosis of degenerative disc disease.
12 As stated, there's a lack of RCTs, limited Level I
13 evidence. There is increasingly more fusions done
14 despite this. There's a lack of clinical
15 diagnosis and indication in some if not most
16 cases, and as stated, the adverse events are
17 significant, fortunately not frequent, but this is
18 one area, low back pain surgery or low back pain,
19 if patients don't get better, then they often do
20 get worse. FDA is approving more devices based on
21 either tacit or an older work regarding scientific
22 validity and safety. The costs are now becoming
23 important and there are questions of who gets the
24 treatment and who does the treatment.
25 And all fusions are not the same. As

00051

1 you heard, posterolateral interbody fusions,
2 posterolateral fusions, PLIFs, ALIFs, XLIFs,
3 corpectomies, taking out the bone, anterior,
4 posterior and combinations. We also use
5 instrumented and noninstrumented, allograft,
6 autograft, cages, and newer devices that keep
7 coming out, and this is just a list of the various
8 interbody approaches on the top four, and
9 posterior fusions on the bottom three.
10 Just as an example, interbody fusion
11 anteriorly, using cages, bone, autografts or bone
12 substitutes, usually supplemented with posterior
13 instrumentation, enabling us to take out the disc,
14 which may be to immediate advantage, but I like
15 biologics to supplement a posterior cage. The
16 TLIFs and PLIFs, posterior lumbar interbody fusion
17 and transforaminal lumbar interbody fusion look

18 alike on x-ray. The PLIFs, however, move the
19 body, incline the body a little higher and there
20 is a higher incidence of damage reported. The
21 TLIF is more lateral and is used to create instant
22 stability and tends to cause less neurologic
23 problems. The standard extreme lateral fusion is
24 used less and less in the literature for low back
25 pain surgery, it is usually done after a

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1 laminectomy or for instability as appropriate for
2 scoliosis and spondylolisthesis, and may have a
3 role for facet pain if we knew what that was or
4 could diagnose it.
5 Instrumentation does increase fusion
6 rate, we saw that in previous slides and I won't
7 go over it.
8 Why are there increased surgical rates
9 for low back pain? There's many patients greater
10 than 65 years old today, they have better medical
11 care, more are living longer, their expectations
12 are to be healthy. Gerontologists and
13 cardiologists are some of my biggest referrals for
14 spine surgery, to get patients out of bed and back
15 to where they want to be.
16 We have better imaging studies, we see
17 more, we don't know what it means, but we see it
18 very well. And then there's better education, not
19 just for spine surgeons, because we have more
20 awareness of spinal stenosis and the differential
21 for low back pain. We know the value of fusion in
22 certain select patients, some of which lead to
23 back pain.
24 We've also had some paradigm shifts in
25 treatment in the last 20 years. We've had better

00053

1 instrumentation with shifts in the treatment of
2 lumbar fracture, more aggressive treatment of
3 tumors, surgical treatments for spine infections
4 and a greater understanding of the negative effect
5 of lumbar deformities. This all leads to more
6 surgery in the lumbar spine.
7 From 1990 to 2000, pedicle screws were
8 approved, cages were approved by the FDA, again,
9 tacit or overt suggestions that these are
10 scientifically valid. There's been literature
11 demonstrating increased clinical outcomes with
12 solid fusion, particularly with stenosis and low
13 back pain, increased better fusions with
14 instrumentation which should lead to better
15 outcomes, long-term follow-up or pseudoarthrosis
16 with some worsening outcomes, and we are more
17 aware of clinical outcomes or clinical measures.
18 In the last six to seven years we have
19 had improved fusion success with devices,
20 instrumentation, DBM and BMP and other tools, with

21 decreased complications from fusion as we become
22 more familiar with it, and better low back pain
23 outcomes in newer devices continually compared to
24 the old.
25 Some DDD/low back pain disorders that

00054

1 you could relate to are better with fusion.
2 Isthmic spondylolisthesis, compared to
3 laminectomy, the fusion success rate is much
4 higher, and this started us on the fusion track.
5 Degenerative spondylolisthesis, a
6 number of articles, particularly those by
7 Herkowitz, showed that the progressive deformity
8 of simple laminectomy, 85 percent success with the
9 addition of a fusion. In Herkowitz's series,
10 first he looked at patients who had fusion not
11 instrumented, for laminectomies, and initially if
12 they had fusion at two years, they had good
13 results even though he had 30 percent
14 pseudoarthrosis. When he followed the same
15 patients for two to five years, those
16 pseudoarthrosis patients deteriorated. When he
17 looked at his patients who had instrumented
18 fusions, the long-term success remained at 85
19 percent.
20 Degenerative scoliosis followed the
21 same track. Laminectomy for leg pain tends to
22 progress, and if you add a fusion, the overall
23 results are better.
24 Low back pain is a different beast.
25 Fusion is not a perfect solution. The Cochrane

00055

1 report, as we heard today, no conclusions are
2 possible about the relative effectiveness of
3 anterior, posterior or circumferential fusion, but
4 remember, they looked primarily at randomized
5 controlled trials.
6 There are some studies to look at that
7 point our attention in the direction of fusion.
8 Turner in 1992 did a mega-analysis with no RCTs
9 but four non-random studies comparing herniated
10 disc surgery, that is laminectomy, with fusion.
11 The conclusion, for several low back disorders, no
12 advantage has been demonstrated for fusion over
13 surgery without fusion, and complications with
14 fusion are common. However, we don't do fusions
15 for herniated discs and primary leg pain today.
16 Malter et al. in 1998, complications in
17 the current study occurred more frequently in
18 patients who underwent lumbar spine fusions than
19 on those who underwent laminectomy or discectomy
20 alone. Again, that's not the operation we do or
21 are talking about. And if you adjusted them
22 demographically, there was in fact a significant
23 difference.

24 Parker et al. in 1996 looked mainly at
25 back pain with a posterolateral fusion, something

00056

1 we don't do quite so much of today, and it was
2 like flipping a coin, you either get better or you
3 get worse. However, if you take out the workers'
4 comp patients, it went from a bad result to a 92
5 percent excellent or good result, and his
6 conclusion then was fusion is good.
7 There are three RCTs that we heard
8 about. Fritzell from Sweden, fusion is better
9 than a nonoperative routine using physical
10 therapy. Brox in Norway, fusion is the same as
11 non-op, even to the extent of cognitive
12 intervention and exercise. And Fairbank gave some
13 criteria for ODIs, he met that criteria and then
14 said oh, by the way, it doesn't work, and this was
15 a cooperative study that's listed as an RCT. So
16 the best thing, the RCTs don't agree, or agree.
17 Comparing Brox and Fritzell, non-op
18 people in the Brox study mainly did a much better
19 job of controlling the non-op, whereas Fritzell
20 did a much better job of controlling who entered
21 the study, who got the surgery, and fusions came
22 up better. It's unlikely in the United States to
23 have entered patients who have not had any
24 preoperative care, any nonoperative care before
25 they went to surgery. So if you look at the two

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1 studies, Brox is better for the results of non-op
2 care, because they were given uniform non-op care.
3 Fritzell, however, did a much better job selecting
4 patients, they weren't just loose, low back pain,
5 you get an x-ray and a fusion, they did more
6 screening, they had a better surgical outcome.
7 There's a number of non-RCT studies
8 showing fusion works for low back pain, but these
9 are the second best available data, and they
10 showed much consistency, 80-plus percent
11 improvement from 2004 to 2005. Moore's is a
12 retrospective study looking primarily (inaudible).
13 When you compare Moore to Brox and Fritzell, the
14 indications as you go up are much more rigid, much
15 more inclusive in Moore's study than Fritzell's
16 study and Brox's study.
17 Interestingly, their surgical outcomes
18 are the same. The more, the stricter indications
19 you put on, the better the surgical outcome.
20 Fritzell's results are on your left, Moore is on
21 your right, and that's because, is it worse
22 because Fritzell used an RCT and looked at them
23 that way, or is it better in Moore's study because
24 he had stringent selection criteria and did only
25 one, as opposed to three or four different

00058

1 operations for the pain?
2 We know fusion methods differ, we know
3 non-instrumented fusions don't heal as well as
4 instrumented fusions. And increasingly, we are
5 going to interbody fusions if not circumferential
6 fusions, because the fusion results are better
7 and, therefore, hopefully the clinical results are
8 better.
9 So what Chris and I take from this is
10 fusion is not a good first-line treatment for
11 discogenic low back pain. Fusion can be effective
12 in select patients who have failed non-op
13 treatment, whatever that is, and I would say that
14 the non-op literature is even softer than our
15 literature. And, interbody fusion seems better
16 than posterolateral fusion alone, and maybe that's
17 because we take out the disc if in fact the disc
18 is the culprit.
19 There are a number of complications
20 both coming from the graft site and the other
21 devices, but these aren't specific for low back
22 pain from degenerative disc disease. Fusion
23 consequences, there are some long-term
24 consequences, loss of motion, but that's the goal,
25 and it's clinically often not apparent. Metal in

00059

1 the body doesn't appear to be a major problem.
2 Adjacent segment degeneration occurs due to
3 natural history or we've done something to it;
4 most, fortunately, are not clinically significant.
5 The tech report says second operation required; I
6 would caution that required, it's elective and
7 chosen. And fusion disease has no
8 literature-based foundation.
9 So our assessment is fusion has a role
10 in treatment of discogenic back pain. Better
11 outcomes are with strictest selection criteria
12 including failed non-op care and more preoperative
13 instability. Our criteria for low back pain
14 surgery is exhausted non-op care and exhausted
15 pain in the patient, x-rays, MRIs showing one or
16 two levels maximum degenerative disc disease.
17 Discogram which reproduces the pain, not how it
18 looks, pain reproduction, at the same one or two
19 levels. And the patient is willing to undergo a
20 rigid part in the back.
21 Our surgery is anterior discectomy to
22 remove the disc, open the disc space and we put in
23 fusion biologics, and posterior instrumentation
24 fusion. With this approach, the literature-based
25 results are overall fusion rate 90-plus percent,

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1 clinical success of 60 to 80 percent, and some do
2 get worse. Is this good enough? Probably not.

3 Is this the best possible? If we could diagnose
4 better, it could be better. Is it bad in
5 selective patients? What is really needed, with
6 exclamation points, are better diagnostic tools
7 and assessments to target the pathophysiologic
8 cause and assess the pain.
9 The ideal study for low back pain, to
10 definitively does or does not help discogenic low
11 back pain, but to do this, we need to clearly
12 define the cause of low back pain. It's not
13 possible at this time.
14 How do we assure all patients have the
15 same cause or treatment before we enter them into
16 an RCT? What are the clear unequivocal and
17 reproducible criteria? We don't have them now.
18 Non-op treatment, we don't know that, and surgical
19 treatment, everybody differs.
20 What is or are the ideal measures?
21 Pain measure, function, performance, quality of
22 life, fusion x-ray, what else? The surgical
23 success is difficult to assess. X-rays don't tell
24 the story. Flexion and extension laterals alone
25 don't tell the story. CT scans are difficult to

00061

1 assess unless you have 1.0 to 1.5 millimeter cut
2 reconstructions, which are seldom done, and are
3 able to compare this rigorously with the surgery,
4 which is rarely done, and they often don't compare
5 to clinical outcomes.
6 Perhaps rather than an ideal study, we
7 need a realistic study. It may not be an RCT.
8 Non-op is an issue, but nothing is proven. I
9 think less rigorous data that is available for
10 surgery. Surgery can't be blinded, shams don't
11 work in a fusion, and patients serve as their own
12 control and you can't follow what occurs once they
13 leave the office. This has been shown currently
14 in the SPORT study by a long large crossover. So
15 a realistic study, everybody enters with chronic
16 low back pain, everybody's outcome is measured the
17 same. We do evidence-based nonoperative care,
18 which may not be possible. Some get better, we
19 study them. Some don't, this is not an RCT. If
20 they fail non-op, they get surgery, we do the same
21 outcome measures on all the patients. The patient
22 is their own control and has to be accepted,
23 because RCTs are almost impossible even in a clear
24 herniated disc, as the SPORT trial has shown.
25 As an aside, Chris and I do 400 to 500

00062

1 spine surgeries a year, which is a fair amount.
2 Most are with fusion, but only a few for primary
3 low back pain. We feel we know, but we probably
4 don't, when to fuse for cancer, when to fuse for
5 fracture, when to fuse for infection, non-union,

6 obvious instability. What we don't really know is
7 who is going to benefit from low back surgery and
8 low back pain. We feel we probably don't offer
9 enough fusion to most of these patients, but we
10 just can't quite get a handle on it ourselves.
11 But we do know in the right patients, it can
12 drastically improve their quality of life.
13 And yes, this is a Medicare population.
14 Discogenic low back pain goes to these other
15 diagnoses, degenerative scoliosis, degenerative
16 spondylolisthesis, and stenosis. And then there's
17 the Medicare disability population which starts
18 out just like I said, in the 30 to 55-year range,
19 and then moves on into these other diagnoses of
20 people, I don't want to say elderly because I'm
21 getting there, older than 65.
22 So, thank you for this opportunity and
23 responsibility, and challenge that it has been an
24 honor to present.
25 (Applause.)

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1 DR. KRIST: Thank you, Dr. Garfin.
2 Next we have Dr. Mirza.
3 DR. MIRZA: Good morning. It's a
4 privilege to be invited to address the panel and
5 the audience this morning. I'm Sohail Mirza. I
6 don't normally address people, I want you
7 informed, but I appreciate the opportunity. And
8 before I begin, let me just tell you a bit about
9 myself. I'm a spine surgeon who has been now in
10 practice for 11 years at the University of
11 Washington. I have a very busy spine practice. I
12 do perform fusion for back pain, also do a lot of
13 tumor surgery, and I think even though the surgery
14 can often be more complicated than the decision-
15 making involved, you have to coordinate with their
16 chemotherapy and staging and radiation and other
17 treatments. I find it easier, I think, and I feel
18 more comfortable in getting an informed decision
19 on a tumor patient that is suffering back pain and
20 is considering surgery. It's a longer
21 preoperative visit, it's more involved, and I
22 think it's mostly because of this variation. It's
23 hard for me to convey to a patient things that I
24 feel they should know and consider before they
25 make a choice, so a lot of my talk will be focused

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1 towards that end, what I feel, the information I
2 feel a patient should know if they're facing a
3 decision about back surgery for degenerative
4 disease.
5 To begin, my disclosures, this is the
6 North American Spine Society form for disclosure.
7 I get royalties from Synthes Spine that are
8 licensed by our university technology transfer

9 office. Our department has endowments from DePuy,
10 Synthes Spine, Surgical Dynamics, also from
11 Medtronic, and I hold one of the lab chairs for
12 spinal research.
13 One nice thing about going after the
14 other speakers is I don't have to review a lot of
15 their stuff. There is a lot of new technology in
16 spine surgery, and I don't think I do procedures
17 today the same way as I trained 10 to 15 years
18 ago. The implants I use, the technology I use is
19 completely different, not just implants that are
20 left in the patient, but also how we get there,
21 the radiographic imaging preoperatively and
22 intraoperatively, and the biological devices that
23 result. There is a lot of new clinical knowledge,
24 and I think Dr. McCrory and Dr. Garfin have done a
25 very nice job covering a lot of the new

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1 information, particularly the more recent
2 randomized trials.
3 And I think we can all agree that in
4 general for patients with spondylosis, treatment
5 with fusion is better. If you do it, the
6 procedure with fixation, with instrumentation that
7 holds the vertebrae together as they heal, you get
8 a better healing rate, you get a better fusion
9 rate. It's not clear whether that really
10 translates to better pain relief or better
11 physical function. It does add to the surgery, it
12 takes longer to do an instrumented fusion than a
13 non-instrument fusion, it involves more
14 dissection, more exposure of the spine, and it
15 does have a higher complication rate. And most
16 recently, artificial disc replacement may get
17 around some of the problems for the patient,
18 particularly the late consequences such as
19 adjacent segment disease, but that I think remains
20 to be shown.
21 So first to talk about variation in
22 decision-making. I think all spine surgeons feel
23 very confident about what they practice and how,
24 the complications, but the reality is we disagree
25 tremendously among ourselves in terms of when we

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1 offer fusion. Fact conditions are fairly
2 homogenous across different populations, it's not
3 that we have more degenerative disc disease in the
4 U.S. than other countries, but if you compare
5 western fusions across each other for how often a
6 fusion is done for a degenerative condition, the
7 U.S. is the highest, five to ten times higher than
8 some of the other European developed nations.
9 Even within the U.S., there is tremendous
10 variation.
11 There was a very nice article by

12 Dr. Lurie, who's on the panel, and Dr. Weinstein
13 just this month in Spine, and the rate of spinal
14 fusion for Medicare enrollees ranges from .21 to
15 4.48 just within various hospital regions of the
16 United States. So depending on where you live,
17 who you see, you can get a very different
18 recommendation on the type of treatment you should
19 get, particularly on whether a fusion is a
20 reasonable option or maybe even a necessary option
21 for what you have. If you break it down into
22 specific rates, there is tremendous variation
23 across states from 1.8 per 1,000 enrollees, to
24 9.2, and across individual cities, within cities,
25 and it's not the same across all surgical

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1 decisions, and it's not the same across all
2 decisions within the northeast.
3 If you have a hip fracture, this is a
4 log scale, so this is 10-fold higher and one-tenth
5 the rate. It's a pretty uniform recommendation,
6 fixation for hip fractures is not something that
7 we disagree on among orthopedic surgeons. For
8 back surgery, for fusion there is a tremendous
9 variation. A little bit for total hip
10 replacement, a little more for laminectomy and
11 discectomy, but a lot for lumbar fusion.
12 Depending on where you live, the regional
13 variation in terms of whether you get a
14 recommendation for fusion is 20-fold for back
15 pain, 8-fold for laminectomy, and I think that is
16 very, very high.
17 What are the causes of the variation?
18 Dr. Weinstein pointed out that it could be lack of
19 scientific evidence, although I think you heard a
20 very thorough explanation of the evidence that is
21 available. Financial incentives and disincentives
22 may both play a role. A lot of it has to do with
23 how you train and what you learn. Surgery is
24 still very much an apprenticeship, and for spine
25 surgery, most spine surgeons go through a

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1 fellowship, and I think a lot of how we approach
2 patients and the kinds of things we offer patients
3 depends on our mentors. And I think new
4 technology has a role, how things are developed,
5 how they are presented to both surgeons and
6 patients, and how they are marketed has a role.
7 I'm going to skip through some of these
8 things. Just compared to other established
9 orthopedic procedures, the increase just in the
10 five-year interval for lumbar fusion for
11 degenerative disease was 100 percent, compared to
12 13 to 15 percent for hip and knee replacement.
13 This shows the same slide. Over an eight-year
14 period the rate of spinal fusion doubled, whereas

15 the rates for hip and knee replacement went up
16 just about 10 or 15 percent. These are
17 population-adjusted rates.
18 And this is for the Medicare
19 population, I think it's very relevant for this
20 panel. It's hard to sort out the shades, but the
21 graphs are in order here, and lumbar fusion is
22 this bar. So if you look here, the other colors
23 don't vary much, but this little bar has doubled
24 or tripled in height compared to these other
25 procedures, such as discectomy here, non-lumbar

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1 fusion, and other procedures such as laminectomy
2 and discectomy, so lumbar fusion has increased
3 tremendously even within the Medicare population,
4 and it's a big budget issue for this population.
5 In 1992, spending for lumbar fusion was \$75
6 million; half of the spinal budget is now spent on
7 fusion.
8 The increase is partly geared or
9 correlated with technology, and not just
10 technology, I would say a lot of other things
11 happened in the mid 1990s, but the rate of fusion
12 went up at a fair pace early in the late '80s and
13 early '90s and then it plateaued, possibly due to
14 litigation involving spinal instrumentation,
15 pedicle screws in particular, and also partly
16 because of newer technology, particularly the disc
17 excision and interbody fusion cases, and I think
18 also some credentialing issues in terms of
19 neurosurgery, orthopedic resident credentialing.
20 But it has dramatically gone up since then and
21 this increase is not uniform across all
22 populations.
23 Also, the percentage of cases, lumbar
24 surgery cases that involve a fusion has gone up.
25 So not only is more surgery being done, but more

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1 of a fusion type of procedure is being done. Now
2 it's over half of the spine operations on the
3 lumbar spine.
4 The increase is also not uniform across
5 patient groups. The increase is most dramatic in
6 the older patients, particularly those who are 60
7 or older. Those are the patients that have had
8 the highest increase for fusion, and I think this
9 primarily relates to fusion in addition to
10 decompression for spinal stenosis in older
11 patients. Previously, many of these patients
12 would have received laminectomy; now often they
13 get a combination of laminectomy plus fusion.
14 Also, the increase is different across
15 diagnoses. Even though we don't offer fusion as a
16 treatment for herniated discs as a primary
17 treatment, it is often done for that indication.

18 The increase is greatest for the lumbar
19 degenerative disc conditions and some of these
20 conditions, even though mostly we're talking about
21 herniation disc disease, they are referring to
22 small disc protrusions or bulging discs, which are
23 coded as herniated discs. The increase in
24 spondylolisthesis and spinal stenosis is less
25 dramatic.

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1 So what do we know about efficacy? I
2 think this section of my talk is going to be
3 brief. This has already been fairly covered by
4 Dr. McCrory and Dr. Garfin. There are five trials
5 which have asked the lead question, which is, does
6 surgery work better than nonsurgical treatment?
7 And I think those studies are very, very hard to
8 do. And as the SPORT publication showed just this
9 last week, it is very hard for us in the United
10 States to conduct that kind of randomized trial
11 than in other countries. And I think it's not
12 irrelevant that all of these studies were
13 conducted in Europe where each of the nations have
14 a nationalized health care system, and in fact it
15 was more palatable to patients to enroll in the
16 study and possibly get a fusion type procedure
17 earlier than if they were to just wait out their
18 turn on the waiting list. So during the one year
19 or even longer waiting list in Norway they could
20 conduct these kind of comparison treatments. I
21 doubt that we would be able to do that kind of a
22 study in the U.S.
23 We tried to do a fusion versus
24 nonsurgical treatment for back pain study back in
25 1988 at the University of Washington, and we had a

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1 very thorough IRB process to make sure that the
2 patients got an unbiased consent. And out of 28
3 patients who were given the choices by a physical
4 therapist, none chose randomization. Patients
5 either said they waited too long, they were going
6 to go ahead and have the surgery, or they said
7 they had no idea this is what surgery involved and
8 they were not willing to do it, so we couldn't get
9 patients to accept randomization.
10 These are European trials that have all
11 been published in the last five years. The
12 Fritzell study had a very long enrollment
13 interval. Most of them, all of them deal with
14 chronic back pain. The difference between the
15 2003 and 2006 Brox study is that one study had no
16 prior, the first publication, patients had no
17 previous surgery, and the second publication, each
18 patient had had a prior discectomy at least a year
19 before the study. The Fairbank study allowed some
20 patients with spondylolisthesis, about 10 percent.

21 They were very well designed studies,
22 very thorough assessments, a wide array of outcome
23 instruments administered both preoperatively and
24 postoperatively, and I think done very well across
25 the board. These are just various quality ratings

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1 that we tried, and they all scored pretty well.
2 They scored low on this scale because a lot of
3 emphasis is placed on the blinding of
4 randomization on this scale, and like Dr. Garfin
5 said, you can't blind when you're comparing
6 surgeries to nonsurgical treatment. The largest
7 studies, Fritzell is 300 patients, Fairbank 350
8 patients, these trials I think were underpowered.
9 The Brox studies really did not have enough
10 patients to show the differences they were aiming
11 to compare.
12 And I'm just going to quickly mention
13 the change in the surgery group from the baseline
14 to the final Oswestry Index was from 9 to 16
15 points in these trials. The big difference
16 between them is the change in the nonsurgical
17 group. In the Fritzell study it was essentially
18 none, a 3-point difference with nonsurgical
19 treatment and about an equal change in the three
20 European trials.
21 The Fritzell study allowed natural
22 nonsurgical healing, patients could continue what
23 had already been done prior to enrollment. The
24 physicians prescribed physical therapy,
25 injections, rehab, and various other things as

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1 they saw fit. These other three studies had a
2 very rigorous inpatient rehab program, the kind
3 that's not available in the U.S. These patients
4 were, in the Brox study they called it a back
5 hotel; they signed in for three weeks, they had
6 five to eight hours of PT and lectures and
7 education each day, and then they had follow-up
8 sessions at six months and one year. So with that
9 kind of intensive rehab, they got the equivalent
10 improvement to surgery.
11 And the change didn't really meet the
12 threshold for what would be defined as benefit,
13 that is, the difference in the changes in the
14 surgical group subtracted, minus the changes in
15 the nonsurgical group were all less than the
16 15-point minimum threshold for the benefit of
17 surgery.
18 A fairly high complication rate. These
19 were prospective studies where they actually
20 defined what they were going to look for and
21 measured it as they enrolled patients and followed
22 them. Higher complication rates in the
23 circumferential fusion group than in the

24 non-instrumentation group, but still fairly high
25 by most standards.

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1 I already mentioned these differences.
2 I think the Fritzell study didn't really specify
3 the nonoperative treatment. The Brox study had
4 small sample sizes. The Fairbank study allowed
5 some patients with spondylolisthesis. They also
6 had dynamic fixation, so they allowed
7 instrumentation in some patients which did not
8 involve bone grafting or fusion, they called this
9 dynamic stabilization, so patients had rods and
10 screws put in to limit the mobility but not
11 eliminate movement, so I think it's less pure of a
12 study in that sense.
13 So to look at outcomes from another
14 perspective, we have been looking at
15 population-based outcomes in the state of
16 Washington. We had access to the statewide data
17 for all spine cases done as an inpatient
18 procedure. And we looked at the amount of
19 outpatient surgery and a very small number of
20 patients were having outpatient procedures. About
21 a quarter of the discectomies and laminectomies
22 were done as outpatients, but most fusions are
23 inpatient procedures.
24 So if you look at a longer horizon, a
25 10-year outcome in terms of the reoperation rate,

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1 those patients that had surgery in 1990 or 1991,
2 what their outcome was at 10 years in terms of
3 needing another operation on the lumbar spine, and
4 we have no way of saying whether this was at the
5 same vertebral levels or adjacent levels, but that
6 risk is not trivial, about 20 percent at 10 years
7 for fusion, but also very high for laminectomy or
8 discectomy, about 18 percent. The fusion
9 reoperation rate is a little bit lower for the
10 first three to six months and then it's higher in
11 the subsequent years, and I think that just
12 correlates to how we take care of fusion patients,
13 you allow some healing time in the first three to
14 six months before you start talking about a repeat
15 surgery.
16 Breaking that down by diagnosis,
17 spondylolisthesis was the only diagnostic category
18 from the lumbar degenerative diagnostic groups
19 where fusion had a lower reoperation rate. All
20 the other diagnoses, herniated disc, and again, if
21 you look at the total number of patients, 16,000,
22 the vast majority did not have fusion, a small
23 fraction had fusion, but the reoperation rate was
24 higher for herniated discs, about the same for
25 degenerative disease, disc degeneration, a little

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1 bit higher for spinal stenosis.
2 If you look for differences over time,
3 earlier treated groups, patients who were treated
4 in 1990 to 1993 compared to a more recent group,
5 and certainly in this interval a lot has happened,
6 and hopefully the new knowledge from clinical
7 studies has improved decision-making, new
8 technology has improved the healing rates from
9 fusion, but even when you compare the earlier to
10 the later cohorts, this is a three-year
11 reoperation rate, the more recent cohort has a
12 higher reoperation rate, and that's all lumbar
13 surgery, fusion and nonfusion. And we've also
14 broken this down to diagnosis and by fusion, and
15 even the more recent fusions compared to the prior
16 fusions have a higher reoperation rate.
17 This is a study we did on injured
18 workers in the state of Washington. Washington
19 has a very special workers' compensation system
20 where they have population-based data and it's
21 very detailed in terms of the clinical information
22 it contains. And we looked at 2,000 patients who
23 had lumbar fusion in the 1990s for a back problem,
24 for a back injury, excluding those who had falls
25 from heights and other work-related incidents like

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1 fractures and dislocations, so these are primarily
2 degenerative disc disease patients. Overall, the
3 point, the outcome that's most relevant to the
4 workers' compensation board is the return to work
5 ability. Looking at surgical technique for
6 fusion, the disability rate at two years was not
7 different than if somebody had a fusion without
8 instrumentation, if they had cages only, or they
9 had instrumentation only without cages, or if they
10 had both, fusion, circumferential fusion.
11 Complication rates, and these are not
12 multivariable comparisons, 6.2 percent -- these
13 are complications within three months of surgery.
14 Higher if you have cages alone, 12 percent, or
15 with instrumentation. If you have both, higher
16 complication rates for the first three months.
17 Reoperation rates at two years, and these are
18 again, unadjusted for the covariants, high, 25
19 percent two-year reoperation rate for
20 uninstrumented fusions, a little bit lower for the
21 cages, and somewhat lower for the combined cage
22 plus instrumentation. This is just a summary of
23 those things.
24 If you adjusted for all the covariants
25 which we think would be relevant, things like age,

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1 gender, diagnosis, numbers of levels of fusion,
2 medical comorbidity, psychosocial comorbidity, if

3 you adjusted for those factors, the disability
4 rate does not differ depending on fixation
5 technique, the reoperation rate is not different,
6 but the complication rate is almost twice as high
7 when you have both as compared to just an
8 instrumented fusion.
9 And I think the safety side,
10 particularly when the efficacy is uncertain, is
11 very crucial, because there are some risks that
12 these patients may be unwilling to take, and I
13 think it's really important for patients to
14 understand that once they're going into surgery,
15 because this is not something you can undo and go
16 back and start over again, because once a fusion
17 is done, it can set off a cascade which is hard to
18 come out of.
19 I put this slide in just to show how
20 hard it is to interpret safety data. This is from
21 an epidemiology textbook and it just shows, you
22 know, if you have a percentage difference, this is
23 a difference between percentage of complications
24 or adverse effects between two treatments, that is
25 if one treatment has a 10 percent complication

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1 rate and the other treatment has a five percent
2 complication, when you look at 10 percent versus
3 five percent, that's a big difference. To show
4 that difference as a significant meaningful
5 difference, you'd need close to 500 patients in
6 each treatment arm. So again, it's very hard to
7 interpret safety data, you need very large
8 studies, and randomized trials are not good at
9 providing safety data. They don't have enough
10 numbers, they're too expensive, they don't follow
11 patients long enough to even give us reliable
12 safety data, and I think this really has to come
13 from observational studies.
14 We looked at stand-alone anterior
15 lumbar cages, specifically that was really
16 popularized in the early part of the cage
17 technology in 1996 and 1997, where surgeons felt
18 that just putting in threaded cages in the
19 intervertebral spaces with some bone graft would
20 be sufficient to prevent movement at that site and
21 allow fusion, and hopefully treat any back pain.
22 But that procedure fairly rapidly fell out of
23 favor, without any real kind of single study or
24 particular event that pointed it out. I think
25 mostly it fell out of favor because surgeons

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1 themselves found out that often they had to go
2 back in and do supplemental fusions to get things
3 to heal.
4 So we were interested in looking at
5 that literature and seeing why were the earlier

6 studies so much more commonplace than the later
7 studies. And we did a systematic review, we
8 looked at studies that looked at patients with
9 stand-alone cages for lumbar disc disease, studies
10 that had more than 10 patients, and we ended up
11 with 30 trials. And in particular, we were
12 looking at the safety side of things, and I think
13 I want to just point out that the safety data in
14 spine studies is really not well addressed.
15 Very few studies actually pointed out
16 if they looked at complications. Even fewer
17 studies described how they looked at
18 complications, what kind of surveillance they did
19 and how they interpreted, and often the safety
20 data wasn't even reported. So this is just the
21 number of studies. So if you're doing a fusion
22 for pain, wouldn't you think that would be
23 important? For posterior fusion, all 10 studies
24 did it, but overall, 15 percent of the studies
25 didn't even comment on fusion rate, reoperation

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1 rate was addressed less often, and then other
2 important things like blood vessel injury, organ
3 injury, rarely addressed in some of these studies.
4 Complication rates, we looked at the
5 amount of variation in the complication rates that
6 could be explained by the study design, either
7 patient age, gender, type of study done, and
8 what -- this should be I-squared, which is a
9 meta-analysis on spinal fusion that identified the
10 percentage of variation that can be attributed to
11 non-random variation. So these are differences
12 that are somehow contained in the studies that we
13 had identified, but they are not random
14 differences for the rates of variation.
15 There are very high rates of
16 heterogeneity for things like nonunion, for
17 reoperation, less so for sexual dysfunction,
18 infection. These are more clear things when
19 people report them, those are real. The things
20 like nonunion are subject to variation that is not
21 explained by the study characteristics.
22 We also looked at whether financial
23 sponsorship of the study made a difference, and
24 the only thing that mattered was judging fusions.
25 Studies that had sponsorship generally had lower

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1 fusion rates than studies that did not have
2 financial sponsorship, or lower nonunion rates,
3 much higher fusion rates in these sponsored
4 studies than the nonsponsored studies. The other
5 issue wasn't so apparent in other complications
6 such as reoperation or neurological injury.
7 So I think potential financial
8 conflicts do have a bearing, particularly on these

9 new technology studies which are often done by
10 people having invested in the technology. It is
11 hard to get public funding to do studies that
12 compare fixation and surgical technologies. And I
13 think just to review some literature, in general,
14 if a study is sponsored, it's been shown in
15 various disciplines that sponsorship leads to more
16 favorable interpretation of the data, and that's
17 true for spine literature also.
18 In orthopedics, where a lot of what we
19 do is use implants such as knee and hip devices
20 and spine devices, it's also been shown that if a
21 study is funded, it is more likely, funded and I
22 should say published, because it could be that the
23 unfunded studies that don't have meaningful
24 results don't get published, but the published
25 literature, a higher rate of favorable results in

00084

1 the sponsored studies.
2 And I think this is important. There
3 are a lot of articles in the press about fusions
4 and about back pain, but I think this one is
5 particularly relevant. This is one of the first
6 ones by Jerome Groopman in Boston. And I think
7 the key point I want to make is that the author
8 and the patients, as described in the study,
9 wished that they had known uncertainties about
10 this diagnosis of back pain, the uncertainties of
11 interpreting diagnostic tests such as discography,
12 MRI scans, and the uncertainties in outcomes of
13 fusion, and that this is a critical part of the
14 informed consent for patients considering these
15 procedures.
16 So to end, I think lumbar fusion rates
17 have gone up despite any real compelling evidence
18 that fusion is a much better procedure than some
19 of the other alternatives. Fusion for chronic
20 back pain compared to rigorous nonoperative
21 treatment like that in the Brox and Fairbank study
22 is probably equivalent. Compared to routine care
23 such as available in the U.S., fusion is probably
24 better. Safety data are limited, advances in
25 technology at least has improved the reoperation

00085

1 rates with the fusion. And financial conflicts
2 have a bearing. Thank you.
3 (Applause.)
4 DR. KRIST: Thank you, Dr. Mirza. Now
5 we're going to turn to our scheduled public
6 comments here, and we have several speakers
7 scheduled. First will be Dr. Matthews, and just,
8 for, you have 15 minutes scheduled, so around 10
9 after 11.
10 DR. MATTHEWS: Good morning, members of
11 the panel, ladies and gentlemen of the audience.

12 I would like to thank CMS and the MCAC for the
13 opportunity to be here. My name is Hallett
14 Matthews, I'm a spinal surgeon from Richmond,
15 Virginia. I am associate clinical professor of
16 orthopedic surgery at Virginia Commonwealth
17 University in Richmond. I do not receive
18 royalties from Medtronic. I am a research
19 consultant. I concurrently sit on three spine
20 society boards over the last several years, and I
21 will continue my clinical advocacy upon the
22 occasion of wearing a new hat in 2007.
23 From our perspective, I would like to
24 discuss several perspectives on lumbar
25 degenerative disc disease as a continuum of care.

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1 I think it's important to understand the
2 difficulty of the diagnosis, I think it's
3 important also to discuss the complexity of the
4 disease, and also the prevalence in the Medicare
5 population. I will also go over a quick evidence
6 review and some new and exciting data in the
7 Medicare population for treatment of degenerative
8 disc disease.
9 As you know, Medtronic has similar
10 missions to this group and this panel today, to
11 alleviate pain, to restore health, and to extend
12 life, and we believe it is important that we
13 consider how we can improve it.
14 Lumbar degenerative disc disease is a
15 continuum of care. Not every patient presents at
16 the same disease state as a clinician. I'm going
17 to put my clinical hat on now, and now I'm in the
18 office trying to take care of and analyze these
19 patients, and their presentations differ. The
20 patients that present earlier in the cascade are
21 often earlier, younger presentations and not in
22 the Medicare population. The patients that
23 present later often have multiple disease
24 processes going on and confounding diagnoses,
25 which makes it very difficult to classify these

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1 patients specifically. So it's very important.
2 It's also important to understand the
3 progression of this disease which varies with
4 regard to genetic factors, aging factors, that we
5 all age differently, injuries both chronic and
6 acute that happen throughout our lives,
7 environmental factors such as using vibration
8 instruments or having a job that involves
9 vibrations, smoking, and different workplace
10 occupational issues, and also associated with
11 other diseases.
12 It's also important that we look at the
13 specific pathologies that create this pain or
14 dysfunction. This is a patient that entered my

15 office about three months ago, and you see
16 multiple disease patterns that are significant.
17 She presented to me with leg pain, she presented
18 to her referral primary care physician with back
19 pain, and she presented to the physical therapist
20 with back and leg pain. Okay? So I'm a clinician
21 in the office. How do I code this patient? I've
22 got five different codes that I can use, and oh,
23 by the way, when you stand the patient up and do
24 flexion and extension, L5 is backward on S1, so
25 she has translational instability in addition. So

00088

1 that in essence describes our clinical dilemma
2 with regard to coding and entering these patients
3 into diagnostic pools.
4 It's important also that we understand
5 how the patient presents with a degenerative disc
6 pathway. The medical issue is extremely
7 important. To me, that's the most important
8 clinical thing that we can do, to establish where
9 the patient is coming from and their morbidity of
10 the process. Not every patient presents the same
11 to the physician, he may present with different
12 diseases but similar symptoms, so clinically we've
13 got to decipher those. The history is important
14 to talk about, walking, standing, their abilities
15 to perform activities of daily living, their
16 abilities to do certain exercises as simple as
17 walking to the office, and these are important
18 clinical parameters to discuss as to whether or
19 not disease is progressing, and it is the trend of
20 clinical history and presentation that alerts the
21 clinician as to what has to happen.
22 Whether they present early or late to
23 design their clinical management, we then often
24 begin a patient education self-management program
25 so the patient can learn to live with their

00089

1 disease, and after nonoperative care has been
2 exhausted do they become surgical candidates, but
3 only if we define a surgical need. We don't go in
4 and explore patients for back pain. And secondly,
5 we use physical exam imaging to confirm our
6 clinical diagnosis, and this is a pattern that we
7 use in the office to help us establish is this
8 patient at risk.
9 Part of the challenge with degenerative
10 disc disease is that it's difficult to diagnose,
11 it has many comorbidities, and it's rare to define
12 pure degenerative disc disease in the population,
13 and often my patients have four or five
14 degenerative disc codes as they present.
15 When we look at demographics, in 2005
16 there were approximately 54,000 lumbar fusion
17 cases performed in Medicare patients of 224,000

18 patients that had lumbar fusion surgery, which
19 represents about 23 percent of the entire
20 population. When we look at the prevalence of
21 DDD, 722.52 code, it's only about one percent,
22 which means 99 percent of disc pathologies are not
23 strictly from degenerative disc disease that we
24 talk about, they come from other etiologies. It's
25 a very complex diagnosis.

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1 Also too, when we look at evidence
2 summaries, we discussed earlier this morning one
3 RCT and several observational studies, but it's
4 important to realize what's going on with regard
5 to industry and what's happening with getting
6 better intensification of research efforts. In
7 2002, Medtronic received approval for an IDE study
8 to look at prospective randomized clinical
9 evaluation of posterolateral lumbar fusion, and
10 these were patients with degenerative disc disease
11 that are being treated with fusion, which is
12 considered the standard of care treatment for
13 those that had failed conservative care
14 management. These patients had already had
15 conservative management and now they're going to
16 get a surgical intervention. The control arm was
17 autograft, the investigational arm was BMP-2. We
18 took the cohort of the autograft control group and
19 subsidized that into prospectively selected
20 patients into Medicare and non-Medicare
21 populations.
22 What was interesting is that there were
23 no statistical differences between numbers of
24 previous surgeries, leg pain, operative time,
25 blood loss, hospital stay, or complications

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1 related to the surgery. However, for many
2 clinical endpoints, there was statistically better
3 outcomes for the Medicare patients. When we look
4 at back pain summaries, those with zero to 20
5 intensity and duration scores, preoperative
6 evaluations of 14 had greater than 50 percent
7 improvement in the over 65 patient population at
8 36 months after surgery for failure of
9 conservative care in degenerative disc disease.
10 Also, you see here that the Oswestry Disability
11 Index was greater than 30 points improved in the
12 Medicare population, for again, patients with
13 significant morbidity and disability had values of
14 50 preoperatively down to 18 postoperatively.
15 That's a clinically significant improvement, which
16 fits the MDA criteria of a 15-point improvement.
17 We also looked at the patients that were
18 significantly satisfied with their surgery and 92
19 percent were satisfied, compared with 75 percent
20 that were not satisfied.

21 If we look also at nonoperative care,
22 we agree that nonoperative care is a good control,
23 it's ethical, it's the standard of care, and to do
24 sham surgery is difficult with regard to the risks
25 and complications in the surgery population.

00092

1 Nonoperative care lets us also look at the true
2 value, as Dr. Garfin phrased it, of the soft data
3 of nonoperative care. We need to evaluate its
4 true value, and using it as a control group for
5 research will help us with that.
6 Medtronic will enter a nonoperative
7 control with the lumbar fusion surgery next month,
8 so we are going to collect that data which is
9 going to be a very powerful study. Research
10 initiatives are important. The Lumbar Spine Study
11 Group is a group of 30 surgeons in 29 centers,
12 which has a 2,000-patient database that's
13 longitudinally managed by PhDx. Over 73 abstracts
14 and publications have been submitted from within
15 this group. This group will also initiate a
16 ProSTOS study, which is the Prospective Spine
17 Treatment Outcome Study Group, which will look at
18 the community-based results from patient outcomes.
19 Now this is a group that is supported
20 by Medtronic, but it is totally independent and
21 retains full discretion as to what it studies,
22 what devices and techniques it studies, and how it
23 reports the data.
24 Some research limitations are certainly
25 there. The study design has to look at the

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1 complex pathology and how difficult it is to
2 enroll pure cohorts of studies. Remember, this is
3 like a changing coastline, this is a changing
4 disease and a continuous evolution over time in
5 particular technology and techniques. I've been
6 in practice for over 20 years and those techniques
7 have evolved dramatically, and we have purified
8 our surgical technique and our indications, and
9 also lessened the trauma and morbidity. There is
10 community practice variability with regard to who
11 can get the care, who has access to the care,
12 whether there is a regionalization of spine care
13 centers that draw from hundreds of miles that
14 centralize the point of service of these fine
15 surgery procedures. It's important that we
16 understand the differences between rural medicine,
17 academic medicine, and private practice medicine,
18 because they're all handled differently.
19 And also too, nonoperative care needs
20 to be better defined. By using that as a control
21 in the future, we will be able to define this both
22 cost-wise and with its efficacy. And
23 evidence-based medicine obviously will continue to

24 be refined as we get better control for our entry
25 criteria, our control and accountability after the

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1 studies are completed, and also too, with regard
2 to better outcome parameters.
3 So we would like to recommend that
4 there would be a multidisciplinary work group with
5 CMS, the societies, and the spine device
6 companies, and the overall objectives of this
7 group would be to determine the appropriate
8 research methods for the Medicare population.
9 Let's get the studies right for this specific
10 group of patients. Also, let's incorporate
11 Medicare patients in our FDA IDE studies so we can
12 get that data set going. Also, let's use that
13 information to help develop specific age, specific
14 clinical guidelines that help us and guide us in
15 what is indicated for the Medicare patients.
16 And also too, look at our outcomes. We
17 saw a lot of outcomes presented today with regard
18 to different outcome measurement tools, but none
19 are specific to the Medicare population. Is it
20 time now to have a senior-specific outcome tool,
21 where we could pick up the sensitivities of the
22 improvement of procedures in the Medicare
23 population, that would help design better
24 treatment options for this population.
25 I would like to thank the panel and the

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1 audience for the opportunity to present.
2 (Applause.)
3 DR. KRIST: Thank you, Dr. Matthews. I
4 just want to remind our scheduled speakers to make
5 sure you introduce yourself and state your
6 conflicts at the beginning. Our next speaker is
7 Dr. Gelb, and you requested 10 minutes.
8 DR. GELB: My name is Daniel Gelb. I
9 am associate professor of orthopedics at the
10 University of Maryland. I have a consulting
11 relationship with Synthes Spine as well as DePuy
12 Spine. This morning I speak on my own behalf, I'm
13 not the official representative of any particular
14 organization at this time. I have been practicing
15 spine surgery for 12 years, practice locally in
16 Baltimore, and have an active elective practice
17 with a lot of Medicare enrollees that form a large
18 part of that practice, and I wanted to give the
19 panel my clinical perspective so when you come to
20 vote later this afternoon, you understand my
21 experience in dealing with this type of problem.
22 Spinal motion segments occur in the
23 discs and facet joints, as well as multiple
24 ligamentous attachments. I think rarely does
25 degeneration occur in just a single portion of the

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1 motion segment. Spinal degeneration occurs as a
2 natural phenomenon, and at times that spinal
3 degeneration can become extremely painful.
4 Thankfully this is rare, but the problem is
5 complex, as we heard. Pain can occur from
6 arthrosis, from instability, from deformity as
7 well as neurologic compression.
8 The first question that was posed is,
9 is there an appropriate measure to measure
10 surgical outcome. Well, I think if you sit with a
11 patient in the office, you could come to
12 understand that they have their issues. Their
13 primary concern is pain, of course. A patient who
14 has debilitating back pain or leg pain that makes
15 it impossible for them to perform simple daily
16 tasks, they can't stand long enough to wash the
17 dishes in the sink, they can't walk in a
18 supermarket long enough to do shopping. When the
19 spine's loaded, the pain comes. The patient may
20 be comfortable when they sit, but they're severely
21 restricted in their activities.
22 I think the customary pain scales are
23 very helpful, functional scales do give us some
24 insight into the degree of disability related to
25 their pain. The questions I ask patients are how

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1 long can you stand, how far can you walk, how much
2 pain medication do you need to get through the
3 day. I think these are the issues, especially for
4 the Medicare population.
5 The committee asks if there is evidence
6 that surgery improves outcome as compared to
7 conservative care. I think there's a large volume
8 of evidence out there that is difficult to
9 interpret, but in my opinion, there is no question
10 that there is evidence that surgery, especially
11 fusion, is efficacious in treating spinal
12 degeneration. Not all these studies are
13 randomized, but the evidence is there. The
14 studies of Fritzell, (inaudible), are some of the
15 best studies that we have and best evidence.
16 Clearly patient selection is a critical
17 factor in determining the outcome of surgery and
18 the benefit. Patients with spinal instability or
19 deformity such as spondylolistheses or scoliosis,
20 especially when it's associated with neurologic
21 compression, clearly benefit from fusion surgery
22 if they fail nonoperative treatment. The scope of
23 surgical complications has been well
24 characterized. This is why surgery is generally
25 reserved for those patients who fail conservative

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1 care.
2 We give patients nonsteroidal

3 inflammatories, sometimes if their pain warrants,
4 we give them narcotics. We try physical therapy,
5 we send them for injection. But when all these
6 things fail, surgery may be the best alternative
7 for some of these patients. Patients become
8 progressively debilitated when they are relegated
9 to a life of minimal activity. Surgery can
10 restore the ability to maintain a more active
11 life-style and the loss of function that occurs
12 with the loss of mobility.
13 Different types of spinal fusion
14 techniques are utilized, and this can be confusing
15 to understand which is used for what and which is
16 better. Anterior fusion may be necessary for
17 standard kyphosis. Pedicle screws are the most
18 efficacious way to stabilize a spine with
19 osteoporosis. These techniques are our tools and
20 they need to be utilized in an equalized basis.
21 In addition, I would add that internal
22 fixation has negated the need for postoperative
23 bed rest and casting. Patients are more
24 comfortable, they can be mobilized more
25 immediately following surgery. It minimizes the

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1 complications related to prolonged recumbency and
2 prevents the deconditioning that occurs following
3 surgery.
4 Finally, the committee asks that the
5 evidence be extrapolated to the Medicare
6 population, and I see no reason a priori why this
7 should not be the case. I do not think that there
8 is any question that the evidence is applicable to
9 a patient with spinal instability or degenerative
10 disformity, or spondylolisthesis with spinal
11 stenosis. These are common conditions for
12 patients in their 60s, 70s and 80s. Even the rare
13 patient who comes in this age group who has only
14 axial pain and limited degeneration, although
15 that's a rare case, I don't see that patient as
16 someone different from someone who is in their
17 early 60s versus their late 60s.
18 As long as a patient can undergo the
19 rigors of surgery from a medical standpoint,
20 having already failed nonoperative care, as long
21 as that patient goes through a clear informed
22 consent process and understands the risks and
23 benefits of surgery, there is no reason why they
24 should not be given the opportunity to undergo
25 that type of treatment. To me the available

00100

1 evidence is clear that this type of surgery is
2 useful and beneficial, and I hope the committee
3 will take that into consideration when you
4 deliberate later. Thank you.
5 (Applause.)

6 DR. KRIST: Thank you, Dr. Gelb. Our
7 next speaker is Dr. Guyer, and maybe at the
8 beginning you can let me know how you all plan on
9 doing this. I understand this is a joint
10 presentation.
11 DR. GUYER: Yes, and I'll explain.
12 First, I'd like to thank the committee for
13 allowing our society coalition to make a
14 presentation today. My name is Dr. Richard Guyer,
15 I'm the president of the North American Spine
16 Society, I'm an associate clinical professor at
17 the University of Texas Southwestern, in Dallas,
18 and I'm a spine surgeon at the Texas Back
19 Institute.
20 I would like to explain how we're going
21 to do this presentation. I will do the first
22 part, Dr. David Polly will then give the middle
23 part, and Dr. Charlie Branch will give the last
24 part, for the sake of time constraints. But I'd
25 also like to recommend the other members of our

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1 team that helped put this presentation together,
2 Dr. Dan Resnick, who represents the CNS as well as
3 AANS, Dr. David Wong representing AAOS, Dr. Hansen
4 Yuan representing SAS, and Dr. Steven Glassman,
5 who represents the SRS, and Dr. Charles Mick, who
6 represents the North American Spine Society.
7 These six societies represent 25,000 practicing
8 physicians, and it was through their help that
9 this whole process came together, and I believe
10 that this is a landmark cooperative effort that to
11 date has not been seen.
12 Pain relief is a primary reason that
13 our patients seek treatment for degenerative disc
14 disease. Improved function can occur with pain
15 relief, but return to work is very complex in the
16 elderly populations. Degenerative disc disease is
17 an evolving process with numerous pathologies and
18 with significant variability in diagnostic coding.
19 It rarely exists by itself in the greater-than-
20 65-year-old population. Nonoperative care, as
21 we've heard before, is always the first line
22 treatment. Clinical experience and patient
23 preference are extremely crucial in determining
24 the proper treatment for each patient
25 individually.

00102

1 When nonoperative treatment has failed,
2 there are clinically significant benefits to the
3 appropriately selected patient from lumbar spinal
4 fusion for degenerative disc disease. Lumbar
5 spinal fusion does not stop the aging process in
6 the remainder of the spine or the patient. It
7 only addresses that particular painful
8 degenerative segment.

9 In my talk I would like to focus on the
10 clinical perspectives, existing nomenclature
11 problems, and then Dr. Polly and Dr. Branch will
12 discuss review of evidence, response to panel
13 questions, and make our recommendations.
14 As we are well aware, the degenerative
15 cascade is a process that occurs in a normal aged
16 lumbar spine. It can be affected by genetics in
17 terms of age of onset and the diffuseness of it.
18 Most commonly it does affect the lower lumbar
19 spine, and it is a process, not the result of an
20 injury. We also know from more recent literature
21 that smoking can speed up the process.
22 When it comes to the term degenerative
23 disc disease, unfortunately this refers to a
24 number of pathologies, and I've only listed five
25 here, but it includes spondylolisthesis,

00103

1 spondylosis, herniated disc disease, degenerative
2 scoliosis.
3 Now in clinical practice, we've heard a
4 little bit about how these patients present, but
5 who is the patient that suffers from degenerative
6 disc disease in this population? Well, they are
7 our parent, they are our aunts and uncles, they
8 are our grandparents. They are people that have
9 had, progressively, increase in low back and/or
10 leg pain that progressively debilitates them.
11 They no longer can play with grandchildren, they
12 can't play golf, they can't even walk from one
13 side of Wal-Mart to the other without leaning on a
14 shopping cart.
15 Our population is healthier, living
16 longer, and we would like it to be more active.
17 But once they fail the nonoperative care that
18 we've heard about so often today, we then will
19 carry out further diagnostic studies, and if
20 indeed they are found to be a surgical candidate,
21 then a frank discussion will be had between the
22 physician and the patient. They will weigh the
23 benefits and the risks, and the patient will then
24 make the decision whether or not the deterioration
25 of his or her quality of life is bad enough to

00104

1 warrant considering alternative interventions.
2 We operate in this population for many
3 different diagnoses. As you can see here, they
4 range from spondylolisthesis, spondylostenosis, to
5 scoliosis, to acquired spondylolisthesis, and a
6 very small segment is degenerative disc disease.
7 When we further break that down, however, that
8 small 14 percent shows that there are many
9 secondary diagnoses as well.
10 Degenerative disc disease is a very,
11 very broad diagnostic category and encompasses

12 many pathologies. The nomenclature doesn't
13 adequately define all the pathologies that are
14 present when we use that term as a primary
15 diagnosis. So we must look at both a primary and
16 secondary diagnosis to get a better idea of what
17 the patient's true pathology is.
18 As you can see, less than one percent
19 of Medicare beneficiaries are fused for pure
20 degenerative disc disease, and we've heard this
21 over and over again in the previous discussions.
22 The scientific evidence shows that the
23 studies for the elderly actually are lacking, but
24 the few that do exist show that these patients do
25 improve. The complexity of the diagnosis

00105

1 compounds study design and current measures lack
2 the sensitivity to account for all nuances of
3 patient pathologies. Even in the best randomized
4 controlled studies such as those from our Europe,
5 and even in our SPORT study, there are methodology
6 problems. There's also problems in terms of time
7 versus the technology and technique, and we've
8 heard each speaker discuss how the technologies
9 have continued to improve with time. There's
10 variations in community-based practice and there's
11 variations in conservative care, and as Steve
12 Garfin said, we really don't know what good
13 conservative care is either. The evidence-based
14 guidelines are slowly evolving and certainly we
15 will get there, but it is a slow process.
16 Nonoperative care is always the first
17 line of treatment and once we embark on surgery,
18 we have to be very careful in how we evaluate
19 these other studies. Dr. David Polly in the next
20 couple slides will discuss the entry criteria for
21 the various randomized controlled studies that we
22 have seen from Europe. There's variability in
23 treatment regimens and also variability of
24 outcomes. I would like now to turn the podium
25 over to Dr. David Polly, who will continue.

00106

1 DR. POLLY: My name is David Polly, I
2 am the professor in chief of spine surgery in the
3 department of orthopedic surgery at the University
4 of Minnesota. I'm the secretary-elect of the
5 Scoliosis Research Society and currently receive
6 grant support from the Department of Defense. I
7 have received no royalties, have no institutional
8 support. I consult for Medtronic, but I own no
9 stock. I previously have served as the co-chair
10 of a panel for the Department of Defense and
11 Veterans Affairs for the development of clinical
12 practice guidelines for low back pain, and I
13 receive financial benefit from the Army as a
14 retiree.

15 In addressing the questions that have
16 been posed to the panel today, we've heard a lot
17 of review of the information about the randomized
18 controlled trials. I think there are a couple of
19 key points to hone back in on.
20 Number one is that in the European
21 RCTs, the average ODI scores were about 40, and
22 they had not necessarily failed a trial on
23 conservative management to date. In U.S. surgical
24 trials, which I will detail in a little more
25 detail in a minute, the average ODIs averaged in

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1 the 50s, so the patients were worse off. They had
2 failed six months of nonoperative treatment to
3 date, so one might even consider their entry ODI
4 of 50 as being a result or an outcome of the
5 nonoperative management to date. So I think it's
6 important to point out that these aren't identical
7 patient populations.
8 And the second issue, as detailed
9 nicely by Dr. Mirza, is the challenge for us in
10 trying to do a similar RCT in the U.S. in our
11 current health care system. However, in spite of
12 that, we have a good wealth of well done surgery
13 to surgery RCTs that have been done in the United
14 States, and I had the opportunity to review the
15 aggregate data on 1,800 patients enrolled in these
16 trials and then compare these to the published
17 data on other surgical interventions.
18 So in this cohort of 1,800 patients
19 from FDA IDE randomized surgery to surgery trials,
20 we looked at the pool of SF-36 data, and this
21 would have been compared to published literature
22 data for other surgical interventions. So here is
23 the key point of the presentation. This
24 represents an SF-36 score, a well recognized
25 metric, with this being at baseline disability, a

00108

1 normalized patient for this age group would be in
2 a different category, and so this amount of
3 improvement across all studies represents a
4 four-times increase of a clinically important
5 difference of benefit.
6 John Ware, the developer of the SF-36,
7 has defined a clinically important, not a
8 statistically important, but a clinically
9 important difference as being a 5.4 change. All
10 of the studies showed at least that and typically
11 three to four times that. So we're seeing a
12 different effect size in the U.S. trials than we
13 saw in the European RCTs.
14 When we compare this to other
15 interventions, looking at total hip and total knee
16 replacements, we're seeing commensurate benefit.
17 Why does this happen? Total joint replacement is

18 currently considered to be one of the most well
19 accepted highest value interventions for
20 musculoskeletal disease in the United States
21 today. The amount of benefit derived from these
22 patients is commensurate with total hip and total
23 knee replacement.
24 In here I have clarified a little bit
25 on the issue of mature versus immature

00109

1 technologies. The increase in spinal fusion
2 rates, I think represents the adoption of maturing
3 technology. The change in total joint replacement
4 with the increases that are continuing represents
5 application of an already mature technology. If
6 we were to go back and look at grafts in the 1970s
7 and potentially the 1980s, as total joint
8 replacement was being improved, we would see a
9 commensurate increase in its utilization compared
10 to where it is today.
11 But what does this kind of benefit look
12 like? Do more patients get better? On the right
13 you see the healthy population scores, on the left
14 you see the disabled patient that Dr. Gelb
15 described earlier. And the intermediate column
16 shows that we are able to improve. Do we make
17 them normal? No, we don't, but we make them
18 significantly better in their activities of daily
19 living, which is in general what the patients are
20 looking for.
21 So, does this data generalize to the
22 Medicare population? Well, because of the way the
23 question was framed, in the past we had not
24 generally broken our patient cohorts into under 65
25 or over 65. As an impetus from the MCAC request

00110

1 for information, we did this in our study group,
2 looking at patients who had degenerative
3 spondylolisthesis. Why degenerative
4 spondylolisthesis? This is our most consistent
5 diagnosis from which we had good data to do the
6 comparison. So when we look at the ODI scores in
7 the over 65 versus under 65 patients with
8 degenerative spondylolisthesis, we're seeing that
9 they're starting in the category of a 50-point
10 ODI, showing a 20-point improvement, and that
11 there's an exact parallel in the improvement in
12 the over 65 versus under 65 population. When we
13 compare the SF-36 data, and here higher scores are
14 better, again, we see a commensurate improvement
15 exceeding a clinically important difference for
16 both the over and the under 65 population.
17 What about other publications? Well,
18 Glassman has a paper on this as well which is now
19 in press, which has also shown an equivalent
20 benefit in these people compared to a younger

21 patient population, so let's look at their data.
22 Again, the patient population is more disabled
23 than the European RCTs, with the aggregate intake
24 ODIs in the 50s. Obtaining 20 points of
25 improvement, doubling the European RCT

00111

1 improvements. And ending up with a clinically
2 important difference of improvement, and there is
3 parallel benefit for the over 65 versus the under
4 65.
5 In terms of the SF-36 benefit, again,
6 we see a similar trend with the over 65 and under
7 65, both achieving clinically important
8 differences.
9 So, relief of pain has been talked
10 about as a measure. The current tool, as
11 mentioned by Dr. McCrory earlier, the visual
12 analog scale, and he cited a 20-millimeter
13 improvement on intensity, and a general consensus
14 also is that a 30 percent overall reduction has
15 been accepted across cancer trials and other
16 trials as being a meaningful difference in pain.
17 And all of the U.S. studies achieved this
18 aggregate result.
19 Function has also been proposed as an
20 appropriate outcome measure, and here the SF-36
21 reflects this, and I'm showing you the data
22 showing the improvement in the SF-36, with Ware
23 stating that 5.4 makes a clinically important
24 difference.
25 We think return to work in an over 65

00112

1 patient population is problematic so we do not
2 feel this is the best outcome measure.
3 In terms of complication rates, we have
4 heard a lot of discussion about this today, and
5 there is great variability both in the way the
6 reports are conducted and what the information
7 shows, but we do not feel that we have any data on
8 which to draw conclusions on this today, and we
9 feel that it does merit further study. But this
10 issue is not just complications, but complications
11 that affect outcome. Many of the complications as
12 reported are mere transient events and do not
13 threaten long-term outcome, and may not even
14 prolong the hospital stay or treatment. So we
15 think that it's important to look not just at
16 complications, but do complications affect
17 outcomes, specifically in this cohort, and this is
18 an important need for further research.
19 In terms of long-term sequelae, it's
20 very clear that fusion is a biologic process, so a
21 well done fusion that is solid, is stable and
22 robust, can adapt to the life of the patient.
23 There are no studies at all that talk about, that

24 have ever demonstrated a solid fusion that has
25 gone on to arthrosis, resulting in a problem at

00113

1 that fused setting.
2 And you heard the debate about the
3 issue of adjacent segment degeneration. That is a
4 challenge for us, to sort out the differences
5 between the intervention and the natural history
6 of the patient. And here I think it's important
7 to talk about revision rates that have some
8 challenges for us. Specifically, if we look at
9 the total joint population, they have a high
10 revision rate too. So a person who has had their
11 right hip replaced and develops degeneration in
12 her left hip would be considered a reoperation by
13 the statistics that we've heard presented earlier.
14 I don't think that's a failure of the primary
15 operation, but rather a representation of disease
16 progression in the host, and I think it's
17 important to keep that in mind as well, that the
18 rest of the patient's spine may experience the
19 continued effects of the aging process which lead
20 to future or further additional issues that may
21 need additional treatment.
22 In terms of trying to understand the
23 pathophysiologic basis, we heard that discussed,
24 and I just included this as a detailed citation
25 about basic science evidence, that there does

00114

1 appear to be a physical structural difference
2 between pathologic deterioration versus
3 age-related changes. And the key point here is
4 that we hear a lot of information about finding
5 asymptomatic patients. Well, that's the challenge
6 that we face. We're not talking about
7 asymptomatic patients, we're talking about
8 symptomatic patients who have significant changes
9 that are attributed as being the cause of the pain
10 from degeneration, and we realize that's a
11 difficult challenge we still face.
12 So, the RCTs have been well addressed
13 today, I don't have anything further to add about
14 the information, other than to reiterate that we
15 think the U.S. patient population cohort is
16 different. I want to reemphasize that the U.S.
17 patients have failed nonoperative treatment prior
18 to entering into these trials, and they seem to be
19 more disabled.
20 So, we don't have key compelling data
21 to date to identify patient characteristics as
22 predictors of satisfactory outcomes, and that
23 clearly needs some further work.
24 We do feel that there are separate and
25 distinct patient populations, but again, I would

00115

1 point out that our surgical patients have failed
2 nonoperative treatment, and the challenges of RCTs
3 in the U.S. are that we would have to have
4 patients that continue treatment in the modality
5 that has currently failed them and agree to be
6 randomized to that.
7 In terms of long-term follow-up, there
8 are challenges in this patient population. I
9 think we have to recognize the issue of frailty
10 and continued aging in the over 65 population.
11 The expectation is that they will over time
12 experience gradually decreasing function. The
13 durability of the intervention to them, we know
14 that fusion is biologically stable. The issue has
15 become one of pragmatic end points and what is an
16 adequate duration of follow-up, and we think two
17 years to date has been reasonable, and there's
18 been no evidence of further deterioration of the
19 treated segment after that two-year period.
20 And at this point I would like to turn
21 it over to my colleague, Dr. Charlie Branch.
22 DR. BRANCH: My name is Charles Branch.
23 I am the chair of the department of neurosurgery
24 at Wake Forest University, and today I represent
25 the American Association of Neurological Surgeons

00116

1 and the Congress of Neurological Surgeons, as
2 chair of the joint section on spinal disorders. I
3 receive compensation as a consultant from
4 Medtronic and I also receive royalties from Wake
5 Forest University relating to licensing in the
6 field of spinal fusion devices. The AANS and CNS
7 have paid for my accommodations and transportation
8 to be here.
9 I'm going to continue our society
10 presentation and try to summarize our positions in
11 the next few minutes. Obviously this is a complex
12 question, as complex as the field it addresses.
13 It not only involves diagnosis, surgeon skill,
14 body habitus, comorbidities, but the evolution of
15 the techniques themselves. The draft technology
16 assessment has occurred. When looking at the
17 reported experience on anterior and posterior
18 fusion, it did not identify the superiority of one
19 approach over another. This review did in fact
20 confirm the benefit of instrumented fusion with
21 regard to the improvement in the ODI or SF-36
22 scores, and I would like to sort of suggest that
23 we consolidate this paragraph of questions into
24 two, does instrumentation help, does interbody
25 fusion help. Even these questions might seem

00117

1 difficult to answer with absolute clarity.
2 The post hoc analysis of Fritzell, 2003

3 randomized controlled trial, fusion had a
4 beneficial effect. The authors did not detect a
5 statistically significant benefit from
6 instrumentation, but frankly the study was not
7 designed to detect such a difference.
8 The lumbar fusion guideline published
9 in the Journal of Neurosurgery by Resnick, et al.,
10 this was a compilation of evidence-based medicine
11 reviews in contemporary literature. And here we
12 find that instrumentation is beneficial when there
13 is presence of radiographic instability, kyphosis,
14 or aggregate instability following the
15 decompressive procedure. And all three of these
16 are associated with the condition degenerative
17 disc disease at one or multiple levels, depending
18 on the severity or the multiplicity of the
19 condition.
20 Glassman in the publication of their
21 multicenter analysis on fusion outcomes with a
22 variety of techniques suggested in the index
23 question, that is the one that they found that an
24 anterior lumbar interbody fusion showed a greater
25 improvement in SF-36 and ODI results when compared

00118

1 to posterior approaches, but admits, and the
2 reference is noted in the tech assessment, true
3 benefit that you get from one technique over the
4 other is just impossible to determine. When
5 reviewing outcomes of patients with degenerative
6 spondylolisthesis, spinal instability associated
7 with degenerative disc disease, PSF showed a
8 benefit having true fixation for improving fusion
9 rate.
10 Kornblum noted that there was an
11 increase in patient symptomatology associated with
12 pseudoarthrosis, and that patients with a solid
13 fusion had a better clinical outcome. In another
14 cohort prospectively studied by Zdeblick published
15 in '93, again, shows improvement in fusion rate in
16 patients with instrumentation.
17 So in summary, I think there is really
18 good evidence that internal fixation improves
19 fusion rates and improves outcomes when carefully
20 applied in a disabling spinal condition with
21 instability, and current techniques do not
22 appreciably increase the rates of complications.
23 The evidence does not clearly identify a specific
24 fusion technique or approach as superior, but the
25 more current reports are positive for anterior

00119

1 interbody fusion with recombinant CMP.
2 And for some of the minimally invasive
3 techniques, the evidence from contemporary
4 carefully designed and heavily controlled FDA IDE
5 studies is that instrumented surgical fusion

6 treatments deliver improvements of 20 to 30 points
7 on the ODI scale, and we believe that this is
8 strong evidence that instrumented fusion improves
9 health outcomes in appropriately selected
10 patients.
11 Question 5 asks, what's the level of
12 confidence about the radiographic interpretations?
13 The draft technology assessment that we reviewed
14 prior to the meeting did not really address this
15 topic in any specific review. Our review of 31
16 studies did not identify a clear correlation
17 between clinical outcomes and fusion rates and
18 frankly, from the patient perspective, it's the
19 clinical outcome that really matters. There's
20 growing evidence that the accuracy of plain x-rays
21 in the identification of solid fusion is in fact
22 weak, and in recognition of that fact we believe
23 that the current fusion studies assessing fusion
24 status for technology in the lumbar spine are
25 going to be optimized with the use of computerized

00120

1 tomographic imaging. We believe that the
2 correlation of a solid fusion with a beneficial
3 outcome is strong in appropriately selected
4 patients, but the historical literature reported
5 is in fact weak. This is a discordance that we
6 believe should be resolved and will be resolved
7 with further study.
8 Question 6. Well, we agree with the
9 draft technology assessment that there are no
10 studies pertinent to this question that focus
11 exclusively on the Medicare population or the
12 impact on health outcomes. Yamashita in a 2006
13 study stratified results by population, but it is
14 difficult to determine significance.
15 Glassman in his study found that the
16 older population benefitted similar to the
17 younger, and this observation I think is borne out
18 in many of our practices where the 65 or 75 or
19 80-year-old patient who's physically active,
20 traveling, playing sports, living life fully,
21 while then having had their previous
22 life-threatening conditions treated successfully,
23 CABG, knee replacement, hip replacement, whatever,
24 now presents with a compound disabling
25 degenerative spinal condition that has failed to

00121

1 resolve with a constellation of nonoperative
2 therapies. And this condition appears to be
3 caused by a clearly identifiable degenerative
4 disability and neural compression, where the
5 patient benefits from a decompressive stabilizing
6 surgery.
7 We believe there is a cohort of the
8 Medicare population that is truly comparable with

9 the younger population, and that there is evidence
10 that the benefit of surgical fusion is
11 generalizable to this cohort.
12 The questions that have been posed for
13 the panel are the same questions we ask ourselves
14 routinely in the office. The ambiguity or lack of
15 clarity in the tech assessment prepared for the
16 panel reflects the collective state of the
17 literature on the subject. When comparing
18 outcomes, we all use the analogy of comparing
19 apples to apples or oranges to oranges, and our
20 presentations, our assessments, our literature
21 unfortunately are not just apples and oranges but
22 are truly an ambrosia, a true fruit salad of RCT,
23 FDA IDE device studies, prospective,
24 retrospective, single, multicenter, cohort
25 analysis, historical, and emerging techniques.

00122

1 But I think there are several distinct
2 flavors that come out of this mix. First, in a
3 painful degenerative condition of the lumbar
4 spine, nonoperative therapy is always the first
5 choice of therapy, but is not always successful in
6 relief of symptoms even after extended effort.
7 Second, the randomized controlled trials available
8 clearly demonstrate that in patients with
9 disabling back pain with an identifiable
10 degenerative condition that fails treatment for
11 weeks or months, there is a clear benefit to
12 surgical treatment. Third, there is evidence that
13 the benefit from operative fusion is comparable to
14 that of total joint replacement or other accepted
15 surgical intervention. And fourth, there is
16 evidence or at least a strong inference that the
17 Medicare beneficiary is as likely to benefit from
18 lumbar fusion as the younger cohort.
19 Do further studies need to be done?
20 Absolutely. The recently completed SPORT trial,
21 unfortunately, was not designed to answer the
22 questions that we're considering today. From a
23 myriad of publications, though, it appears that
24 this study does affirm the cumulative medical
25 experience in spine care that recognizes that

00123

1 appropriately selected patients benefit from
2 nonoperative and/or operative care, depending on
3 their unique condition.
4 We also realize that methodologic
5 purity is challenging in a large randomized
6 controlled trial studying these conditions.
7 What's the model of the study we might propose?
8 Well, the design of the Fritzell study probably
9 comes close. Its strict diagnostic, ODI, SF-36
10 inclusion criteria would have to be determined and
11 included. We can't have another Brox or Fairbank

12 challenge where the entry criteria in these
13 oft-quoted RCTs are way outside what we consider
14 to be the best medical practice in this country.
15 The cohort of patients, especially in the Medicare
16 benefit group, are going to be difficult to
17 randomize, especially the patient with disabling
18 pain who has already failed nonoperative therapy.
19 This is going to require a tremendous recruitment
20 effort, potentially comparable to the scale of the
21 SPORT trial, making the feasibility of this study
22 challenging.
23 What are some of the practical studies
24 that we could implement expeditiously to enhance
25 our knowledge? Well, there's cohorts of data that

00124

1 we've already seen, IDE studies that are certainly
2 relevant. We can initiate observational studies,
3 similar design to SPORT, to the observational
4 cohort of SPORT. Clarification or tidying up of
5 coding nomenclature for processes will provide
6 more meaningful analysis of the large population
7 data set which is in MedBar in the future.
8 In summary, lumbar degenerative disc
9 disease is a real and maybe painful and maybe
10 disabling entity that presents in a constellation
11 of conditions reflected by the ambiguity of the
12 diagnostic coding nomenclature. It's rarely found
13 in isolation in the older-than- 65 Medicare
14 beneficiary population. In most stable
15 degenerative conditions of the lumbar spine,
16 nonoperative care is the first line of treatment.
17 When nonoperative treatment has failed, there is
18 clinically significant benefit to appropriately
19 selected patients for lumbar fusion. It appears
20 that there is a consistency of magnitude of that
21 benefit to patients older than 65 when compared to
22 those younger than 65, but further study is needed
23 to understand the optimal roles for both operative
24 and nonoperative treatment strategies for these
25 patients whose ongoing aging and degeneration are

00125

1 going to confuse the analysis of benefit of any
2 isolated treatment. Thank you.
3 (Applause.)
4 DR. KRIST: Thank you very much. Now
5 we're going to move to the section of our
6 discussion today with the open public comments,
7 and five individuals have signed up to speak. I
8 would ask that if you signed up to be one of the
9 open public speakers, if you would come to the
10 front of the auditorium here, and we will have you
11 speak into this microphone over here. And I
12 remind you to state who you are, your
13 affiliations, and disclose any conflicts of
14 interest that you might have.

15 For the panel members, you'll notice
16 there are no breaks for bathroom or anything, it's
17 been pretty obvious. Our break is around noon for
18 lunch, so if you need to excuse yourself for a
19 couple minutes, feel free to do so.
20 I'm going to read these the best I can
21 based on what you've written here on the sheet, so
22 I'll apologize if I get things wrong. The first
23 person who signed up is R. Pocelli, and since we
24 have five folks here, I'm going to ask that each
25 of you try to keep your comments to two minutes.

00126

1 DR. POCELLI: Okay, we'll go quickly.
2 My name is Richard Pocelli, I presently work for
3 DePuy Spine as the vice president of clinical
4 affairs. I was a former academic spine surgeon at
5 the University of North Carolina. I just wanted
6 to talk to you a little bit about our feelings at
7 DePuy as to what we've heard here today and the
8 future as we move forward.
9 We think obviously DDD is a complex
10 disease, and as we've seen today, there are
11 limited treatment options. I think what we're
12 trying to portray here, and I think some of the
13 docs did that pretty well, is this seems to be a
14 pretty significant disease for patients. In its
15 most severe form it can destroy a patient's
16 quality of life. These patients seek all
17 standards of there, some of them have been listed
18 here, but we know of others as well that do occur,
19 and no present cure exists for these patients.
20 The social and economic costs of low
21 back pain is well documented, and this disease
22 remains a large public health concern, and I think
23 we all agree with that. Spinal fusion surgery has
24 been the mainstay surgical treatment for the last
25 40 years. For thousands of patients it has

00127

1 remained and should remain an important option for
2 those patients, and those who have been carefully
3 selected and have failed nonsurgical treatment.
4 But clearly more research is necessary.
5 And we at DePuy are committed to supporting these
6 efforts, working with all stakeholders so that if
7 a surgical therapy is indicated, the right
8 procedure is performed for the right patients at
9 the right time, and by a highly trained
10 professional.
11 In the meantime, doctors and patients
12 must carefully weigh the risks and benefits of
13 surgical versus nonsurgical treatment and
14 determine the appropriate course of action based
15 on their individual circumstances and the data we
16 have today.
17 In summary, DDD is a terrible disease

18 for which options are limited. More research
19 needs to be done and we need to find newer and
20 better solutions. We along with you have reviewed
21 the evidence. We acknowledge that stronger data
22 are needed to permit these patients to make the
23 most informed choices. We are committing to work
24 with CMS to construct clinical studies to clearly
25 identify the superior benefits of both

00128

1 conservative management and surgery, so that more
2 patients achieve positive outcomes. We want to
3 thank you for the opportunity to comment, and look
4 forward to more discussion and collaboration in
5 the future. Thanks.
6 DR. KRIST: Thank you. Next on our
7 list is Todd Albert, and then after Todd Albert I
8 have Steven Glassman, so if you could come forward
9 in a queue.
10 DR. ALBERT: Thank you. I'm Todd
11 Albert, I'm a spine surgeon from Philadelphia.
12 I'm the incoming chairman of orthopedics at Thomas
13 Jefferson University and the president of the
14 Rothman Institute there. My conflicts, I'm on the
15 medical advisory board of three spinal companies,
16 Case Medical, Genesis and Axial Med. I'm a
17 consultant for DePuy Spine. I was reimbursed for
18 my transportation here today by DePuy Spine, but
19 I'm not being compensated to come here, and I felt
20 strongly and wanted to make a couple comments.
21 I was pleased to be able to hear some
22 of the comments made by the societies, which I
23 felt were excellent, and I will just try to expand
24 on a few of those. I think the most important
25 point to understand, for us to all realize is that

00129

1 when we use the term degenerative disc disease,
2 we're talking about something with multiple
3 diagnoses which importantly do cause low back pain
4 but also cause leg pain. We think the very
5 positive effects of surgery are in degenerative
6 spondylolisthesis, I think the evidence today is
7 excellent, the quality of evidence is excellent.
8 They include degenerative disease in axial back
9 pain with a flattened disc, and I think few people
10 would argue that we have good evidence that we
11 help patients with surgery for back pain, although
12 it's a rare diagnosis in the over 65 population.
13 I guess I would just remind you that many people
14 covered by Medicare are disabled and much lower
15 than 65, and fall into that group of diagnostic
16 categories studied by Fritzell in the Swedish
17 spine study showing the positive effects of
18 surgery.
19 So we don't have good evidence for the
20 over 65 population for that solitary diagnosis,

21 not inclusive of degenerative spondylolisthesis,
22 not inclusive of degenerative scoliosis with
23 spinal stenosis, but patients with significant
24 back pain and leg pain.
25 And I think the evidence that we

00130

1 pointed out relative to degenerative
2 spondylolisthesis, best done by the Beaumont group
3 in the Fishburn and Kirkwood article, following
4 patients, looking at them, at two years showed no
5 difference between instrumentation and no
6 instrumentation in outcomes, but a significant
7 difference in fusion rate. Fast forward when they
8 reviewed those patients at five years, they showed
9 a significant difference in outcomes for patients
10 who had pseudoarthrosis and those who did not. Go
11 backwards, instrumentation led to higher fusion,
12 less pseudoarthrosis and, therefore, better
13 outcomes. So I think they proved that fusion was
14 better than no fusion in those studies, and they
15 again showed the benefit of instrumentation in a
16 randomized controlled trial.
17 Finally, I would say Dr. Glassman, who
18 I know is going to speak, has done a lot of work
19 in terms of looking at meaningful differences, and
20 has shown that the degenerative scoliosis
21 population again in the lumbar fusion population,
22 very positive effects of surgery.
23 I was also an author and a site
24 investigator on the SPORT study. That is, as you
25 know, a study that's looking at three diagnoses.

00131

1 Only the one first one has been published, the
2 largest prospective trial funded by NIH, and there
3 are difficulties. I can tell you that enrolling
4 in that study and having lived with it, there are
5 incredible difficulties in signing up patients to
6 be inside that trial and then have the patient
7 either have to be randomized to nonoperative
8 treatment end up with searing leg pain where they
9 cannot work or live, and demanding to be switched
10 over to the surgery arm and --
11 DR. KRIST: Dr. Albert, I'm going to
12 have to ask you to wrap up your comments.
13 DR. ALBERT: Okay. But there are more
14 trials coming for fusion. I appreciate you
15 listening to me and allowing me the time. Thank
16 you.
17 DR. KRIST: Thank you. After
18 Dr. Glassman, I think the last person is Sean
19 Aclasia, I apologize if I got that wrong.
20 DR. GLASSMAN: I'm Steve Glassman, from
21 the Leatherman Spine Center in Louisville. I'm
22 here today on behalf of the SRS. I have conflicts
23 including being a consultant, I receive royalties

24 from Medtronic, I have researched for both
25 Medtronic and Network Healthcare.

00132

1 What I would like to do is just briefly
2 talk to you a little bit about the study that was
3 alluded to by some of the other presenters when we
4 looked at patients in the over age group. There
5 were 85 patients, it's in press for Spine journal,
6 but not available to you yet. Maybe there's a
7 copy of it that you have received.
8 We looked at both generic and
9 disease-specific outcome measures, all
10 prospectively at two years, and the ODI
11 improvements of 20 points in that group for the
12 primary surgeries wasn't a surprise, because those
13 are the patients that we see do well, those who
14 can't get to the grocery store, who can't sit on
15 the bench and watch their kids play tee ball, and
16 we know that those patients get better. But in
17 the older patient population, I think the concern
18 of all of us is, are these patients taking a hit
19 in their general medical state in order to get
20 that benefit in their disease-specific improvement
21 in disability.
22 And in all honesty, I sort of
23 anticipated that that was what we would find, but
24 we didn't. What we found was an improvement not
25 only in ODI, but a substantial improvement in

00133

1 SF-36 too. And the reason we compared it to a
2 younger group, which was a 50 to 65-year-old
3 group, was that that's the group that people don't
4 look at and say they might be too sick, we
5 shouldn't operate on them. And yet, there is no
6 difference in the general health measures between
7 those two groups. So I think with our added study
8 techniques and our general health, this is a group
9 at this point that we can give the benefit of
10 these operations without overriding risk.
11 And so I would just like to talk a
12 little bit about complications. One of the
13 studies that we talked about before, my data as
14 well, we reported on the complications in these
15 older patients, but one of the things we looked at
16 in this study was the two-year outcomes as
17 compared to complications. And there was no
18 deterioration in outcomes in two years in the
19 patients who did or did not have complications.
20 Which is not to say that there aren't any isolated
21 patients who had complications whose outcomes
22 certainly will deteriorate. I think what it
23 reflects is that the majority of these patients,
24 you're talking about minor events, urinary tract
25 infections, ileus, which you know is an important

00134

1 thing to be on top of, but isn't the kind of thing
2 that's really affecting your outcome, and I think
3 as you look at complication rates, you need to
4 differentiate those issues, and I'd ask you to be
5 cognizant of that. Thank you very much.
6 DR. KRIST: Thank you, Dr. Glassman.
7 And then our last individual signed up for open
8 speakers, Sean Aclasia. I might be getting this
9 wrong so if you signed up and I haven't called
10 your name, come on up. Okay.
11 Well, at this point, we've finished
12 with our scheduled presentations and scheduled
13 public comments and open public comments, and
14 we're going to turn here and give the panel some
15 time before lunch to ask questions of our
16 presenters. So, this is your opportunity to
17 clarify any of the information that you've heard,
18 and try to get details from any of the presenters.
19 David.
20 DR. FLUM: Dr. McCrory, I would like to
21 start with the evaluation of randomized trials
22 that you formally meta-analyzed in your report,
23 the Fairbank and Brox studies. Can you give us a
24 point estimate for the sense of the impact of the
25 interventions on the patients?

00135

1 DR. MCCRORY: I'm sorry, the question
2 is what?
3 DR. FLUM: Was it a formal
4 meta-analysis with point estimates?
5 DR. MCCRORY: No, we didn't combine
6 them. You know, I guess we entertained the idea,
7 but we felt like with a small pool of four
8 studies, that wasn't a reasonable way of
9 approaching it. You know, the differences between
10 trials and differences in results are apparently
11 what they are, and I'm not sure that I would trust
12 a single synthetic estimate of effect size.
13 DR. KRIST: Mark.
14 DR. FENDRICK: Doug, while you're up
15 there, I found it interesting that many of the
16 comments had different interpretations of
17 randomized trials and stated clear evidence from
18 the trials that there is a benefit to surgery over
19 the variety of therapies. I would presume that
20 there were no data that concluded that in the
21 studies you looked at. Is there any reason you
22 can see, or explain the clear difference between
23 them on the overall assessment of the RCT data?
24 DR. MCCRORY: I think one of the -- I
25 can think of at least two issues. One issue is

00136

1 that's talking about, you know, the idea of
2 benefit, is the before to after change in the

3 index of 15 points is clear enough evidence of
4 benefit, or whether it requires a difference
5 between a change that occurs before and after
6 surgery from a change that may occur after rehab.
7 I think fundamentally, that's the thing that led
8 us to our conclusion that was, you know, sort of,
9 we lacked data enough to say that, to convince us
10 of that.
11 I think the other issue, I have been
12 reflecting more on this since we submitted the
13 report, and that is that there is just more
14 uncertainty, perhaps more uncertainty when you
15 compare conservative management to surgery, both
16 in terms of what therapy and what, you know, what
17 the aggregate of those therapies might be. So I
18 think when, I think that I could almost argue, or
19 someone could argue that the benefits of surgery
20 are clear, and what's unclear is the benefits of
21 the conservative treatment, I don't think that
22 there is a great deal of value to that, or that
23 they are reaching conclusions that aren't
24 supported by any evidence. I think it's just the
25 degree of evidence that we required.

00137

1 DR. KRIST: Kim.
2 DR. BURCHIEL: I was interested in one
3 of the slides you showed that, we discussed the
4 short and long-term outcomes of fusion (inaudible,
5 off microphone). And it strikes me, though, that
6 the missing element there is sort of quality of
7 life -- (inaudible, off microphone) -- increased
8 quality of life issues, but that's not mentioned
9 in your discussion. In other words, there is
10 substantial improvement over time. Was that a
11 conclusion?
12 DR. MCCRORY: I think the purpose of
13 putting up that slide was more to deal with the
14 issue of post two-year outcomes. I felt like, I
15 think our interpretation of the data was that
16 there is some support there, but there was under
17 two years improvement that was clinically
18 significant from that data, and what happened
19 afterwards wasn't as certain, so that's what
20 happened in that area of the curve.
21 DR. BURCHIEL: So just basically
22 flipping it around, the outcome collapsed towards
23 the same point, roughly at eight years. There may
24 be no significant difference. But what happens in
25 that intermediate time, the time between short and

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1 long-term outcomes, may actually be substantially
2 beneficial to the patient in terms of quality of
3 life in your calculation, but that's never
4 mentioned in your discussion.
5 DR. MCCRORY: Or perhaps an omission.

6 There is a lot of data in the intervening years.
7 DR. KRIST: While you're there, I would
8 like to hear your comments on the differences in
9 the patients in the European studies versus the
10 U.S. studies for the surgical candidates, and what
11 your perception is of that.
12 DR. MCCRORY: Well, there was one
13 additional comment that I think I agree with very
14 much, and that's that the baseline ODI disability
15 did tend to be lower in those trials, and I didn't
16 actually comment on it in my slides. There was a
17 fair amount of difference in the starting point
18 and the disability level in the studies that we
19 looked at, and those studies tended to be the
20 lowest.
21 And I heard Dr. Mirza talk about, they
22 were able to produce some data that was far more
23 detailed than what we were able to regarding the
24 details of the conservative therapies in the Brox
25 study, for example, where, I'm not sure where he

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1 got his data, but he must have some source he was
2 able to tap. So I'm not sure I feel like I had a
3 good enough handle on the varieties of the
4 conservative management or in the baseline patient
5 characteristics to be able to comment any more. I
6 didn't have that additional data.
7 DR. FLUM: I have a follow-up. So one
8 of the themes that emerged in the other
9 presentations was that in the United States,
10 people who failed nonoperative therapy would go to
11 surgery, implying that in the European studies,
12 they hadn't already gone through a period of
13 nonoperative therapy. My reading of it, I didn't
14 pick that up in the European studies, but I wonder
15 if you could comment on that.
16 DR. MCCRORY: My reading of it is it's
17 a little hard to determine. They did have lower
18 Oswestry scores. It wasn't as clear to what
19 extent they received nonoperative therapy before.
20 It was our impression, I can't quote you line and
21 verse what the specific studies say, I think
22 that's a generally true statement, but I might
23 want to defer to my colleagues, and Dr. Turner or
24 Dr. Richardson might be able to comment on that.
25 SPEAKER: I don't think there was as

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1 much specified about, particularly in Brox, about
2 three randomization therapies offered, with the
3 presumption that there was some, but they weren't
4 specified very well in the articles.
5 DR. KRIST: Well, in one of the Brox
6 studies they had surgery a year prior, right? One
7 of the criteria was they had to have surgery a
8 year before, and I assume something happened over

9 that one-year period between when they had the
10 surgery and when they were randomized for the
11 second study.
12 DR. FROM: This seems like a critical
13 issue because I think we have to discuss whether
14 there were significant improvements with
15 nonoperative therapy. Three of the four
16 randomized studies showed significant ODI
17 improvements with nonoperative management. The
18 question is whether or not all the benefits were
19 even achieved in the United States, or it would
20 render our U.S. randomized trial not helpful to
21 this point. So I think it's critical that we do
22 understand what data we're getting in these
23 European studies.
24 DR. ONDRA: This is another
25 qualification about the difference in the studies.

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1 Do you feel that the selection criteria, you
2 commented on that, that many of the studies were
3 procedurally driven rather than patient symptom
4 driven, or do you think the patient selection
5 criteria led to the differences?
6 DR. MCCRORY: Well, let me distinguish.
7 When you talk about the procedure driven, we were
8 referring to the series of uncontrolled studies,
9 which many of them were. I think in the
10 randomized controlled trials that were done, the
11 European ones, the issue is that the patient
12 population was not precisely described in terms of
13 the nonsurgical therapy that they had, and indeed,
14 some of them were in the context of the post-
15 randomization or a new trial. So we were aware of
16 that data. I mean, example, one of the studies
17 had citations for the nonoperative therapies that
18 were used in the trial, and when we go back and
19 look at those, they're really not very helpful in
20 providing any detail on, you know, a protocol, or
21 any very detailed collaboration of what was
22 expected to be done.
23 DR. KRIST: Kim.
24 DR. BURCHIEL: Maybe you shouldn't be
25 the one in the hot seat here, but my question has

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1 to do with the outset, I mean the whole, I think
2 as Steve said, this is such a vital issue, are
3 these populations comparable or are they not, at
4 the beginning of these studies? David, the other
5 David implied that they weren't. My question is,
6 looking at validated measures, has it ever been
7 validated across populations? I mean, some of
8 these results would imply that the fusion rate in
9 the U.S. being five times or ten times more than
10 other countries. Is it possible that we're just a
11 more disabled population in general, and that's

12 not a mixture or not a result of more aggressive
13 therapy, but in fact of just how the population
14 norms are different. That's one question I have
15 concerning outcomes, has it ever been validated
16 internationally.
17 DR. MCCRORY: We did do a fairly
18 extensive follow-on evaluation (inaudible) and did
19 a lot of digging and read a bunch of articles, and
20 it has been described as an acute back pain with
21 people who are starting with us on treatment not
22 involving surgery, some around 40, some around 50,
23 some around 60, and we found a range of severity
24 of level of disability. And one of the unique
25 things I think about the Oswestry as well as some

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1 of the other measures was that there were no floor
2 or ceiling factor, it was like a rolling index.
3 And there were, you know, these different
4 populations had either floor effects or ceiling
5 effects, it was an international problem, and one
6 of the (inaudible) on function was that they
7 seemed to be responsive over a wide range of
8 starting points in terms of level of disability.
9 It also seemed to have validity in
10 terms of correlating with patient's improvement.
11 A lot of people have used it with a 10 percent
12 improvement or something, and the score was
13 determined to be a clinically important
14 difference, and I don't think the data was found
15 to support an absolute point change, so I am
16 actually pretty pleased with the properties of
17 that measure.
18 DR. KRIST: You had mentioned that the
19 meaningful improvement was about 15 for acute pain
20 but it was a lower number for chronic pain. Is
21 there a number that's established on that, or did
22 I hear wrong?
23 DR. MCCRORY: Well, the data
24 (inaudible) between 10 and 15 with focus on 15 as
25 the level because the FDA selected that one as

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1 their criteria. You know, one might argue that it
2 could be a little bit lower, but not lower than
3 10. I think some argue that the level for acute
4 pain sure should be higher, I think the 10 to 15
5 was specific for chronic pain.
6 DR. JARVICK: I actually have a
7 question for Dr. Branch, which is a follow-up
8 question to a question Mark had regarding
9 interpretation of the RCTs, and it is that the
10 RCTs essentially showed a benefit of surgery, and
11 I was just wondering if you could comment a little
12 bit more about that in light of the other
13 presentations that have been made.
14 DR. BRANCH: If you take the surgical

15 cohorts of each of these studies, in the surgical
16 cohorts of all of these studies, there is a
17 benefit. Whether it was 10, 15, 20, 25, 30, 40,
18 depends on what study you look at. Even in the
19 RCTs, when you look at them and compared them to
20 the nonoperative therapy, depending on how you
21 look at it, you may not have a clinically
22 significant difference between the two in
23 improvement, but every single study had an
24 improvement associated with surgical treatment.
25 DR. JARVICK: So this was just looking

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1 at before and after.
2 DR. BRANCH: If you look at the impact
3 of surgery, there is, of all the studies that all
4 of us have looked at, there's one study, Brox
5 2006, that showed a modest, a less than minimally
6 clinically important difference in the benefit of
7 surgery, but that was the one of probably
8 literally thousands of patients. So there's a
9 benefit of surgery. The question, you know,
10 depends on which patient cohort you assign to
11 which, I think that's what we're finding in the
12 European studies.
13 You know, if you take patients who, the
14 Fairbank study, look at their paper, what are
15 their criteria for entering the study? The
16 uncertainty principle, and this is quoting their
17 language, the uncertainty principle about it, this
18 is as good as you get. Then a physical therapist
19 concluded that patient was studied, and then the
20 patient is randomized.
21 The Brox study, degenerative disc
22 disease on a plain x-ray, then they're recruited
23 into a randomized study. So that the folks that
24 had surgery, they got better, but the folks who
25 had nonoperative therapy, they got better. But

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1 these are patients that we would not consider,
2 certainly not consider for surgery surgically in
3 the arms that we randomized, and that was the
4 issue we addressed.
5 DR. KRIST: Do you want to follow up on
6 that?
7 DR. FLUM: I would like to extend on
8 that. I think there are few surgical procedures
9 out there that have four, I think if we include
10 the Muller and SPORT trial, there are few
11 procedures that have four randomized trials that
12 have looked at comparative evidence. I think in
13 many ways we have a richness of randomized trials
14 if we change this data a little bit. We may not
15 like the results of them, but there are four of
16 them that have been done, and we may not like the
17 way they have been done, and they may have varying

18 criteria, and we could improve upon them.
19 But I think one of the questions is,
20 how can we plan fusion studies that will be
21 better, and it seems like Dr. Polly himself has
22 taken the idea of another randomized trial off the
23 table a little bit. And I wonder if it's really
24 true that we can't do a randomized trial given the
25 significant number of tax dollars that are spent

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1 on these procedures.
2 DR. BRANCH: I think most of us are
3 going to say that if we're going to do a
4 randomized trial, then we have to sort of back up.
5 Right now people who at least surgeons are seeing
6 in the office and considering for the randomized
7 trials that we're doing to compare one technique
8 or one technology or one approach to another,
9 okay? For us to do a randomized controlled trial,
10 we've got to back all the way up to the SPORT
11 entry criteria, and we'll see what happens with
12 the degenerative spondylolisthesis cohort in the
13 SPORT trial. I mean, that's out there, it's
14 coming in, so we don't want to get too far down
15 the trail of designing a new randomized study
16 before we see that.
17 But we know, one, there is a lot of
18 methodology challenge that's going to have to be
19 overcome there. Number two, we have to sort of
20 back up three or four steps and say which patients
21 are, or when are we going to see patients in their
22 diseased state, and then begin the analysis,
23 randomization, treatment process. So it's either,
24 one, we might commit to doing surgery on these
25 people earlier in the process, that's a

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1 challenging thought, or -- I mean, you even
2 basically commented on the thought of sham
3 surgery. That's an interesting thought, but
4 that's a real tough one. So conceptually, back
5 up, treat people earlier, offer, expose, depending
6 on your favorite, surgery earlier in the treatment
7 process, or do like we're doing now and take an
8 observational perspective and see where that goes.
9 I think there are a lot of options and certainly
10 over the next few months and years, I think we as
11 collective health care professionals and
12 government payers are going to try to sort this
13 out.
14 DR. FLUM: But your interpretation of
15 those RCTs, I agree with Dr. Jarvick, was
16 emphasizing the surgical arm, and I think SPORT
17 along with three of the four RCTs in this area
18 have also shown that in the nonoperative area,
19 there is also improvement, whether or not it's
20 better or worse.

21 DR. BRANCH: There are many RCTs that
22 are European that there is improvement in both
23 groups. All of those studies, the patient was
24 entered into the process long before, or much
25 earlier in their disease state than we see in our

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1 environment. Most of us who practice spine
2 surgery, number one, see the patient; number two,
3 wouldn't consider entering him into a randomized
4 trial that would include surgery as a treatment
5 arm. So what does that mean? We don't know,
6 okay? But the studies are the studies, no
7 question. But the folks that got entered into the
8 surgery arm earlier in the process got better.
9 DR. KRIST: Barbara, and then Steve.
10 DR. BOYAN: I actually have a couple of
11 questions, and I think they're to Dr. Mirza and
12 the gang of three. The questions really stem from
13 the fact that, and this is coming from a
14 non-surgeon who actually was present in most of
15 the FDA panels for which the clinical studies that
16 we looked at today were presented. So I've seen a
17 lot of these clinical studies in a different
18 context.
19 And what struck me about them was the
20 fact that surgeons don't just do the protocol
21 that's defined, they do the protocol that's
22 defined plus their own little special tweak on it.
23 And there is a tremendous variation indicated.
24 I'm wondering how much of that data is
25 attributable to a variation, to the secret sauce,

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1 and by secret sauce I mean autograft, allograft,
2 DBM, a little bit of each, whatever it happens to
3 be, that makes that surgeon feels like he or she
4 has treated the patient adequately during the
5 surgical operation. That's question one.
6 And question two comes to deal with
7 male and female. Most of the studies that were
8 presented here were not adequately powered to say
9 anything about males and females, but there are
10 studies in Spine where they were adequately
11 powered, they were prospectively randomized
12 clinical trials where there was at least a hundred
13 males and a hundred females. And looking at
14 nonsurgical therapies, where they found that there
15 are actually statistically significant differences
16 in how males and females respond in therapy. So
17 how are we accommodating that in the conversations
18 that we're having today about the fact that the
19 demography of this group is not worried about
20 smokers, it's worrying about who the main patient
21 is over the age of 70, because most of the guys
22 have fallen by the wayside, that we have taken
23 into consideration what these outcomes are doing

24 to my side of the population. Over to you.
25 DR. MIRZA: I'm not sure, but let me --

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1 I'm not sure I can address either of your
2 questions.
3 DR. BOYAN: I thought you were the one.
4 DR. MIRZA: I think each surgery is
5 individualized, and that's one of the challenges
6 of doing surgical trials over various medication
7 trials. There is no uniform standardized surgical
8 procedure. It does depend on the surgeon's
9 experience, on their skill, on their particular
10 preferences, and it goes all the way from the
11 initial encounter with the patient to how you
12 frame the issues and how you present the
13 information, to how you carry out the surgical
14 procedure and what is the postoperative course.
15 It is very hard to standardize that.
16 DR. BOYAN: Is there some way in the
17 analysis data at the end that a surgeon kept a
18 record of what was actually used in the additives,
19 that they then could go back and see how that
20 impacted the outcome?
21 DR. MIRZA: I think you already
22 answered that. These studies are very unpowered
23 to study the impact. It would be very difficult
24 for them to try to look at the ancillary effects.
25 And the same applies to gender differences. I

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1 believe they are hard studies to conduct, and to
2 look for subtle difference when the main effect is
3 debatable would be hard to interpret. So I'm not
4 sure we have large enough or rich enough data to
5 really look at the specifics of surgical details
6 and postoperative variations, or the specifics of
7 patient characteristics like gender or duration of
8 symptoms.
9 You know, I think those four trials
10 that have kind of been discussed a lot, but none
11 of them had MRI as an entry criterion. The second
12 Brox study did mention MRI scan, but only as a
13 condition to indicate there was no residual or
14 adjacent segment disease. But they did not
15 specify how many levels of disc disease they were
16 looking for changes, and all these factors are
17 probably important depending on what they see,
18 that is the surgeons, and depending on the
19 specific procedure to that particular patient.
20 DR. ONDRA: I have kind of an
21 observation that, from Dr. Garfin and Dr. Polly
22 and beyond, everyone talked about the fact that in
23 the U.S. practice, nonsurgical treatment often is
24 what constitutes conservative treatment, so
25 nonsurgical treatment is always done before we

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1 consider surgery. I think that's the part of the
2 behavioral validation which, as Dr. Garfin pointed
3 out, we don't really know a lot of where we are
4 with this.
5 And so this gets down to how do you
6 study? And the answer is, we've got four studies
7 randomized, which is one of the most important to
8 researchers, but if we have 20 badly designed
9 studies, 30 badly designed studies, it doesn't
10 really increase our knowledge. So my question is,
11 given the difficulty in SPORT with the RCT, if
12 we've learned nothing over the last couple
13 thousand years of science, is that there is more
14 than one way to the truth. Is an RCT, given the
15 difficulty of getting that in the SPORT study, and
16 it would be even bigger doing that in the
17 degenerative disease groups, is that the only way
18 to the truth? Is there an alternative path where
19 you could look at population studies that would
20 obviate the need for an RCT? So before we focus
21 our thought on RCT alone, it looks like Dave is
22 ready to come out of his chair there, is there any
23 other way to get at this answer? David.
24 DR. POLLY: As a member of the gang of
25 three, I think there are a couple of comments on

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1 that. One is the issue of practical applied
2 clinical trials as published in JAMA in 2003,
3 suggesting looking at effect size in the analysis,
4 and I think that's one of the points that we need
5 to make in the difference between the U.S. data
6 versus the European data. The effect size in U.S.
7 data is roughly twice that in terms of benefit of
8 ODI, versus the Europeans. Now you can argue, are
9 we seeing a different patient population, a worse
10 off patient population, or is our intervention
11 substantially different? However, the effect size
12 is clearly different in well done surgery versus
13 surgery RCTs, so we think it's reasonable quality
14 level one data.
15 Now, it's not surgery versus
16 nonoperative treatment, but Dan Resnick just
17 reviewed for us and confirmed what we thought, in
18 three of the four RCTs there was no run-in period
19 of physical therapy, so they had zero treatment to
20 date, which is not really a technical paradigm for
21 us in the U.S. in terms of ethical care, at least
22 as most of us think of it, you walk in with your
23 first episode of back pain, receive no treatment,
24 and are randomized for the surgical versus
25 nonsurgical arm. Most of those patients are not

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1 enrolled for surgery because we feel their natural
2 history is so good.

3 So the question that you're asking, I
4 think, has several different points. The run-in
5 part, which I think in the U.S. has altered our
6 patient population as it sees the treating
7 clinicians. The second one is the effect size
8 analysis, and I think the effect sizes that we're
9 seeing are substantially different, but that's why
10 you're seeing divergence of information. Patient
11 differences, effect sizes, but I think when you
12 have multiple RCT data relating surgery versus
13 surgery, that effect size is no longer an
14 aberration, that now becomes real.
15 And that gets back to what some of you
16 were saying, that the question is how much
17 benefit, and I think those anterior interbody
18 fusion studies contained adequate male-female
19 differentiation to suggest that the effect size is
20 commensurate in perhaps the best controlled
21 surgical technique studies that we have. So I
22 think the answer is, we can find that information
23 from large, well done cohort information. We can
24 look at effect size analysis and see in the run-in
25 period, is there a difference in our patient

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1 population, and from that I think there is valid
2 information to be gained outside of RCTs that may
3 not represent the patient population that we are
4 treating.
5 DR. KRIST: For the panel, when we get
6 to our open discussion, I want to make sure that
7 we discuss RCTs versus this cohort data, and I
8 think that will be an important thing to think
9 about. But right now here before lunch, what I
10 want you to do is think about what information do
11 you need to have to inform you for that
12 conversation, so that's going to be very
13 important. Did you have a question?
14 DR. KIRKPATRICK: Thanks. First of
15 all, I would like to acknowledge my appreciation
16 for all of those that went to great time and
17 personal sacrifice to prepare your presentations.
18 There's also a number in the audience that I am
19 aware of that are missing out on the Cervical
20 Spine Research Society meeting which started
21 actually yesterday, and I don't know that our
22 panel members are fully aware of the professional
23 sacrifice that some people are making. In fact,
24 we have the past president of that organization in
25 the audience.

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1 The issue that I would like to refocus
2 all the presenters on, if they could for me, is
3 the fact that every one of us has talked about
4 this waste basket term of degenerative disc
5 disease; it has included scoliosis, degenerative

6 spondylolisthesis, has talked about back and leg
7 pain. My interpretation of the questions posed to
8 us are degenerative disc disease and low back
9 pain. In my mind I would like for each of you to
10 exclude all of those that have any portion of leg
11 pain, so that we're looking at the pure, quote,
12 degenerative disc disease low back pain patients,
13 and please revisit the question of whether in your
14 reviews you believe that there is any, some, or
15 good evidence to show that there is improvement.
16 Thank you.
17 DR. POLLY: That's how we initially, as
18 the societies looked at the question, and so when
19 we saw this tech assessment as it became public
20 domain, we thought that that expanded, perhaps
21 appropriately so, to look at additional evidence.
22 But our focus on trying to find exactly what you
23 were identifying, especially in the Medicare
24 population, is a challenge. And I think that the
25 anterior interbody fusion studies probably best

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1 represent that cohort, in that their entry
2 criteria were degenerative disc disease with back
3 pain predominant.
4 Now the issue of trying to remove any
5 leg pain becomes difficult, but it was clearly
6 back pain predominant patients, not radiculopathy
7 patients. So I think that is the best data set
8 that we have, and I think how we break out the
9 best information that we have if you're
10 specifically addressing the over 65 population,
11 about the small subset of those patients who were
12 included in those RCTs, and that it is a small
13 number, but in those patients, the benefit that we
14 saw clinically was on the order of 20 points on
15 the ODI, which is a substantial clinical benefit
16 by anybody's definition of it. So I think that is
17 the best information we have on the pure
18 discogenic disease extant with all the other
19 items. I don't know that we can do better than
20 that.
21 DR. KRIST: Yes, John.
22 DR. LURIE: (Inaudible, off
23 microphone.) There are two things from the
24 presentations that I have trouble reconciling in
25 my own mind and hopefully somebody can help me

00159

1 with it. We heard from Dr. Garfin that we don't
2 do fusions for herniated discs, that's not what
3 we're about. And yet from the Medicare claims
4 data, it looks like somebody does lots of fusions
5 for herniated discs. So if we're not doing them,
6 who is doing them?
7 And the related question has to do with
8 the number of speakers who said if we're going to

9 study this, you know, the European criteria are
10 too loose, we're much more selective about who we
11 operate on in this country, we make them fail a
12 lot of nonoperative treatment, we don't take them
13 as early, we're talking about a very small subset
14 of people here, and reconciling that with the much
15 higher rate of surgery, fusion surgery in this
16 country than in those other countries. So if
17 we're not doing surgery for disc herniations,
18 where are all -- you know, if we're not fusing
19 discs, where are all the fusions with disc
20 herniations coming from? And if we're so much
21 more selective about who we operate on in this
22 country, where does the rate of fusion in this
23 country come from.
24 DR. GARFIN: I certainly can't answer
25 for everybody that's a surgeon, and as you know

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1 from either vascular surgery or heart surgery, in
2 many cases techniques vary. We have, somebody
3 showed, I think it was Hal, all these codes that
4 we use, so somebody may code a protruding disc or
5 a disc degeneration, and somebody may code a disc
6 herniation as the same thing. There is no
7 consistency. Reoperations, reherniations,
8 particularly in L4-5, there's a 10 percent, at
9 least, reherniation rate after a discectomy. We
10 tend at L4-5 to fuse those to prevent instability
11 or a third herniation, we tend to go a little
12 longer than 5.1, so that may be some of it, what
13 are we coding.
14 And two is, there are some indications
15 to fuse in disc herniation, and I quoted from, I
16 think it was Turner, I don't know if it was the
17 same Turner that was on this panel, that was a
18 time past. But as Hal said, we're trained by our
19 environment. There are still many surgeons out
20 there who don't read everything or aren't paying
21 attention, haven't really in their practice
22 differentiated the results between laminectomy,
23 discectomy and fusion, when in many cases they may
24 not need the fusion. But the results are okay, so
25 they have continued to do that for the last 30

00161

1 years.
2 When we get back to the SPORT study,
3 there's really nothing new that Jim showed,
4 unfortunately. We've known that from these same
5 Scandinavian groups that we reported today, it's
6 just not new. It's just being reported in a
7 randomized controlled trial so all of a sudden it
8 becomes gospel because it's an RCT, not because
9 it's new, when other studies show the same thing.
10 I don't know if that answers your question, but it
11 goes to it.

12 DR. FLUM: How about the second part,
13 the second part about the variation in national
14 rates of spinal fusion, given what we're talking
15 about, how there's a higher surgical rate here?
16 Because I find it hard to reconcile with long
17 waiting lists in the European countries, hard to
18 imagine that there's a rush to do surgery without
19 preoperative, the same kind of preoperative
20 evaluations that we do here.
21 DR. GARFIN: I can't tell you what goes
22 on in Europe, I have some good friends there,
23 particularly in Scandinavia, and they, it does
24 take a while to see the patient, it does take a
25 while to get in. As the SPORT trial showed, and I

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1 don't mean to be coming back to that because not
2 everybody may be familiar with it, but there was a
3 huge crossover rate, and they also had a huge
4 out-of-office treatment that they couldn't handle.
5 So when we say nonoperative in Europe, it doesn't
6 mean people weren't taking over-the-counter
7 ibuprofen and going to their local massage
8 therapist, or they got some of this stuff because
9 they preached it on TV, and that's how you do it.
10 So they probably do have the same degree of
11 nonoperative stuff, but with all our physical
12 therapy that doesn't have any science behind it to
13 any degree, to all the injections we give people
14 preoperatively, does that add anything except
15 time? Are we doing any more other than waiting as
16 long as the Europeans are? The ODI would suggest
17 we hurt more, but we're conditioned to hurt more.
18 A lot of countries after surgery don't take any
19 medicine, they just don't give it to them. We
20 just feel like we have to, it's part of our fifth
21 vital sign, I hurt, we treat. And we tend to say
22 we hurt more than I think other countries say, in
23 individual patients.
24 Part of the fusion problem, and I had
25 some slides but I don't think I was able to get to

00163

1 them, so I'll just say it. In spine fusion we
2 have two codes, fuse with or fuse without
3 comorbidities, and that's it. And fusion includes
4 tumor, trauma, infection, spinal stenosis,
5 scoliosis, every diagnosis that we fuse is in that
6 one code or two codes. So when Hal gets up and
7 shows regional variation, or Jim Weinstein reports
8 it, theoretically you're saying there's the same
9 amount of tumors around the country, the same
10 amount of infections around the country, but that
11 may not be. Urban centers or non-urban centers,
12 or referral centers in the middle of Oregon may
13 get more tumors, may get more infections, and
14 therefore, fusion more, so it doesn't mean low

15 back pain fusions necessarily. We can't pull
16 those numbers out from your data, the Medicare
17 data. There probably is regional variation but
18 our numbers are hard to handle.
19 DR. BURCHIEL: Can I just ask you one
20 question before you step down? You touched on the
21 issue of discography, which might have escaped
22 some attention. We don't have a lot of tests.
23 And you said it was 70 percent reliable and I just
24 wanted to expand on that, because that is one of
25 the few things that at least some people believe

00164

1 in, as a measure of potentially what we call
2 discogenic pain.
3 DR. GARFIN: Discography, for those who
4 are unaware, is putting a needle in a disc with
5 the patient awake, giving them a sedative to take
6 the sting away, and inject a dye. Some people
7 report on discography as the volume of fluid
8 injected, small volume in results in a positive.
9 Some put dye in and get a CT after or a
10 fluoroscope to see if the dye is inside and they
11 call that positive. And others ask the patient,
12 is it pain, not is it the worst pain you've ever
13 had, but is it your pain. And not everybody asks
14 the question, I assume, the same way.
15 Dr. Weinstein, an author in the SPORT
16 trial, did a very innovative and creative study 15
17 years ago, where he videotaped patient's faces and
18 asked them to respond, and tried to correlate
19 their facial response with their pain response,
20 and it didn't always correlate.
21 Dr. Hershey, a researcher at Stanford,
22 has looked at a variety, done a variety of studies
23 on discography, and patients who hurt in general
24 report more pain with discography, the hurt is
25 neck pain. They do a lumbar discography and have

00165

1 no complaint, and then oh, yeah, that's my pain, I
2 have reproduced my pain. So we depend on
3 patient's response which is the only thing we
4 have, because we're operating on pain, we're not
5 operating on neurologic deficits, we're operating
6 on poor quality of life, so we are dependent on
7 their response. So I use discography to try to
8 correlate it with the MRI, correlate it with the
9 x-rays, correlate it with my gestalt of the
10 patient, because this isn't so much science in a
11 vacuum.
12 DR. BURCHIEL: Would you say your level
13 of confidence in discography would be
14 intermediate?
15 DR. GARFIN: Yes, but my level of
16 confidence in operating on back pain without
17 discography is about zero. I'd like to try

18 something besides looking at an x-ray in David,
19 who may have severe back pain, and you who have
20 no, you may be identical or yours may be worse.
21 So without just MRI or x-rays, you try to put
22 something of the patient into the study.
23 DR. JARVICK: Just to follow up on
24 that, (inaudible) psychological properties of the
25 patients were extremely important in identifying

00166

1 which patients would or would not have a positive
2 discogram, and following up on that, we talked a
3 lot about surgery versus conservative therapy, but
4 there is certainly no paucity of preventative
5 conservative therapy here. And one of the things
6 that's sort of striking about the randomized
7 trials is cognitive behavioral therapy seems to be
8 important in a positive result. I was just
9 wondering about the role that cognitive behavioral
10 therapy might play in a conservative therapy
11 regimen, which I don't think is routinely done in
12 this country, and have we really exhausted all the
13 possibilities for conservative therapy.
14 DR. GARFIN: I was going to say, we
15 don't do cognitive behavior therapy, it is very
16 time-intensive, three to four weeks of almost
17 psychoanalysis and learning and education, and
18 behavior work and exercise physiology. It's a
19 broad spectrum that we don't do or at least don't
20 do well here, probably because the people who do
21 that don't get paid for it very well for all the
22 time that theoretically is supposed to be put in.
23 DR. KRIST: Barbara?
24 DR. BOYAN: One last question for all
25 of you, or any of you. Every last one of you has

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1 stated clearly that there is not a lot of
2 information on the Medicaid population, Medicare
3 population, that can be used to, for the
4 discussion, all these trials have been done on a
5 lot of reasonably young, comparatively younger
6 people, but older people do have this, especially
7 women who have now also developed osteoporosis,
8 as well as other things as they age, and drugs
9 like phosphonates are taken to fuse the healing
10 process. If your goal is fusion in the surgery,
11 then you have to, fusion is bone formation, that's
12 what fusion is. Is there any information that you
13 have or that, or information that you feel that
14 you need to adequately treat this population?
15 DR. POLLY: Tim Kuklow has done a very
16 nicely designed study looking at the effects of
17 BMP in combination with those phosphonates. In an
18 animal model with phosphonate therapy, the healing
19 rate is significantly better. With the addition
20 of RHP and BMP-2, that is overcome and that's now

21 got some clinical experience beginning to build
22 behind it. So I think that's the best information
23 that we have to date looking specifically at the
24 modern therapy techniques. I don't think we have
25 any good data looking at forte or PTH in future

00168

1 mass, but for the phosphonates, we're beginning to
2 get emerging data that the RHP and BMP-2 is
3 seemingly involved with more common effects.
4 DR. FLUM: I have a follow-up for
5 Dr. Garfin. Dr. Garfin, this is the second time
6 you said you have very little faith in doing these
7 operations in the absence of a positive
8 discography. I wonder if you have a sense of how
9 often spine surgeons are using discography before
10 they do operations in the back and whether or not
11 your comments about the faith in the operation
12 working in the absence of it have implications for
13 that.

14 DR. GARFIN: Let me recover myself a
15 little bit. Number one is, I don't have an answer
16 to how many do it. I do know that some of the,
17 and again, you have to correct me if I'm wrong,
18 the clinical trials, FDA clinical trials for
19 artificial discs, some of them did not routinely
20 include discography. So what I said is me, and
21 certainly not a defined world view, so I can't
22 quite answer that, but most of the studies are
23 done without discography. The results are very
24 close. I mean, you can say there is a range from
25 60 to 80, and that gets you into the orthopedic 70

00169

1 percent range of, almost everything we do unless
2 we have a specific diagnosis is about 70 percent.
3 I do a lot of revision surgery, a lot
4 of things that have enough problems associated
5 with them that I don't like a 20 to 30 percent
6 failure rate given up front, this puts a certain
7 amount of bias into the patients, they have to be
8 willing to accept that failure rate. Others say,
9 well, wait a minute, 70 percent of the people are
10 going to get healthy, why not me. It may be with
11 selection that it may be 80 percent. Some people
12 may be clinically better than I am, maybe they can
13 examine a patient and say yes, that's the source
14 of your pain. I mean, we know chiropractors say
15 it's L4-5 or L3-4, C1-2, they seem to know exactly
16 where the pain is. I'm not that good of a
17 clinician, but maybe others can sort of localize
18 the pain to axial mechanical back pain. I'm just
19 looking for another piece of help that I can to
20 get 70 percent into the 80 percent range, if not
21 higher.

22 DR. KIRKPATRICK: If I could just add
23 to that, as a clinician who spent 14 years in

24 Alabama before moving to Florida, there was a
25 number of surgeons in that community that would

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1 not use discography, and their patients would end
2 up in the clinics with me or my partners seeing
3 failed backs.
4 We don't know what the best way to find
5 the painful disc is. At least those that are
6 doing discography are taking as much of a
7 scientific approach as our current technology
8 allows to identify those patients that they think
9 may benefit. Does that make sense?
10 DR. MIRZA: I think we had some data
11 that primarily dealt with, in the study of injured
12 workers, the highest reoperation rate was in the
13 diagnosis of degenerative disc disease, and among
14 those, the cognitive predicted an even higher
15 reoperation rate. So at least in the state of
16 Washington, these are not selective surgeon
17 practices, but they are, for the hundreds of
18 patients there, they are real patients and real
19 surgeons dealing with very complicated patients
20 such as workers' compensation patients for back
21 pain, discography did not improve disability
22 ratings and did not help reduce reoperations.
23 DR. ONDRA: Do you think the workers'
24 compensation pool is a valid pool of patients to
25 judge any treatment from? I just know from other

00171

1 studies, you could pretty much give them a magic
2 wand, and I'm not sure it would help those people.
3 DR. MIRZA: The numbers are what they
4 are.
5 DR. ONDRA: But is it an appropriate
6 population?
7 DR. MIRZA: Well, they are appropriate
8 for receiving the kinds of treatment. Somebody is
9 doing the operation on these various injured
10 workers that you might feel nothing is going to
11 help with, but at least they are getting fusions.
12 DR. FLUM: And then reoperation is 25
13 percent, something like that?
14 DR. MIRZA: Right. And the other point
15 about variation, we can be very particular about
16 our specific skills as surgeons and our diagnostic
17 criteria and selection criteria, but the fact is,
18 I think variability is real, and the studies that
19 we looked at do exclude some factors such as
20 scoliosis, but even more practical than that, we
21 now have a practice where there are 700 spine
22 surgeons, and that means a patient can see two or
23 three of us and get three different opinions. And
24 currently when they go across the street from the
25 university to a private hospital, they're going to

00172

1 get a fourth different opinion. So these are very
2 real patients with the same findings, same
3 symptoms, same gestalt, but they're getting
4 different opinions.

5 DR. ONDRA: But I still have a
6 question. Do you think that the selection
7 criteria are something we're trying to get at and
8 so forth, do you think we can get those answers in
9 a workers' compensation group of patients that
10 clearly have disease, but have so many other
11 social factors that have been well demonstrated
12 across the board, can we get any information valid
13 from them about selection criteria for a
14 procedure?

15 DR. MIRZA: I think the results only
16 apply to the population they're studying. I would
17 not extrapolate to noninjured workers or would not
18 extrapolate to a 65-year-old who is not working.
19 I think all of these randomized trials, it's
20 interesting that we debate about the subtleties of
21 preoperative or nonoperative treatment and all
22 that stuff, but the fact is, the results for
23 surgery in these trials were not dramatic. And
24 then with certain other types of treatment, and I
25 think it's worth exploring what exactly was the

00173

1 other case, and nothing that I mentioned did
2 anything other than what was published in those
3 papers, maybe they had a paragraph on nonoperative
4 treatment. And in the pain article from Brox this
5 year they do have a couple paragraphs more
6 detailed on nonoperative treatment.

7 I think it's worth exploring and I
8 think patients need to know that. I think both
9 the SPORT trials and the European trials tell us
10 that this at least is not a cash cow situation.
11 It's not something that's going to create horrible
12 outcomes unless you get surgery, and then with the
13 proper information, these patients can choose for
14 themselves. I think the most important thing out
15 of these trials is to quantify that the magnitude
16 of benefit is going to be very modest, and the
17 patient needs to expect that. If they have
18 unreasonable expectations, if they think they're
19 going to be off narcotics and going back to
20 playing better and more golf and tennis and stuff,
21 then you need to probably moderate some of their
22 expectations. And I think that's what the trials
23 at least tell me the most, is that the
24 expectations need to be realistic.

25 DR. KRIST: If it's a quick follow-up.

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1 Mark's been waiting to say something for a while.

2 DR. KIRKPATRICK: I'll defer then.

3 DR. FENDRICK: Even as we're winding
4 down, I feel that the level of the evidence for
5 benefit in these interventions starts to diminish
6 as the morning goes on. I think it's very
7 important for us to focus on the other part of
8 this, the risk/benefit that four of the presenters
9 mentioned and talked about individual patients.
10 Three is a tremendous paucity of information of
11 the safety of these procedures, at least presented
12 to this point.
13 I remember seeing in the MRC trial that
14 10 percent of the surgical patients, 19 out of
15 about 180, had reportable surgical adverse
16 complications. And since Doug, you did mention
17 that, as did the last gentleman, if there is a
18 benefit to me that's modest, we really have to
19 focus, as we have in so many of these
20 interventions over the years, on safety.
21 And I would like Doug to start, and I
22 can't imagine, although no surgeon in this room
23 has ever had a complication, I imagine in
24 Washington and other states that there are people
25 being harmed from this operation either, probably

00175

1 not systematically, but we all know that surgery
2 does have risks. And interestingly, the
3 nonsurgical therapies, we don't know if there is a
4 risk and there's never been reported a risk, but I
5 imagine that physical therapy might see a risk
6 now, and it's probably less than surgery, I would
7 imagine.
8 DR. MCCRORY: Right. The adverse
9 reporting in general is highly variable. We found
10 the single best study for reporting was the FDA
11 reporting in connection with the arthroplasty
12 devices where they had the most complete reporting
13 in terms of the catastrophic events, so a lot of
14 what we described in the report was based on that
15 study.
16 The comparison rates we had for the
17 other procedures were basically reports which we
18 felt were much less reliable in terms of how these
19 results were ascertained and which adverse events
20 were looked at. The adverse events in general
21 were sort of high, a little uncertain. The
22 duration of the various events were difficult to
23 judge. Like one of the other presenters noted,
24 many of the adverse events that occurred were
25 perioperative and short lived, and don't affect

00176

1 the long-term outcome, and that certainly appeared
2 to be true from my analysis.
3 Even though we looked at some of the
4 neurologic complications, sexual dysfunction and
5 some of the other effects that might be prolonged,

6 we did see that many of those in fact improved
7 over time. There wasn't much data in that
8 intermediate period after the perioperative period
9 to the six-month to one-year data about what
10 happened to people, it's very infrequently
11 described. So it is interesting, but not enough
12 of that data exists.
13 DR. FENDRICK: And is this always done
14 under general anesthesia, so we get the typical
15 effects of anesthesia as well from the operation?
16 DR. MCCRORY: That's my assumption,
17 yes.
18 DR. FLUM: Dr. Mirza, can you comment
19 any more about perioperative events, there are
20 those who are bleeding, there are those who are
21 discharged to, or not being discharged to home
22 after discharge, and specifically in the
23 population over 65.
24 DR. MIRZA: When we looked at this and
25 chose that population for that particular reason,

00177

1 because we think that's a more reliable end point
2 than some of these other things, I think it was
3 very hard to classify or actually report
4 complications. I think for a surgeon it's
5 difficult to deal with complication and yet, we do
6 focus on it a lot, we have morbidity and mortality
7 conferences and we all change practices, so
8 I think it's very important information, but I
9 don't think they are terribly reliable for that.
10 The workers' comp group that we looked
11 at, it had better information and we could
12 actually do chart review in the post-op, but
13 that's not routinely done across Medicare
14 patients.
15 DR. FLUM: How about the
16 instrumentation data in patients over 65?
17 DR. MIRZA: The data that we have is
18 from day one, that's prior to all instrumented
19 fusions, certainly prior to any fusions done for
20 degenerative scoliosis. So I think that's
21 something we're looking at, but again, it's hard
22 to get recent data on that. Mortality is not
23 something many patients think about. I mean, we
24 do talk to them and often they're so overwhelmed
25 by their pain that they are not paying attention

00178

1 to that side of things. But I think it's not
2 trivial over 70, certainly over 80, though I don't
3 have any particular data yet.
4 DR. FACISZEWSKI: As a follow-up to one
5 of Dave's questions, the question about patients
6 who were getting fusions for lumbar disc
7 herniation, how confident are you that based upon
8 the interesting data that you've presented, that

9 those patients that are having fusions for that
10 diagnosis are actually having fusions for the
11 specific ICD code? In other words, the
12 granularity of that ICD code is well known.
13 DR. MIRZA: I think there are
14 limitations, and there is no way around
15 limitations of coding errors and administrative
16 data, but it's the one population in which it is
17 seen, even if -- and it's a very small fraction of
18 fusion patients that have the sole diagnosis of
19 disc herniation. We looked at things by
20 diagnostic scheme so that if somebody had
21 degenerative disc disease as a primary code but no
22 other code in addition, but somewhere in their
23 hospital records a code for disc herniation, we
24 would step them up to that, and with
25 spondylolisthesis and spondylostenosis you'll see

00179

1 the same thing. So the primary diagnosis goes
2 through a hierarchical coding scheme.
3 And I think even though we don't
4 typically do them just for disc herniations, I
5 think, as Dr. Garfin mentioned, probably are
6 diagnoses. When you see disc herniations,
7 particularly third and fourth time with herniation
8 at the same level, the patient's got tremendous
9 back pain in addition to that, the patient's got a
10 lot of collapse at that disc level, in addition to
11 disc herniation. I think I've seen actually among
12 our group and in our community, patients get
13 surgery for that.
14 DR. FACISZEWSKI: Focusing on the
15 question that Dr. Kirkpatrick had about
16 degenerative disc disease, from an incidence
17 perspective, would you agree with what the
18 presenters have said regarding the impact on the
19 Medicare population of the diagnosis of DDD and
20 fusion?
21 DR. MIRZA: Could you summarize what
22 you're referring to?
23 DR. FACISZEWSKI: Well, in other words,
24 do you think it's a huge number of patients that
25 have DDD as defined by Dr. Kirkpatrick? In other

00180

1 words, have all the massive increase in fusion
2 rates, is that a big component we're talking about
3 today, or is that a really small component?
4 DR. MIRZA: That's a smaller component.
5 I think most of the increase in the fusion in the
6 Medicare population is related to spinal stenosis,
7 not necessarily degenerative disease.
8 DR. KRIST: At this time we're going to
9 go ahead and break for lunch. When we come back,
10 we'll finish up with our questions for our
11 presenters and then we'll have a panel discussion.

12 (Luncheon recess.)
13 DR. KRIST: I know a couple of folks
14 have flights to catch and what not, so it would
15 behoove us to make some progress on our
16 discussion. When we stopped at lunch, folks were
17 still asking some clarifying questions of the
18 presenters, and what I was thinking we would try
19 to do is maybe for another 15 to 20 minutes, try
20 to finish up with clarifying questions for the
21 presenters, and then we can focus more on the
22 discussion centered around these questions. So,
23 I'll open it up to any panel member who wants.
24 DR. BOSWELL: Is Dr. Mirza back? Thank
25 you very much for your presentation this morning.

00181

1 In conclusion, I think you mentioned that
2 regarding spinal fusion and degenerative disc
3 disease, the benefit based on randomized
4 controlled trials is small to none, but it does
5 seem to be detectable. In terms of a randomized
6 controlled trial, do you think that that equates
7 to value, not in terms of the degree of value, but
8 in terms of a yes or no, there is evidence for the
9 value of fusion for DDD?
10 DR. MIRZA: I think the answer is yes.
11 Almost all the studies show the right direction,
12 improvement.
13 DR. BOSWELL: Now in terms of specific
14 diagnoses, I think you also mentioned that the
15 outcomes are more driven by the procedure that's
16 done and looking at the outcome, rather than
17 looking at the cohort of patients with a specific
18 diagnosis. Maybe that wasn't you who said that,
19 but I think spondylolisthesis, for example, was
20 mentioned.
21 DR. MIRZA: Yes, I think there are
22 several trials that have more consistently with
23 degenerative disc disease shown large benefits
24 with fusion and with instrumented fusion.
25 DR. BOSWELL: Right. And then finally,

00182

1 one of the other presenters did mention, or one of
2 the other presentations did point out that
3 spondylolisthesis may be a good surrogate in the
4 Medicare patient population for the benefit of
5 fusion. Do you think that that's a reasonable
6 assumption?
7 DR. MIRZA: I do. We try to, or tend
8 to lump these things as degenerative disc disease,
9 but older patients are more likely to have
10 spondylolisthesis or stenosis, and less likely to
11 have just simple disc disease.
12 DR. BOSWELL: Thank you.
13 DR. KRIST: Kim.
14 DR. BURCHIEL: I have a question for

15 you. So, with reference to Mark's question of
16 benefit, let's go down there, what's the benefit,
17 what do you mean, ODI, VAS? It's certainly not
18 return to work, I think if we go straight across,
19 there's no definitive difference between the
20 procedures. So we're going to eventually get to
21 this issue of what are the appropriate criteria
22 that we should be looking for, so what is your
23 take on the appropriate criteria for, let's say
24 future studies?
25 DR. MIRZA: I think it's very important

00183

1 for the surgeons to report the results of their
2 Oswestry scores, and I think it's practically
3 impossible for patients to understand what an
4 8-point or 10-point or 15-point difference is
5 going to mean, but I think one of the most
6 important things that could come out of a panel
7 like this is to have more clear definitions of
8 what is successful outcome, and I think it would
9 have to be, in my mind, something of a composite
10 nature, like the artificial disc, where you have
11 some component of improvement and function,
12 probably some measure of pain medication, because
13 again, we are recommending treatment for something
14 that is primarily pain, and maybe some component
15 of safety. The artificial disc studies set
16 thresholds, I think, of 15 points on the Oswestry
17 scale, or 25 percent improvement, plus no major
18 medical complications. But beyond that, I think
19 maybe pain medications should also be a
20 consideration. But I'm not sure what we have
21 currently in terms of, as the randomized trials do
22 not -- where they give on average changes across
23 groups, I really don't think they're as easy to
24 interpret.
25 DR. BURCHIEL: Maybe this is a question

00184

1 we should ask generally, valid measures for future
2 studies, but my impression is that taking the menu
3 approach is a difficult thing to do statistically,
4 and (inaudible) but in other words, taking one
5 column, column B, is that ever going to give you a
6 primary outcome measure that's going to be looked
7 at, use of narcotics, VAS improvement of 20, ODI
8 improvement of 15, and going down to check point
9 Z. I guess I'd throw that to the panel, because I
10 think this is not going to give you a measure
11 that's very reliable, even though it may be more
12 real world.
13 DR. MIRZA: Well, I think you could
14 calculate a percentage and you could come up with
15 an aggregate percentage saying, you know, 40
16 percent achieved a 30 percent reduction in pain.
17 And then if you add physical function improvement,

18 maybe you went down to 35 percent or 30 percent.
19 If you added no narcotic use, maybe the percentage
20 would drop even further. If you added return to
21 work, it would probably go to zero. But I think
22 those are the numbers that the patients would find
23 it easier to understand. This is the pattern on
24 aggregate with this surgery, this is the
25 probability we will achieve this result.

00185

1 DR. BURCHIEL: The problem with that,
2 taking it to the extreme, if you look at patient
3 satisfaction, it's probably one of the most
4 invalid things to look at, what that means in
5 terms of a real outcome. So I guess I, if we went
6 down the road, let's assume for a minute that a
7 randomized controlled trial, that's what we're
8 going to have to have done, showing us outcome
9 measures or, you know, a primary outcome measure,
10 and the primary outcome measure has to be
11 determined. And I just don't know that it could
12 be a mixture, a blend of things, but does anybody
13 have any comments about that.

14 DR. FLUM: Dr. Mirza, I want to
15 clarify. Your point about the ODI not being an
16 adequate measure is that it's hard for patients to
17 interpret and hard for doctors to explain or
18 interpret?

19 DR. MIRZA: Yes.

20 DR. FLUM: That's irrelevant. I mean,
21 it's a validated metric that has good testing
22 principles, good internal validity. If you ask a
23 patient are you feeling better than you were
24 before, that means a million things to different
25 patients, it sounds like what we think it means,

00186

1 but it means different things to different people.
2 That's why a metric that attempts to measure
3 disease-specific quality of life is very
4 meaningful as a measure of functional status that
5 has been well validated, and I'm not sure I
6 understand your problem with the ODI.

7 DR. MIRZA: I didn't mean to take
8 anything away from a validated disease-specific
9 measure, and it's very useful, in fact. But when
10 you're trying to judge whether a treatment is
11 successful or not, I think it would be hard to use
12 the ODI change. I think all these randomized
13 trials show somewhere in the range of 10 to 14
14 points, or 10 to 13 points improvement. I'm not
15 sure I can really convey that to a patient as a
16 reasonable expectation. I think the greater the
17 magnitude, you know, if you say a 10-point change
18 in the ODI leads to this much greater
19 satisfaction, I mean, there are some studies that
20 tried to look at what is a clinically important

21 difference, and actually maybe Dr. Glassman can
22 comment in that area, but I think we need a
23 simpler measure of success, so when a patient
24 comes in and is trying to sort out whether to
25 continue nonsurgical treatment or choose surgery,

00187

1 we need to be able to convey to them what their
2 probability is, and if they're not sure of that,
3 then they couldn't make a consent.
4 DR. KRIST: I see kind of two issues on
5 the table. I mean, one is for this panel or
6 Medicare or some other organization to decide if
7 an intervention improves outcomes, and I think a
8 validated instrument is a good way to do that.
9 Another is what a doctor would say to a patient,
10 and that's a whole different set of things, and I
11 think it will be important for us when we kind of
12 do our discussions to talk about what should the
13 outcomes of this ideal study be, when we do that
14 for Question Number 3. So, Kim, you had a
15 question?
16 MS. KUEBLER: Yeah, I wanted to follow
17 up with Dr. Boyan's comments earlier about
18 comorbidities. We know patients with chronic pain
19 also have depression, and unfortunately, we also
20 know very well that depression and pain also
21 contribute to poor function. So I mean, are those
22 considered, is depression even considered in any
23 of these follow-up trials?
24 DR. MIRZA: The European trial
25 certainly measured depression. The results

00188

1 haven't really shown what the effect was but it,
2 they said it was not different for the treatment.
3 But from other literature, it's clear that
4 depression or other psychological comorbidities
5 have a profound effect, probably more so than any
6 imaging findings, probably more so than the
7 diagnostic pattern.
8 MS. KUEBLER: Thank you.
9 DR. KRIST: I would like to hear from
10 some of the investigators of studies about their
11 experiences in trying to enroll patients in RCTs,
12 because we heard earlier that an RCT might not
13 work in the United States. And some have done,
14 and I would find it helpful to hear about
15 experiences in doing this.
16 DR. GARFIN: Dr. Albert, who talked
17 before, is he still here?
18 DR. ONDRA: Don't be shy.
19 SPEAKER: The SPORT study is the
20 enrollment problem that you're looking for, where
21 patients, you know, were having to -- hadn't had a
22 lot of conservative treatment anywhere, and the
23 doctor's decision to assign to the conservative

24 versus the surgical arm is a difficult decision to
25 struggle with in those patients. In our fusion

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1 patients, they've had all conservative treatment
2 and I think that enrollment is going to be
3 difficult.
4 We've done a number of randomized
5 studies that are not conservative, or not versus
6 conservative treatment. I've done the BMP studies
7 and we've done an INFUSE versus bone graft study
8 that we randomize people to things where you're
9 telling them, you know, I think these things are
10 exactly the same and you haven't had either of
11 them, I think the challenge is randomizing someone
12 that has had their PT and their medication and
13 their blocks, and to say you can do that again or
14 you can have surgery is going to be a real
15 challenge.
16 I do have a suggestion, I don't know if
17 you'd like it or not, of a place I think you could
18 randomize. And that is, we see a lot of patients
19 clinically who have had therapy and who have had
20 medication, but who have not had injections. And
21 for the older patients with stenosis, that is a
22 viable treatment that, you know, we generally try
23 before we send people on to say now you ought to
24 have surgery. And I think you could find a
25 substantial cohort of patients who have had a

00190

1 fairly long period of therapy and medicine, but
2 have not had blocks, because those patients come
3 to surgeons at that stage. And you could
4 randomize them to you're going to go on and have
5 blocks, because only people who have pathology
6 that is clearly surgical pathology, you know,
7 probably just spondylolisthesis and stenosis, but
8 you could randomize them to either now you're
9 going to have blocks or you're going to have
10 surgery, because those are both viable options
11 that people would be recommending. And then if
12 they cross over, they have their blocks and failed
13 and crossed over into surgery, that would be a
14 failure of the blocks. If they did well with
15 blocks and didn't have to go on to surgery, that
16 would be patients starting at a reasonable
17 centrist position with a nonsurgical or
18 medisurgical. And I'm sure you could find faults
19 with that, you know, setup, but at least it is an
20 effort to randomize people in a way that I think
21 would fit into how we practice patient care.
22 DR. FLUM: I have a quick follow-up.
23 In the SPORT trial, it really wasn't a nonsurgical
24 arm that they were randomized to. They either got
25 operation or whatever, whatever the docs want,

00191

1 usual care. And as we saw, I think in one of the
2 earlier randomized trials, just continuing what's
3 failed obviously is not going to give the patient,
4 it's not a beneficial intervention. And I wonder,
5 as a spine surgeon, whether or not a nonsurgical
6 intervention, truly intervention, we talked about
7 cognitive behavioral therapy or any of the things
8 that have been studied in Europe might be worth
9 trying here.

10 SPEAKER: I want to take exception of
11 the description of efficacious. The trials that
12 we looked at, you know, Fairbank and Brox, those
13 patients had 75 hours of structured therapy, far
14 more than you would ever approve or pay for here.
15 And they ended up with an ODI improvement of 3 to
16 13 points. I mean, that's a lot of input for not
17 a lot of benefit, you know. And I think it would
18 be important to have structure in the conservative
19 treatment in anything that we formulate. I agree
20 with you completely about that.

21 DR. FLUM: The cost of the nonsurgical
22 intervention is relative to the cost of the
23 surgical intervention, so just because we don't
24 have it yet, is there a possibility for a
25 nonsurgical intervention that is something other

00192

1 than what we seem to be doing? You said something
2 about injections, and I wondered if that 75-hour
3 approach might be something that would work in the
4 United States.

5 SPEAKER: I think the patients that we
6 see in the Medicare population who are typically
7 coming to us because they say I can't walk through
8 the grocery store, if you tell them, I know you've
9 done therapy before, I know you had medicine
10 before, I know you had injections before, but now
11 we're going to do a cognitive therapy and more
12 intensive physical therapy, I think you're going
13 to have trouble holding people in that arm, and I
14 think you're going to have the same problem you
15 saw in SPORT with a crossover in one direction,
16 you know, people in a much greater magnitude saw
17 it in the SPORT study.

18 DR. JARVICK: But what if you were
19 going to combine the injection with the new
20 therapy?

21 SPEAKER: I think that would be
22 reasonable. I think if you're giving them
23 something new, the injections they haven't had
24 before, you could entice them into a program that
25 you could do as something else along with that. I

00193

1 think that after the surgery, in the surgical arms
2 of those studies, people got no rehab. I think

3 they would do better if you did concentrated rehab
4 postoperatively, and people should have that. But
5 I think if it's something that you could sell them
6 on, that I'm having a new treatment, and the
7 injections might be an option, and you could add
8 the therapy as well, if they accept that
9 potentially.

10 DR. GARFIN: Could I make a comment? I
11 wasn't involved in this RCT but I was involved in
12 another one on kyphoplasty years ago, that really
13 was almost experimental at the time. We didn't
14 have (inaudible), nor did we have any data about
15 the nonoperative arm. I mean, there were very few
16 people back in '96 or '97 who were using Fosamax
17 or Actonel, and kyphoplasty was brand new. So we
18 identified 25 centers just to do kyphoplasty, set
19 up a program, randomized it to the nonoperative
20 arm or failed therapy in time, or kyphoplasty.
21 After two years, we had less than 30 patients
22 enrolled because they could go across the street
23 and get vertebroplasty, which didn't require state
24 approval or anything else. So this is going to be
25 roughly the same thing.

00194

1 My concern about developing a study of
2 fusion for low back pain, if that is still what
3 we're talking about, unless we're talking about
4 spinal stenosis now, but we're still talking about
5 back pain, why should they enroll in the
6 nonoperative arm when they can go across the
7 street to get the operation if they feel they need
8 the operation. It's not even a tool or device or
9 a hook to bring them in on. We had that hook and
10 we still couldn't get them in. Back pain is a
11 different beast. People don't like it.

12 DR. JARVICK: I too would just comment
13 about vertebroplasty and kyphoplasty because I am
14 currently involved in an ongoing randomized trial
15 of vertebroplasty versus a controlled
16 intervention, and this was not an industry-
17 sponsored trial, not a sponsored trial, where we
18 were experiencing a certain amount of futility
19 early on in enrolling patients, and there was an
20 article in the New York Times about we had only
21 gotten three patients into this trial after
22 several years of trying.

23 Well, up through the last year, we're
24 actually now close to 60 subjects who have been
25 randomized, partly in this country, but most of

00195

1 the subjects have come from the U.K. and from
2 Australia, and I think that there is a tremendous
3 cultural difference between this country and other
4 countries as far as the attitude of both patients
5 and physicians as far as the willingness to

6 randomize and to give up their freedom of choice
7 about their treatment. And whether you think of
8 people as altruistic or whatever, that difference
9 is real.
10 And it's not to say that it's not
11 insurmountable, and somebody referred to the
12 principle of uncertainty, some also call it
13 equipoise, because they really have to believe,
14 the surgeons, the treating physicians and patients
15 have to believe in their heart of hearts that they
16 don't know the answer to this question. And we
17 are able to randomize patients at Mayo as one of
18 the sites, with an equal rate of any other sites
19 in the U.S., but that's only 20 percent of
20 eligible patients being enrolled in the studies.
21 In the U.K., 80 percent of eligible subjects are
22 typically enrolled in the studies. So there are
23 real hurdles, real differences, but they are not
24 insurmountable, I would say, in this country if
25 the study is designed right and there is the right

00196

1 hook.
2 DR. KRIST: I was just reminded, if you
3 come up to the microphone, just state your name
4 again for transcription.
5 DR. RESNICK: My name is Dan Resnick,
6 from the University of Wisconsin, and my
7 disclosures are that I participated in the
8 cervical disc trial with Medtronic and we had no
9 problem whatever getting people to sign up for
10 that, because they all thought it was the best
11 thing to do, people were eager to have that, and
12 they were disappointed if they weren't placed in
13 the group that actually got the prosthetic device.
14 I wanted to mention a couple
15 methodological concerns regarding the Fairbank and
16 Brox studies which may help to elucidate some of
17 the problems that we have in the United States in
18 terms of getting these studies done. In the Brox
19 studies, patients all had x-rays and back pain,
20 and had not had any sort of conservative care at
21 the time of entrance into the study and prior to
22 randomization.
23 They were entered into the study
24 because they were given the promise that if they
25 were randomized to surgery, they would have the

00197

1 surgery within three months. Otherwise, they had
2 to wait 12 to 18 months to have their surgery
3 through the regular channels. In the United
4 States, people aren't going to wait 12 to 18
5 months to have the procedure done when it's been
6 determined they're a candidate for that procedure.
7 So their goal was the ability to get people into
8 treatment sooner than they otherwise would have

9 been treated.
10 In the Fairbank study, similarly,
11 patients had had no pre-randomization therapy, and
12 the only patients included were those in which the
13 surgeons weren't sure that these patients were
14 going to get better with surgery or not, so those
15 were the only patients who were entered. Despite
16 that, despite the fact that they had an intention
17 to treat analysis with almost a 30 percent
18 crossover away from conservative therapy to the
19 surgery group, they still had statistically
20 significant improvement with surgery compared to
21 the nonsurgical group in terms of the back and leg
22 pain.
23 The other thing that I wanted to
24 mention, all these studies are done looking at
25 patients who presented to have surgery for low

00198

1 back pain. These are the type of patients who
2 many would get a discography on, but these are not
3 the patients that are the Medicare population. I
4 can't remember ever doing a discogram on a patient
5 with spondylolisthesis, it is just not part of the
6 equation. (Inaudible) anterior post, and I've
7 seen it in patients who have other problems and
8 are having fusion as an adjunct to their treatment
9 of other problems, and as part of salvage
10 procedures on people who have already been through
11 the whole gamut of (inaudible).
12 On the cognitive therapy part of it,
13 the European studies did a pretty good job in
14 addressing depression, and it turns out that both
15 cognitive counseling and surgery both had an
16 almost identical effect on the depression scores,
17 except for avoidance behavior, that was the only
18 statistically significant difference from the Brox
19 studies. But that's part of the patient
20 selection, and we don't stop doing physical
21 therapy once we operate upon them, the physical
22 therapy continues, that's part of the ongoing care
23 of these patients.
24 DR. FLUM: In the early 1990s, thoracic
25 surgeons felt very strongly that lung volume

00199

1 reduction surgery was very effective in dealing
2 with COPD, and at several centers it was being
3 done often with varying mortality rates. Medicare
4 made a decision to only cover that procedure in
5 the context of the clinical trial, randomizing
6 patients to surgery or pulmonary rehabilitation.
7 Obviously that trial had no problem generating
8 patients because for patients it was the only way
9 to get the operation performed. Do you think
10 there's enough equipoise based on these four
11 randomized studies that we've seen here to show

12 really no significant dominant clinical effect of
13 fusion surgery or one that shows a more dominant
14 effect?
15 DR. RESNICK: I think if we were
16 studying a 40-year-old patient with low back pain
17 and an abnormal x-ray, we could make that
18 assumption.
19 DR. FLUM: And less so on a 65-year-old
20 because you said none of them had to do it?
21 DR. RESNICK: Well, no, because we had
22 significant evidence that decompression, that
23 patients with back pain in the Medicare population
24 are a subsection of the one percent that we saw.
25 The vast majority of fusions that are performed in

00200

1 the Medicare population are performed as an
2 adjunct to another procedure or a stabilization
3 procedure because of something that happened
4 before, or neurologic deficit.
5 In the case of a sham surgery
6 procedure, I think there are also ethical
7 considerations when you consider that all
8 surgeries are completely elective. If someone has
9 end stage COPD, that is a very important thing
10 that you need to know and that is probably worth
11 knocking some people off to find out what that
12 answer is. We're not saving lives here. We're
13 just getting rid of back pain and leg pain.
14 DR. FLUM: The thinking (inaudible)
15 same, almost the exact same model where there is a
16 condition, a quality of life improvement is the
17 goal, and there's a surgical and nonsurgical
18 approach.
19 DR. KRIST: I can sense we're shifting
20 our conversation from questions to the presenters
21 to our panel discussions, so I want to see, do
22 folks have further clarification questions for
23 presenters?
24 DR. KIRKPATRICK: I have a very quick
25 clarification that I want to point out happened

00201

1 here just now, okay? The questions that we're
2 reviewing are based upon spinal fusion for the
3 treatment of low back pain secondary to
4 degenerative disc disease. In my mind as a spine
5 surgeon, we have excluded spinal stenosis, we have
6 excluded spondylolisthesis, okay? So we don't get
7 that confused anymore, let's make sure that we're
8 talking about that fraction of a percent that he
9 said was in the Medicare population. So it's a
10 small percentage of the overall degenerative disc
11 disease population we might be doing a fusion on.
12 DR. RESNICK: It is a small percentage.
13 DR. KRIST: Regardless of the
14 percentage size, that's the focus of what our

15 deliberations will be on, so that's the condition
16 we will be talking about, low back pain, and not
17 spondylolisthesis and spinal stenosis and those
18 issues.
19 DR. PHURROUGH: Just to clarify too,
20 the purpose of this meeting is to provide
21 information to the community and not to the people
22 who come to the meeting. Because in general,
23 those of you who are here are appropriately
24 selecting patients who need the procedures that
25 you do. That's not necessarily the case for the

00202

1 broad Medicare population where the people with
2 low back pain who are getting spinal fusion aren't
3 necessarily a small percentage in the broad
4 Medicare population.
5 DR. RESNICK: I would disagree. I
6 mean, the data shows it is an isolated fraction,
7 it is a very small proportion of the Medicare
8 population.
9 DR. PHURROUGH: I think we would differ
10 on what we define as a small isolated fraction.
11 DR. FACISZEWSKI: Maybe we could have
12 some clarification. I asked the question about it
13 before, and I believe that statement is based upon
14 the administrative database, I would assume. And
15 my question, and maybe you can readdress it, how
16 confident are you in that administrative database
17 as it relates to either a very specific group of
18 patients or even any individual patient? Based on
19 the administrative database, it shows the
20 prevalence or, in this case the incidence of
21 surgery and the reason it's performed in the
22 Medicare population.
23 DR. MIRZA: The data I presented
24 relating to fusion have to do with State of
25 Washington operations, not Medicare databases. So

00203

1 this is administrative data on hospital discharges
2 from community hospitals and academic hospitals in
3 the State of Washington. And in those categories,
4 certain things stand out that the rates have gone
5 tremendously, have increased very significantly in
6 the degenerative disc disease indications and they
7 have also increased in older patients. In the
8 older patients, it is mostly spinal stenosis, and
9 in the younger patients, degenerative disc
10 disease.
11 DR. FACISZEWSKI: So to answer the
12 question which I think was queried, it is in fact
13 true or not true that you believe that the reason
14 or that the source of the increase in patients
15 being operated on in the Medicare population is
16 because of back pain and degenerative disease,
17 would you agree with that statement?

18 DR. MIRZA: I don't know what to say
19 about the Medicare population, I'm not sure.
20 DR. KIRKPATRICK: I'd just like to
21 clarify this issue for the panel, because it may
22 not be clear what we end up doing as surgeons.
23 When we have an admission of a patient with, say,
24 degenerative scoliosis, and they have
25 radiculopathy or claudication, they're going to

00204

1 have on their coding sheet on the hospital records
2 an ICD-9 for degenerative disc disease, for
3 scoliosis, for neuroclaudication, and if it's seen
4 in the leg, radiculopathy. So they have all four
5 of those that feed into his database. So the
6 problem for those patients, he can't tell us
7 which, if we're going to throw out one of those
8 affecting low back pain, he can't tell us what
9 proportion of those were isolated degenerative
10 disc disease and what proportion were combined
11 with other diagnoses; is that correct?
12 DR. MIRZA: That is correct, there is
13 no way to make any statement about symptoms from
14 our database.
15 DR. FLUM: But in the absence of the
16 radiculopathy or in the absence of the sciatica
17 and the other codes you just described.
18 DR. MIRZA: I mean, I don't know how
19 people code, or exactly what the subtleties are
20 with various codes, but in general, for spinal
21 stenosis, there are about an equal number of
22 patients that are getting decompression as well as
23 decompression plus fusion, and I'm not sure how
24 that decision is being made. Now it could be that
25 the surgical procedure is so extensive that a

00205

1 fusion is deemed necessary to maintain alignment
2 of the spine or improve alignment of the spine, it
3 could be that some of those patients have low back
4 pain and other patients appear with claudication.
5 But patients with the same diagnosis are getting
6 both treatments, fusion or decompression without
7 fusion, and we can't tell that from the
8 administrative data.
9 DR. KRIST: And one helpful thing for
10 the panel, I mean, our purpose is to discuss the
11 state of the evidence. And so, you know, as part
12 of our discussions we can bring up, for these
13 indications we believe the evidence is good, and
14 for these indications we have issues with it. So
15 that will be something to bring up in our
16 discussions as we're talking about this. And as
17 we go through and we vote on these topics, we
18 should talk about the indications, I think a
19 discussion point is which patient criteria or
20 which patients benefit best from these. But when

21 focusing on the numerical voting, we should narrow
22 it down and make sure that we're all considering
23 the same topic as we have been discussing here.
24 So, yes, Jon.
25 DR. LURIE: I just want to make sure we

00206

1 have some clarity on how the European randomized
2 trials are being represented. So, I have heard, a
3 couple people have said that the European trials
4 involved people very, very early in the disease,
5 and two, that they had no nonoperative treatment.
6 And I want to know whether anybody actually knows
7 that those things are true or whether they're just
8 an impression, because the fact is that the trial
9 did not record in their manuscript all the details
10 of the nonoperative treatment that people
11 received, and in the Brox and Fairbank studies,
12 these people had to have symptoms for a minimum of
13 a year, or two years to be eligible, so they
14 weren't early. They may not have gotten extensive
15 nonoperative treatment, but I think the answer is
16 we don't know what nonoperative treatment they
17 got. I mean, I know the Europeans are hardy folks
18 and not quite as demanding as Americans, but it's
19 hard for me to believe that they had two years of
20 back pain with no nonoperative treatment. I think
21 that is a stretch.
22 DR. RESNICK: All I can report is
23 what's in the papers. I happen to have the papers
24 here, I would be happy to share.
25 DR. LURIE: That's the problem, they

00207

1 didn't list the criteria.
2 DR. RESNICK: Symptomatic for two years
3 and required having failed preoperative physical
4 therapy. That's in the papers.
5 DR. LURIE: That doesn't mean they
6 didn't have it, that means that they --
7 DR. RESNICK: I'm not arguing that
8 point. Another significant point from the papers,
9 they were primarily based upon plain films,
10 as well as the presence of disabling pain for a
11 year. That's what it says in the papers.
12 DR. LURIE: But I just want to make
13 clear that that doesn't mean that they had
14 nonoperative treatment before they entered. We
15 don't know.
16 DR. RESNICK: It wasn't required by the
17 study.
18 DR. FACISZEWSKI: I have one final
19 question. Are there any social differences
20 between Europe, particularly the Scandinavian
21 countries, and the United States that made RCTs
22 easier and/or patient selection different than we
23 may have here in the United States?

24 DR. POLLY: I would like to comment
25 from my perspective of having been in sort of a

00208

1 captured health care system previously and now
2 being in a different health care system. When I
3 was part of the Department of Defense and the
4 patient beneficiaries had a defined access, oral
5 pathway to health care, we were able to do a
6 series of randomized trials that were generally
7 intervention trials, randomizing intervention A
8 versus intervention B, but the patients were
9 generally accepting of that. Also, I had
10 incredibly long wait times for surgery, at one
11 point nearly one year, and my total joint column
12 at one point got to two-and-a-half years for joint
13 replacement surgery once the diagnosis was made.
14 And in some of those patients who were waiting
15 two-and-a-half years for a hip replacement, they'd
16 have GI bleeds, so I think there is morbidity from
17 nonoperative treatment.
18 But in that health care system, a
19 mechanism to increase access appeared to alter
20 patient behavior would be my interpretation, as
21 opposed to my current system where if they can't
22 get an appointment next week, they're very upset
23 about that and want to know why. So I think that
24 is representative of a different sense of
25 entitlement or sense of affiliation with the

00209

1 health care system that may lead to a difference
2 in behavior, so I think there is something to
3 that. Trying to quantify that becomes very
4 difficult.
5 And I would just share a final point.
6 We attempted to develop a study comparing
7 operative versus nonoperative treatment in Canada
8 for exactly this diagnosis, not the over 65
9 population, but just for degenerative disc
10 disease. We spent about a year trying to put this
11 together in conjunction with the Canadian Spine
12 Society and we ran into a couple significant
13 problems.
14 We had a very nicely outlined
15 nonoperative regimen administered by the Hayes
16 Back Institute, which did an aggressive
17 combination of kinds of therapy, and we had
18 surgeons who would agree to try to randomize
19 patients, and then they got into the discussion
20 about the ability to enroll patients, and their
21 ethics boards at their hospitals which would not
22 allow the incentivization to increase assets to
23 the surgeon as part of that trial, and so that
24 ultimately was I think the final straw that broke
25 the camel's back, even in a state-run health care

00210

1 system, in trying to design a specific trial,
2 which is all we're asking for, that we have not
3 been able to figure out how to do today. So I
4 think there are differences in health care systems
5 that do alter patient behavior, and I think that
6 this issue of a looking for a method to gain
7 access is a real powerful force in patient care.
8 DR. KRIST: Last comment, and then
9 we're going to focus in on our panel discussions
10 here.
11 DR. WONG: David Wong. I'm the
12 representative of the American Academy of
13 Orthopedic Surgeons. Just to Dr. Faciszewski's
14 point, I practiced in Canada's socialized system
15 so I'm aware of waiting times, and I think that's
16 a significant behavioral issue in terms of trying
17 to attract people. If you can give them a faster
18 track, and I think that's one thing about the
19 European studies when there's a long wait time, is
20 giving them a faster track.
21 The other thing that hasn't been
22 discussed here is in the European socialized
23 system, there's another track outside the trial,
24 which is disability. And it was interesting, I
25 was on a panel with Dr. Alan Masterson a number of

00211

1 years ago, and it was brought up at that point
2 that the rates of people becoming disabled in
3 Sweden from back pain had reached a point where
4 they actually had to change the criteria because
5 of the rate at which people were disabled, and it
6 was taking up a huge percentage of the budget. So
7 there is another track to become disabled there,
8 as opposed to the United States, functional and
9 still productive here in this culture, it's a
10 different scenario.
11 DR. KRIST: Now to orient the panel,
12 what I would like to do is focus on discussions
13 that we need to have to clarify the evidence from
14 our standpoint. When we get to voting, you'll see
15 there's one thing in your packet and there's
16 numbered cards in front of you. When we come to
17 each of these questions, we're going to ask you to
18 hold up your numbers and write it on your packet,
19 and I guess Michelle will come by and pick these
20 up, and then the votes will be tallied and posted
21 on the web site.
22 But let me open it up for discussion
23 here so that we can clarify these issues, these
24 six questions before we turn to voting, or
25 alternatively, we could go ahead and vote if

00212

1 people are ready.
2 DR. BURCHIEL: Can I ask a trivial

3 question. I'm still hung up a little bit on
4 outcome measures and the idea that we focus at a
5 point in time with, say, (inaudible) disabilities.
6 I do think as a practicing neurosurgeon who does
7 spine surgery including pain patients, but for a
8 patient to enjoy some years of better life, pain
9 relief, for example, has value.
10 And so I'm asking a little bit about
11 what is the data that we have that quality of life
12 years has really been looked at for the
13 intervention that we're talking about, and that is
14 a measure that could be used. So it's a little
15 harder, I think, but as a real world test, we kind
16 of keep coming back to that issue, to me that's a
17 real world test. The patient would say to me, I
18 will take five years, that's a benefit to me, even
19 if I know at the end of five years I'm going to
20 fall apart, I would rather have those five years,
21 rather than staying in pain for five years. So
22 I'm asking of the panelists here their expertise
23 on handling Question 4.
24 DR. KRIST: I would just like to make
25 it, we could even discuss this more broadly, and

00213

1 the evidence that we've seen on the RCT studies
2 and the cohort studies and the outcomes, what do
3 people think of the outcomes that we're looking
4 at?
5 DR. FLUM: I think that there's an
6 opportunity to address the point you just made by
7 using a quality of adjusted life years. That
8 requires a certain degree of longitudinality.
9 DR. KRIST: I want to hold this for
10 right now.
11 DR. FLUM: The quality of life years is
12 a metric used in other studies and I think that's
13 where you draw that kind of information from.
14 They too are (inaudible) as Dr. Mirza was talking
15 about. There are really two goals; one is to
16 accurately reflect the impact of the procedure on
17 the patient and the other is to try to inform
18 patients about what to expect. And these operate
19 on almost two different realms. Quality of
20 adjusted life years speak to the health care czar
21 who is trying to decide how much health care they
22 want to give, and the intuitive value of the
23 measuring quality of life is worthwhile and you
24 have 100 percent longitudinal follow-up, and I
25 think that clearly is an opportunity.

00214

1 I was going to add, now that we have
2 Part D Medicare, Medicare has tremendous offerings
3 of outcome assessments using health care
4 utilization. It hasn't been a main feature of a
5 lot of the work that's been out there, but

6 patients, the true way that patients use the
7 health care system related to back pain in terms
8 of braces and walkers and narcotic uses, those
9 things can actually be measured, and they can
10 provide a very meaningful objective measurement of
11 the improvement after, maybe not any intervention,
12 but certainly for this type of intervention.
13 DR. ONDRA: I think as a surgeon, I
14 think Kim's question is what do we want to see as
15 our entry criteria into a study and for a
16 procedure, what are the proper outcomes, not only
17 in terms of ODI, but what their disability
18 improvement is, their overall health impact. You
19 know, are these people getting older, not younger,
20 and you know, so how does that factor in, how is
21 improvement measured for nonsurgical or surgical
22 means as well as overall improvement. You know,
23 in addition to just a small slice of their pain
24 and function, for instance, patients who are
25 active, who have fewer other health problems

00215

1 relative to the population. So I think what we're
2 really looking for is how do we design a study to
3 answer these questions, there's going to be an
4 entry selection criteria, and it's going to be on
5 different treatments that we want to look at.
6 DR. LURIE: I wanted to raise an issue
7 that is not so much what outcome measures per se
8 but how the outcome measures are interpreted, and
9 in particular this very attractive but perhaps
10 only skin deep attractive idea of clinically
11 important improvement, which is something we have
12 a great desire to understand but I don't know that
13 we have a great ability to understand it.
14 And in particular, it is generally
15 determined in the medical literature as a graded
16 analysis of the individual, how much of a change
17 in the measure is associated with a perception of
18 the benefit for the individual. It is often
19 misused to compare the difference in mean scores
20 between two groups, which it is not designed to
21 do, and we have seen people say we get an average
22 in this group and a difference of X points, and
23 that's not a clinically important difference. But
24 that minimal clinically important difference might
25 be defined by the difference between two groups,

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1 it's defined by the changes in the individual, and
2 it has to be applied that way to make it
3 understandable, and that's something that we need
4 to be cognizant of when we talk about outcomes.
5 DR. KRIST: So you would be advocating
6 more for a percent of individuals who have a
7 minimally clinically significant improvement, and
8 using that as a unit of comparison?

9 DR. LURIE: Yes. And the problem with
10 that approach is that that reduces the statistical
11 power. When you dichotomize the different
12 variables, you lose power. But that is probably
13 the metric we're talking about. Well, how do you
14 measure changes in the patient so they know what
15 the heck you're talking about, because they don't
16 know what 14 points on an Oswestry score is. The
17 percent of people who get at least a minimal
18 clinically important change in that score probably
19 is something that they can understand without
20 having to come up with a new metric that is not
21 validated.
22 DR. KRIST: I think in one of the
23 studies, or one of the presenters showed us in one
24 study, 68 percent of people, but it was just a
25 pre-post looking at surgery and I think our

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1 comparative groups, or nonsurgical comparison
2 groups, we don't have that number of results, as
3 far as I'm aware.
4 DR. BOYAN: I have a question I want to
5 ask, I think probably you. In some of these
6 questions that are sort of floating around, none
7 of these studies were powered to get the answer,
8 but would a meta-analysis allow us to get at the
9 answer? I don't understand the business of
10 meta-analysis enough to know if you took all the
11 studies together and combined them, is there some
12 statistical way that we could sort of tease out
13 what the comorbidities are?
14 DR. LURIE: The answer is sometimes,
15 maybe. In the subject presented here, I think
16 Dr. McCrory had it right and if you ask him if he
17 did a meta-analysis, no, he didn't. Why? Because
18 if you look at studies and you can tell that they
19 are heterogenous, that is, what's happening in
20 those four studies is not the same thing.
21 Therefore, combining them is probably not the
22 right thing to do. So that's the problem.
23 Meta-analysis is very helpful when you have
24 multiple small studies that are all studying the
25 same thing about the same way, they just don't

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1 have the numbers, and typically a meta-analysis is
2 useful when you have a study that shows a moderate
3 or a large effect that's not statistically
4 significant, because the problem there is that
5 there is probably a good effect but you're not
6 powered to see it. When you have a moderate sized
7 study that shows no effect or tiny effect, the
8 problem is not the power, the problem is there is
9 no effect.
10 DR. KRIST: Or Fairbank, he had the
11 ability to detect a 4 percent difference, and

12 that's a pretty significant power, more than
13 minimal clinical significance.
14 DR. FLUM: If there were 14 studies of
15 this type, you would have been able to do this,
16 but four, you tend to smooth over differences more
17 than you probably want, but there have been many
18 worse groups of studies that have been analyzed
19 successfully. These happen to be four studies
20 that have really pretty clear interventions being
21 the same. Then as we talked about, the inclusion
22 criteria were similar if not perfect. But if
23 these were meta-analyzed, you just wouldn't get
24 much benefit from that. The reason I ask that is
25 if you look at point estimates and say that the

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1 effect on these four studies when you take them
2 all together is 0.7 with a confidence interval of
3 .6 to .13, it is really just a way to administer
4 precision to a science, but agree with the
5 decision not to meta-analyze.
6 DR. ONDRA: I want to get back to the
7 question I raised before, and I sort of gathered
8 that no one is in agreement that we have the
9 definitive answer on this issue with the current
10 studies that we have. So given that and the
11 difficulties with RCTs, are RCTs going to be the
12 only way we can get at this? And if it is, how do
13 you design that, or is there any other way, given
14 the difficulty of doing an RCT in the United
15 States? What are our ways to get there?
16 DR. FLUM: I totally disagree that the
17 outcome (inaudible) surveyed the investigators in
18 this field we looked at were reliable, it's been
19 validated, it's a good solid metric and captured
20 what we think we wanted to capture.
21 DR. ONDRA: That's not my question.
22 DR. FLUM: Right, but the outcome
23 metric just drives whether or not -- the outcome
24 metric often drives the randomization. I mean in
25 fact, the practical barrier you all laid out was

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1 about recruitment. (Inaudible) unethical and
2 totally impractical, and all of a sudden it became
3 ethical and practical and added a lot of
4 information.
5 DR. BOYAN: I might have an answer that
6 isn't going to be friendly but, although it's how
7 we should do it. I don't think there's enough
8 information about anything to compare the two
9 things we were asked to compare, and if the study
10 has to compare usual care or nonsurgical care to
11 surgical care, somewhere in this room we have to
12 define some unified unit of nonsurgical care,
13 which we haven't done. So I would suggest that
14 the appropriate studies are to say let's accept

15 that we're looking at nonsurgical care, and take a
16 variable in nonsurgical care and see if it
17 matters, because we're trying -- I feel like I'm
18 talking to my students.
19 But you've got to define your question,
20 you've got to have a single variable to have a
21 rational study, and build up to it, get a protocol
22 of nonsurgical care that could actually be given
23 according to a protocol. I would suggest we
24 take -- surgery is now an accepted thing, we're
25 going to do surgery, but we're going to determine

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1 if we do surgery in old people, are they going to
2 have estrogen treatment or not estrogen treatment.
3 Make it simple so you can get a number you can
4 use. What we've done today is talk about a lot of
5 stuff that I'm not sure we can use.
6 DR. ONDRA: In the lung volume study,
7 there was, I don't know enough about it to know if
8 that's a fair comparison, but that was a procedure
9 with some mortality associated with it, but again,
10 I'm not sure that that is -- I think it's a well
11 designed trial, I'm not sure it's a fair
12 comparison, so we would have to look at it a
13 little more closely to see if we're really talking
14 about the same sort of thing. And number two, the
15 number of people that it affects would be much,
16 much smaller in terms of back pain.
17 DR. FLUM: It depends on how many
18 people, because we really don't do all back pain.
19 DR. ONDRA: Well, for back pain it's
20 very high. I was referring to degenerative disc
21 disease.
22 DR. FLUM: To stay on topic, you can't
23 look at a big group and the smaller group at the
24 same time. I think we are not here to design a
25 perfect trial, but I think that these are the

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1 issues that come up to address the adequacy of the
2 outcome metrics.
3 DR. BOYAN: I don't think we are going
4 to design the perfect trial, but I think we're
5 arguing over minutia about an imperfect trial that
6 we cannot fix with another imperfect trial, so I
7 think we have to simplify our goals a little bit.
8 DR. ONDRA: I don't think we're
9 designing anything, we're just giving CMS advice
10 on what we would like to see.
11 DR. BOYAN: Exactly.
12 DR. PHURROUGH: Right.
13 DR. KIRKPATRICK: Let me just summarize
14 what I understand this discussion was about. We
15 are currently to weigh the spectrum of
16 professional or educated opinion as far as the
17 literature breakdown. We would like to be up to

18 randomized clinical trials for everything. And
19 what I'm hearing, especially from my colleague
20 here, is that we need to work towards the middle
21 instead of working toward the other extreme,
22 because the other extreme is not likely to be
23 obtained with the multifactorial issues in the
24 field. And I would agree with that pursuit of
25 moderation, so to speak.

00223

1 And given that, I do think that we've
2 heard some very valid comments about outcome
3 measures, we have an ODI which is reliable at this
4 point, but it is not refined enough to be very
5 specific. We have visual analog pain scales we
6 can use. We have quality adjusted life years we
7 can use. I don't think we can focus on one. We
8 have to look at a multifactorial approach of
9 saying whether it helps the patients. And that's
10 something that will help the surgeon say, because
11 now I can go to the patient and say well, based
12 upon questionnaires of how people do, many of them
13 do well for three or four years after the surgery
14 and do better than the ones who don't have
15 surgery. Or I can tell them, we found that after
16 so many years, they all do the same. It kind of
17 depends on what the patient's questions come up
18 as. And then if they want to balance that against
19 the risk that they have to go through, then we get
20 a risk table to help.
21 So, we need all these different factors
22 as part of our analysis in our measures, and it
23 may mean that there is a new one developed, and I
24 don't want to complicate this with developing
25 measures, but either a combination of measures or

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1 a progressive development of a new measure is
2 important to be able to look at patient function,
3 how they deal with life, and nobody has really
4 talked about coping mechanisms, but that's huge
5 and hasn't even been brought up. So you know, I
6 don't know that we want to get into that ball of
7 wax at this stage, but in the future it may have
8 to be incorporated, so I think multiple different
9 measures are important, not just one.
10 DR. KRIST: I'm going to ask the basic
11 question, because if we're talking about how do
12 you design, or what's the perfect study you want
13 for this, in a sense it implies that there are
14 problems that are current. So why don't we talk
15 about, is there a problem with the current
16 evidence in the four RCTs that we have and the
17 number of cohorts? I have some issues with the
18 cohort versus the RCT data, but let's talk
19 explicitly about this.
20 DR. FENDRICK: I completely agree. We

21 have heard nothing about (inaudible) trial in the
22 U.S. elderly population that are going to prove
23 that it's different from these substantial
24 variations that we've seen in four randomized
25 trials. So we would ask, is there some

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1 physiologic mechanism, is there something that
2 is -- I can understand that there might be a trend
3 toward a difference, but the fact that there are
4 four randomized trials in people without
5 comorbidities, and I would imagine probably it
6 would be easier to perform surgery to a higher
7 level of specification if the differences weren't
8 large in those people, so why would we think that
9 they would be much larger in the people in the
10 Medicare population, unless there is someone in
11 this room that can say that nonsurgical therapy
12 doesn't work well on them.
13 I think we know everything we're going
14 to know for a while on surgery. I think what is
15 quite clear that we don't know yet is the value or
16 the impact of nonsurgical therapy in the U.S.
17 elderly population. I think some of us who read
18 these studies in Europe were quite surprised, not
19 how well surgery worked, we heard from surgeons on
20 how well surgery worked, right?
21 But surprisingly, it mentioned the
22 nonsurgical therapy, and given that it was
23 mentioned in two of the European trials, given
24 there was no relevant intervention trial, the
25 natural history of the disease could also be the

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1 same. People could have just gotten better at
2 those same rates if nothing was done at all. And
3 I think that's where a strong argument needs to be
4 made to do another trial that's addressed to this.
5 DR. ONDRA: I got something completely
6 different from listening this morning and that was
7 while we saw that these trials were very flawed, I
8 know one trial had a one-year follow-up, which is
9 strikingly short considering recovering from
10 surgery is going to take up a large part of that
11 year, so I don't know that we have the ability to
12 make all these answers relative to surgery. I
13 find that very myopic.
14 DR. FENDRICK: Specifically, why do you
15 think there's a difference between these markedly
16 variables in what we saw in younger versus older,
17 so whatever outcome measures we have, why would
18 the marginal if not at all clinical meaningful
19 difference that we saw in the pretrial, why do you
20 think they'll be different in a different
21 population, and that's a question that I don't
22 know the answer to, but we need to do it in the
23 U.S. because --

24 DR. ONDRA: Well, I think we need to do
25 it correctly because I think these are all flawed,

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1 very flawed studies.
2 DR. FACISZEWSKI: Maybe I can help.
3 Two comments. One is that at the risk of going
4 very far backwards, I think there is concern among
5 the panel about, that there is a concern about
6 whether this is a high incidence problem or low
7 incidence problem. And from a spine surgeon's
8 perspective, we're very much split and I think you
9 hear that amongst the surgeons. And with all due
10 respect, I think with the administrative database
11 researchers, their numbers, everybody has
12 degenerative disc disease. In surgery, very few
13 have degenerative disc disease.
14 And maybe I can help define that term
15 in my mind, and then address very briefly the tech
16 report, which I think helps confound the
17 confusion, not give us a solution. Degenerative
18 disc disease is the painful syndrome, people hurt,
19 and it can't be made on radiologic evaluation.
20 The MRI scan does not tell me as a surgeon what
21 hurts. And so I read the tech report and I see
22 that in the radiology section they talk about
23 degenerative disc disease. In my mind that
24 doesn't compute, because the radiology evaluation
25 doesn't tell me about disease. It has

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1 degenerative disc changes, they may have facet
2 changes that are spondylitic, but they don't have
3 the disease.
4 So I think we see some of this
5 contamination of unclear thought, and that brings
6 us further to the point of what's really going on
7 with the Medicare population. I think that's what
8 the question asks us. The ICD codes don't reflect
9 it, the ICD codes that we as surgeons have to put
10 down are confusing. We wrote some papers in the
11 early '90s about presumptive coding. If you code
12 certain things in the hospital and your code is
13 okay, they go for it, they get paid for it. But
14 if you have the complication of anemia, which now
15 all of a sudden is a complication where the
16 hemoglobin is below 30. So these things are
17 terribly confounding.
18 So, to the point. I think they are
19 very flawed studies because they don't define the
20 patients that are enrolled. In fact, very few of
21 them get MRI studies. In a multilevel
22 degenerating patient, degenerated, not diseased, a
23 different patient might had a single level
24 degenerated disc, so we need randomized controlled
25 studies that are all the same.

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1 And so if I could just address for one
2 second and talk about what this means to me. If I
3 were an internist and I was reading a study about
4 cancer, and the study dealt with cancer patients,
5 and cisplatin was given to all of them, and guess
6 what, some of them got better. And the conclusion
7 was that cisplatin actually was beneficial, but it
8 really wasn't that much more beneficial than doing
9 nothing. And we didn't control for bone cancer,
10 breast cancer, prostate, they just had cancer.
11 So my problem with these studies and in
12 listening to the reports and reading the tech
13 assessment was that there's no granularity, and
14 the administrative databases don't help us with
15 that. So I believe strongly that if nothing else
16 happens from this panel, we have to define these
17 terms and we can study in the future, and so when
18 someone says degenerative disc disease in the
19 future, I know exactly what that means, because
20 I'm not convinced that we panel members all agree
21 on that term itself, and that makes answering this
22 question very easy.
23 DR. FLUM: (Inaudible) probably a good
24 idea, and this is what I gleaned from this
25 morning. One is, the study population is totally

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1 different, and we've all said we don't know how
2 these patients would respond to any intervention.
3 Two, we all have seen the same results, we're
4 interpreting them differently. There's lots of
5 different interpretations of what's positive,
6 what's not a positive result, and mostly because
7 the nonoperative events are being interpreted
8 differently. So we have to design a really clean
9 nonoperative event of the type that we discussed
10 earlier, that would be a wonderful opportunity.
11 Also to clarify with MRI, whatever the state of
12 the clinical standard is right now for defining
13 the disease process.
14 Those would all seem like great
15 opportunities to pursue randomized studies, and
16 use whatever metrics we use, but I don't think the
17 outcome metrics is the problem. I think that we
18 could convince the spine community and patients
19 and the clinicians who are referring patients
20 better if we had a state of the art study that had
21 clean entry criteria and clean nonoperative
22 intervention. I don't think we should say that
23 just because right now there's no good
24 nonoperative intervention that's paid for, I don't
25 think that should be a limiting factor. I think

00231

1 we need to learn from these studies what a good
2 nonoperative intervention may look like, and

3 create one. That's where I think the opportunity
4 is.
5 DR. KRIST: I have a quick clarifying
6 question for the panel. The SPORT study, is there
7 an argument about that looking at this population
8 we're talking about?
9 DR. LURIE: No, there is no back pain,
10 degenerative disc disease or back pain fusion.
11 There's a spondylolisthesis, there's spinal
12 stenosis and leg pain predominant, that's the
13 remaining arm. And again, I share some
14 frustration in reading the tech assessment because
15 you can't put isthmic spondylolisthesis,
16 degenerative spondylolisthesis, axial back pain
17 with dark discs, you can't put those things
18 together and make any sense of it because they're
19 different diseases, they present differently, they
20 respond differently, the surgical outcomes are
21 different between those diseases, the nonsurgical
22 outcomes are different between those diseases, the
23 long-term things you see are different for those
24 diseases. They're all sort of degenerative,
25 because that can mean whatever you want, but

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1 they're very different diseases, and to put them
2 together, it's a mish-mash.
3 DR. KIRKPATRICK: It sounds to me like
4 we need to stick to the specific question we need
5 to answer. We need to design a randomized
6 clinical trial that will probably take four to
7 five years just to develop, and in the meantime we
8 need to be doing prospective follow-up on
9 everything we do.
10 DR. FLUM: And also get better
11 information for what the indications of the
12 operation are. We should have a spinal fusion for
13 back pain, if that's the issue we want to be
14 looking at. That's something that Medicare can
15 influence and can add to their (inaudible) which
16 goes out to these patients. And then as, you
17 know, Medicare does this in many ways, where no
18 patient gets covered unless they are on a
19 prospective registry. This give us an opportunity
20 to learn about these patients while we're figuring
21 out the best way to do this study.
22 DR. ONDRA: And that's probably much
23 more reasonable ground than just coverage or
24 noncoverage, and, you know, the other thing is
25 what outcome measures should be used for these

00233

1 patients. You know, are we just looking at a
2 single one, are there a group we should be looking
3 at, and those are things that I hope we will be
4 looking at.
5 DR. KRIST: Are we ready to look at

6 voting?
7 DR. LURIE: No, I'm not. Besides that
8 issue, there are at least two other things I need
9 to be clear about what I'm voting about. So one
10 is, we've sort of talked about, what's
11 conservative care or nonoperative care in the
12 studies. If we're voting on level of evidence
13 compared to conservative care, what is it that we
14 had in our minds that we're comparing it to? Is
15 it the extensive tertiary function and
16 rehabilitation like that provided in the Brox
17 study, is that conservative care, or is it the
18 physical therapy and whatever, like was provided
19 in the Fritzell study, is that conservative care?
20 Because the outcomes of those two things between
21 those two studies were very different. So I would
22 call the Fritzell study conservative care and I
23 would call the Brox study intensive tertiary
24 rehab. I think the outcome of those two things in
25 the literature are different and I think the

00234

1 comparison between, you know, the surgery outcomes
2 in all these trials is just about the same, but
3 some of them showed a difference between a
4 comparator arm because the control arm got better,
5 and others showed a fairly big difference because
6 the control arm didn't get better. So which of
7 those studies am I supposed to have in my mind
8 when you ask me to hold up a number?
9 DR. KIRKPATRICK: All of them.
10 DR. KRIST: The answer is all of what
11 the evidence showed us, that's all we can comment
12 on. And yes, there is a big variation in what
13 nonoperative care is, but what we need to think
14 about is in aggregate, the surgical decision
15 versus nonoperative care, so we include all of
16 them.
17 DR. LURIE: My next question is
18 clearer. When it comes to the question of whether
19 we're talking about how likely are these various
20 procedures, fusion procedures, and we're supposed
21 to talk about the without instrumentation and with
22 instrumentation. So the question is for the with
23 instrumentation patients, is it with
24 instrumentation compared to conservative care or
25 is it with instrumentation compared to without

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1 instrumentation? So instrumentation makes no
2 difference, if that were somebody's world view,
3 and if you think that fusion without
4 instrumentation helps and that adding
5 instrumentation does nothing, how would you answer
6 the question about with instrumentation? Would
7 you say it doesn't help if it's done without
8 instrumentation, or do you say it does help if

9 it's exactly the same as without fusion, but it's
10 better than nothing?
11 DR. KRIST: Well, I go back to, we have
12 to think about the information that we have. Most
13 of the studies that I saw in our tech assessment
14 compared an operative intervention with and an
15 operative without, and that would be one way to
16 compare their relative importance. I mean, an
17 ideal study to assess that would be a nonoperative
18 control group, an operative control group with and
19 an operative control group without. I don't know
20 that we have that information to that level. But
21 we have to think according to the same yardstick,
22 so when you pick your numbers for each, it would
23 be judging each against the same baseline
24 yardstick.
25 DR. KIRKPATRICK: There is a subtlety

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1 with regard to the interbody fusion that I would
2 like clarified. Are we saying that an anterior
3 lumbar fusion done with a plate and BMP, is that
4 with instrumentation or without? Because some
5 people will put in a cage and also put an anterior
6 plate on, which is with instrumentation, whereas I
7 didn't recall seeing any reports of that. So I
8 think some of these with and without are
9 complicated concerns. My recommendation would be
10 if there is data there, you say there is data
11 there; if there is not data there, there's not
12 data there.
13 DR. KRIST: And that can bring up a
14 larger point about Question 4 in general, and
15 we can talk about that now. I mean, a large
16 amount of the data that we heard, even just
17 looking at the difference with the four different
18 procedures there, there was some amount of data
19 saying that they were relatively comparable,
20 right? I'm not saying that they are, but maybe we
21 should just be looking at with versus without any
22 instrumentation. So there's a number of ways to
23 think about maybe clarifying Number 4, so what are
24 the panel members' thoughts on that?
25 DR. KIRKPATRICK: I would suggest that

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1 there are several things that we've heard that
2 show there's no difference among them, but some of
3 those studies are larger than others, and so we
4 might be able to say that from an evidence
5 standpoint, we have certain levels of evidence to
6 support it, but as far as the surgeons in the
7 crowd, I want to make sure that we're not saying
8 that we have a rationale to support one or the
9 other as different based on what the evidence is.
10 DR. KRIST: Yeah. The question starts,
11 based on the evidence presented, how likely.

12 DR. KIRKPATRICK: And I'm trying to
13 emphasize that because that's been a hangup in
14 prior panels that I have been on.
15 DR. BOYAN: I have a point of how
16 things are done. Do we have any discussion time
17 at the end of each vote?
18 DR. PHURROUGH: Yes.
19 DR. BOYAN: Good.
20 DR. JARVICK: I have a question about
21 the patient population that we're dealing with and
22 with respect to degenerative disc disease and
23 imaging criteria. I heard a number of presenters
24 say that if they had patients who have one or two
25 level degeneration (inaudible) wouldn't operate on

00238

1 him. When we talk about patients who are over the
2 age of 65, you're distinctly abnormal if you don't
3 have any disc degeneration and it is present in
4 virtually 100 percent of those folks, and the
5 number of people who have multiple herniated
6 discs, it goes up a little bit. So is this group,
7 are we talking about only those folks that on MRI
8 have only one or two levels of disc degeneration?
9 DR. FACISZEWSKI: I think your question
10 is exactly the question that needs to be asked,
11 and that is the question of these questions, and
12 that is the extent on one or two discs, but we are
13 left with two categories, there is the less than
14 65 and there's the greater than 65.
15 DR. KRIST: Well, the way the questions
16 are worded too, the very last question is the
17 Medicare population, right.
18 DR. FACISZEWSKI: But I think his
19 question is, what do the other ones refer to.
20 DR. KRIST: I would read the other
21 questions as in aggregate, overall, does this
22 improve health outcomes for patients, not just
23 specific to the Medicare population. And then the
24 last question is okay, now, specifically for the
25 Medicare population, how does what we said apply,

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1 or how does what we said earlier apply to just the
2 Medicare population.
3 MR. QUEENAN: I was interpreting it
4 actually to mean that until the last question,
5 we're basically looking at the evidence based on
6 the population studied by the evidence, and the
7 last question is, is that population or those
8 populations representative.
9 DR. KRIST: Yes.
10 MR. QUEENAN: I have a related
11 question, though, which is on Question 3 in
12 particular, since we had a discussion. A lot of
13 people mentioned that there has to be certain
14 patient selection relating to the discussion about

15 whether or not there was conservative treatment
16 prior to surgery. I guess what we should assume
17 is the case for Question 3, and I guess the way I
18 was looking at that is that that would refer to
19 what we glean from the evidence, but for the U.S.
20 population, the population that would be, if not
21 Medicare-eligible, at least in the U.S. health
22 system, so we would interpret that in the context
23 of treatment as it occurs in this country. That's
24 just the way I interpreted it, but I'm really
25 asking the question of how we should interpret it

00240

1 in that context.
2 DR. FLUM: I didn't get that. I
3 interpreted it the other way. We only have the
4 evidence in front of us to use. If nonsurgical
5 treatment in Europe is what the evidence is based
6 on, it is what it is, and that's the only evidence
7 of conservative management or nonoperative
8 management we have here today.
9 MR. QUEENAN: But then there is no
10 question that allows us to answer the question as
11 to whether that's applicable to the U.S.
12 population.
13 DR. FLUM: Except the last thing that
14 talks about it being applicable for the Medicare
15 population.
16 DR. KRIST: I think the way I would
17 interpret that, we're interested in thinking about
18 the U.S. population, but I wouldn't by definition
19 exclude studies that were not done in the United
20 States. If you have a particularly strong reason
21 to think that the information is not applicable to
22 the U.S., if there is strong evidence and
23 information from there that you don't think that
24 this applies to patients that we're caring for --
25 MR. QUEENAN: There was a lot of

00241

1 discussion about that because the RCTs that were
2 done were done outside the U.S.
3 DR. FLUM: And the nonoperative arm
4 they doesn't necessarily exist in the United
5 States for whatever commercial reasons. So I
6 think those are valid issues. And you don't want
7 to get boxed in by a question that, in answering,
8 that's not really what the points are that are
9 important.
10 DR. KRIST: Well, and I think we will
11 make an opportunity to have comments to fill in
12 those details, to be able to say yes, in this
13 scenario I think if you have these alternatives,
14 that it's not necessarily better. And that would
15 be helpful, I think, for the group to come out
16 with the background and thoughts behind why you
17 feel the way you do on these various topics.

18 That's going to be probably the most important
19 information for directing everyone in the room
20 here as well as other people as they move to
21 figure out where do we go next with this.
22 I see people looking down and writing
23 things on their sheets, so I'm going to take that
24 as tacit approval to go ahead and start voting on
25 these.

00242

1 DR. KIRKPATRICK: Just to clarify, are
2 we going to take a vote and then have a discussion
3 of each question, or do you want us to make sure
4 we've discussed the discussion part of each
5 question before we vote?
6 DR. KRIST: We'll take the vote first,
7 but if you feel like there is a specific thing you
8 want to talk about with the panel to clarify
9 beforehand, let me know before the question.
10 DR. KIRKPATRICK: What I'm saying is
11 the question and discussions are related, but one
12 doesn't necessarily support the other.
13 DR. KRIST: Correct. We're going to do
14 the discussion points after the votes. But if
15 there's something that you want to talk about to
16 clarify the question that you're voting on, just
17 let me know before that question. Does that make
18 sense?
19 So for Question 1, what level of
20 confidence does the evidence provide in addressing
21 the outcomes needed to determine the effectiveness
22 of lumbar spinal fusion for low back pain due to
23 degenerative disc disease? And if you would write
24 on the sheets as well as hold up your numbers,
25 Michelle will pick those up.

00243

1 (Panelists voted.)
2 DR. KRIST: And we talked some about
3 the discussion point on this, which is, is relief
4 of pain the appropriate primary outcome, or should
5 it be restoration of function, return to work or
6 something else? I have heard from the group a lot
7 of talk about ODI. Are there other comments or
8 things that people would like to bring out on that
9 discussion topic?
10 DR. FLUM: I think we made the point
11 about harnessing the power of Medicare in light of
12 Part D Medicare as an opportunity of upgrading the
13 way we understand the outcomes of surgery.
14 DR. BURCHIEL: But if we don't expand
15 that to something that has more real world
16 meaning, we're going to end up with the same
17 results and not be able to interpret them either.
18 I think there needs to be an additional criteria
19 developed.
20 DR. FLUM: And just by way of

21 mentioning that, you know, in a bariatric surgery
22 coverage decision, they were leaning towards, the
23 Medicare coverage decision was leaning towards
24 hospitals that were accredited by the American
25 College of Surgeons or another, the American

00244

1 Society of Bariatric Surgery, and part of that
2 accreditation process included yearly assessments
3 of the patient-driven outcome, which is a way that
4 could certainly be the ODI, and that would be a
5 very nice eloquent mechanism to make sure that a
6 yearly quality of life for the disease could be
7 measured out. That's the type of thing that's
8 already on line with the prospective registry, and
9 would be a wonderful way to justify the procedure,
10 and as a way to understand how this population
11 plays out.

12 DR. FACISZEWSKI: So in bariatric
13 surgery, they looked to a society?

14 DR. FLUM: The American College of
15 Surgeons, and the American Society of Bariatric
16 Surgery, they established a set of accreditation
17 criteria based on structure, how they handle
18 bariatric patients, processes, and required a
19 follow-up at one year with a patient level outcome
20 and then some outcomes, and that model has really
21 marked to the power of the care as well.

22 DR. JARVICK: One of the things I
23 wanted to point out is the outcome measures, we've
24 touched on it a little bit, but you have the use
25 of disability of function status rather than pain

00245

1 to be focusing on, and I think it's important to
2 focus on those measures, and if you give more
3 weight to that than just assessment of pain, I
4 think you will have all sorts of problems
5 associated with them.

6 DR. KIRKPATRICK: I think we pointed
7 out that while we don't have a perfect measure, we
8 need to improve the ODI or something very close to
9 it that's well validated, visual analog data. For
10 non-workers' compensation, I think it would be
11 reasonable to look at return to work status, I
12 don't think it's appropriate for the workers' comp
13 population because of a number of issues that
14 we've already brought up. And then I think
15 somewhere either in the pain scale or somewhere
16 else, we should include whether you're on
17 narcotics anymore or non-narcotics, and I also
18 agree with the idea of the quality of adjusted
19 life years.

20 DR. KRIST: Okay. Move on to Question
21 Number 2 then. What level of confidence does the
22 evidence provide for characterizing complications,
23 adverse events and other harms from lumbar spinal

24 fusion for degenerative disc disease? And we will
25 start with Question A, short-term, and short-term

00246

1 being defined as up to two years after surgery.
2 (Panelists voted.)
3 DR. KRIST: And why don't we go ahead
4 and do 2.B right now, long-term, and that's
5 defined as more than two years after surgery.
6 (Panelists voted.)
7 DR. KRIST: Just to remind folks, this,
8 all the averages and the vote will be on the
9 Medicare web site tomorrow, or this afternoon,
10 okay.
11 Discussion point for Number 2, what
12 does the variability in surgical risk depend on?
13 And let's lump these together, as this procedure
14 is permanent, are there other potential long-term
15 harms that have not been discussed.
16 DR. FLUM: My comment on variability,
17 as we heard from Dr. Mirza about variability and
18 utilization, undoubtedly there will be variability
19 in outcomes, but we haven't heard too much about
20 that. Outcomes were measured by what would be the
21 question, I guess. Would they be due from the
22 interventions or secondary to the spine, but
23 that's probably the best way to look at it, at
24 health care utilization as an outcome measure.
25 In the bariatric community, once again,

00247

1 this issue of variability was borne out, we were
2 looking at mortality rates in that population, and
3 the way our society approached that was to say
4 that we don't know yet what the variables are
5 affecting adverse outcomes, or in the operating
6 room, but we probably know better than anybody
7 else how to track down what's the quality of care
8 for accreditation, some volume criteria, past
9 record of performance, and once again, an
10 accreditation model that looks at variability
11 issues.
12 DR. ONDRA: On the long-term, it would
13 be important to look at what is the rate of
14 adjacent segment disease relative to the rate of
15 fusion compared to the nonsurgical population.
16 DR. KRIST: We saw some outcomes on
17 repeat surgery rates, and it would be good to have
18 good comparison groups for that as well. It's a
19 little difficult to put that into context because
20 obviously the people who have surgery are at risk.
21 DR. FLUM: One nice way to do it would
22 be through administrative data, and I'm sure
23 Dr. Mirza would agree. It's not hard to get a
24 modifier for an ICD diagnostic code, but there are
25 ways to make it clear that this is reoperative

00248

1 surgery, and that would go a long way in
2 indicating whether or not this was a quality
3 issue, recurrent disease, or what.
4 DR. KRIST: Why don't we go a step
5 further and say there is a randomized controlled
6 trial against nonoperative techniques, and do a
7 comparison with reoperative rates in those two
8 groups. I think that would be very helpful. For
9 the few studies we saw that had follow-up for up
10 to ten years, I think that would be tremendously
11 important.
12 DR. KIRKPATRICK: I'd like to add that
13 with this question of variable risks, there is
14 surgical risk and there is nonsurgical risk. Of
15 great concern to a surgeon, of course, are medical
16 comorbidities on the patient's side, and that
17 needs further investigation, it has not been
18 revisited in a number of years. Surgical
19 technique, some of us talked about in terms of
20 volume of case load and that sort of thing, or
21 complexity of the procedure, and these can also be
22 surgical control factors.
23 The majority of the complications do
24 seem to be a risk of simply having a surgical
25 procedure, anesthesia complications and that sort

00249

1 of thing.
2 As far as long-term issues, you know,
3 we don't know much beyond two years, and I think
4 that's something that may be ripe for study, but
5 we don't know exactly what to look at.
6 DR. FLUM: I would like to extend on
7 that one, I don't want to go back to accreditation
8 for the third time, but one of the things it does
9 is it allows the society to define the outcomes.
10 Maybe ODI doesn't improve more than ten, you know,
11 and I guess you guys know better than we do what
12 the optimal outcome and risks would be, and then
13 what patients are high risk for that and
14 performing a risk adjust. It would allow people
15 to compare apples to apples as opposed to apples
16 to oranges. I think that should be part of the
17 next generation out there.
18 DR. KRIST: Okay. I'm going to move on
19 to Question Number 3. Based on the evidence
20 presented, how likely is it that lumbar spinal
21 fusion for lumbar degenerative disc disease
22 improves clinical outcomes as compared to
23 conservative treatment? And we'll start with A,
24 short-term, once again defined as two years post
25 surgery.

00250

1 (Panelists voted.)
2 DR. KRIST: And let's move to 3.B,

3 long-term, more than two years post fusion
4 surgery.
5 (Panelists voted.)
6 DR. KRIST: Okay. The discussion point
7 on this is one of the ones we have been dancing
8 around a lot, and it looks like there's a series
9 of four questions. Why don't we look at the first
10 three and then we'll focus in on the last one?
11 What are the causes of low back pain? Is patient
12 important, and if so, what are the clinical and/or
13 patient characteristics that are reliable
14 predictors of satisfactory outcomes? And if there
15 is an absence of evidence of long-term benefit,
16 would evidence of short-term benefit be sufficient
17 to justify a fusion procedure? Let's start with
18 those and then we will readdress one last time if
19 a clinical trial were to be done, what would it
20 be.
21 DR. BOSWELL: A lot of my time is spent
22 doing interventional pain management, and the key
23 problem we are having right now is figuring out if
24 any of our treatments are effective in treating
25 the diagnosis. I'm going to say that I think the

00251

1 outcome studies aren't so bad, I think the problem
2 may reside in the fact that we don't have a clear
3 handle on our diagnoses in our patient population.
4 So we're getting the best results we can with the
5 outcome studies we have because we're looking at a
6 mixed patient population. I think there has to be
7 some emphasis on patient selection in some manner
8 based on diagnosis.
9 DR. FLUM: And that point has been
10 raised several times. In a randomized trial, if
11 there is classification basis, and undoubtedly
12 there is, in a randomized trial, we have to look
13 at it as one of the arms of an appropriate powered
14 randomized trial.
15 DR. BOSWELL: That's right, but what it
16 means is that we have to determine that before we
17 can tell what the difference is.
18 DR. FLUM: Right, but we can say for
19 the hodgepodge of people that are called back
20 pain, if you look at the criteria in the European
21 studies, if you look at the people who meet those
22 criteria, albeit with mixed diagnoses, it would
23 highlight the results that we would see. And
24 that's why I voted one for these, because I think
25 if you have four randomized trials and three are

00252

1 telling you that there is not a significant
2 comparative difference, that both arms got better,
3 then the question is what's different about the
4 last, the fourth study. And that's where I think
5 this body of evidence falls down a little bit, on

6 the comparable efficacy. I think clearly both
7 arms improved, but the question here was did one
8 arm, did the surgical arm improve more than the
9 nonoperative arm.

10 DR. KRIST: But there is a differential
11 response to the different therapies for different
12 diagnoses. One group of diagnoses might improve,
13 or one group or the other might improve. I mean,
14 one might improve for surgery and the other might
15 improve for nonsurgical outcomes, so the average
16 looks the same.

17 DR. FLUM: Well, that's accounted for
18 by the fact that they're randomly allocated and
19 you have enough of each group in each arm.

20 DR. KRIST: You have to know the
21 diagnosis at the beginning, though.

22 DR. JARVICK: And that's precisely the
23 problem. One of the things we're hearing is that
24 we don't have a specific way of separating out the
25 different diagnostic categories. MRI, we all

00253

1 agree is not great. Discography certainly has its
2 problems. We simply don't have the diagnostic
3 sophistication, and I'm somebody that reads these
4 things for a living, and I'm the first to admit
5 that we're not there yet. So patient selection,
6 undoubtedly it's patient selection going in to do
7 trial to get the appropriate intervention, but in
8 the absence of the tools to appropriately select
9 the patients, or the success with what we've got,
10 and, you know, it becomes an effectiveness trial,
11 which is what our experience has been. And the
12 results are what they are, that there's no
13 clearcut difference between the two groups.

14 DR. BURCHIEL: I want to make sure
15 we're (inaudible) NIH panels, low back pain, I'm
16 not sure they shed a lot of light on origins of
17 back pain except to say it's complex and there's a
18 menu of possibilities. I think that was mentioned
19 a couple of times today. So if we're going to
20 have a real etiologic basis for therapy, I think
21 we're a long way from that, it may still be five
22 years, or maybe not even in five years.
23 So on a measure of granularity, I think
24 what we're talking about is yeah, we can define a
25 few things. I think radiologically we can say

00254

1 there is degeneration or not degeneration, but the
2 fact is that most of these patients come, at least
3 in my experience, with several diagnoses, and
4 that's basically the way they come. Stenosis,
5 other degenerative disease, so we have to get away
6 from this pragmatic classification, to not lump
7 them all together, and ultimately we're going to
8 separate degenerative facet joint disease from

9 degenerative spondylolisthesis, and we're going to
10 have to put some of these definitions down that's
11 reasonable. Otherwise, we'll never be able to
12 power our studies.
13 DR. JARVICK: But the problem is
14 they're getting these diagnoses based on
15 radiologic criteria, and it may have nothing to do
16 with their pain, or it may have something to do
17 with their pain.
18 DR. BURCHIEL: Right. Whatever
19 criteria we use, we're going to have to settle on
20 a reasonably small number of discrete medical
21 conditions that are very common to an observer,
22 and not try to go beyond that, and we'll never get
23 to the granularity of simply degenerative disc
24 disease.
25 DR. ONDRA: This gets to entry

00255

1 criteria, and some of that is, you know, you have
2 an analogy with cancer, you don't say you have
3 cancer, you say you have a lung carcinoma, or
4 maybe adenocarcinoma (inaudible, off microphone.)
5 So you get somebody with loss of this kind of, you
6 know, for DVT, no stenosis, no leg pain, no
7 arthropysis, however you want to clarify it, no
8 spondylolisthesis, that's the population, but some
9 entry criteria included that's really designed to
10 not be granular to the point of undoable, but not
11 a garbage bag.
12 DR. KIRKPATRICK: Did I miss it, did we
13 go to the last part of that four-part question?
14 DR. KRIST: We are starting to slip
15 into the trial.
16 DR. KIRKPATRICK: We were going to talk
17 about the first three and then go full bore into
18 the fourth, right?
19 DR. KRIST: Yes.
20 DR. KIRKPATRICK: Number one, to
21 paraphrase the argument, we don't know, 90 percent
22 of the time we don't know the cause of back pain.
23 Number two is yes. Every speaker we heard said in
24 properly selected patients, but we don't know what
25 the selection criteria are, so that's another area

00256

1 for further study. I think avoidance of workmen's
2 comp is a key element to evaluating multiple
3 medical comorbidities, and there may be other
4 issues that have further refinements of the
5 diagnosis such as discography, which is still
6 controversial. And then number three, I think we
7 saw a nice slide that showed over a five or
8 ten-year period, the two curves end up converging
9 at the end. So the surgical arm came down in six
10 months quite well with ODIs being reasonably well
11 satisfied, and I believe they would ultimately

12 meet the quality adjusted life year benefit that
13 Kim is looking for, so I think there is in
14 short-term a reasonable expectation that the
15 patients may do better.
16 DR. KRIST: Yes.
17 DR. LURIE: (Inaudible, off
18 microphone.) You have to be clear about what it
19 means for not having a good outcome or what
20 predicts a difference in treatment value. So in
21 the studies where we can look at it, the big
22 lumbar spine study being the best one, the
23 workers' compensation patients didn't do as well
24 as the non-workers' compensation patients did.
25 They didn't do as well in the surgical arm, they

00257

1 didn't do as well in the nonsurgical arm, and the
2 difference between surgery and nonsurgery was the
3 same. Actually, it was a little bit bigger in the
4 workers' compensation population.
5 So when people say the workers'
6 compensation patients don't do well, we don't want
7 to look at them, we have to be clear about whether
8 they don't do as well as everybody else or whether
9 there is something about workers' compensation
10 that affects what we see in terms of treatment,
11 and the evidence that we have is that they never
12 do as well as the non-workers' compensation
13 population, but the treatment effect is probably
14 about the same, if not a little bit bigger in that
15 group, and we have to be careful about that.
16 DR. KRIST: I think that's the
17 advantage of the design when you have a comparison
18 group to look at differential change, as opposed
19 to just pre-post.
20 DR. KIRKPATRICK: To clarify, I'm not
21 saying we shouldn't operate on those patients or
22 study them at all. I'm just saying we should
23 exclude them if we're trying to figure out what's
24 appropriate for the Medicare population, because
25 when under workers' comp they're not getting

00258

1 Medicare. They may ultimately be, but in trying
2 to sort these issues out, I think it's muddying
3 the water more than anything.
4 DR. KRIST: Now taking up the last
5 question, we've talked a lot about it, and I want
6 to try and be concise on what we have to say, but
7 if one clinical trial were to be done, what should
8 it be?
9 DR. BURCHIEL: I know even though we
10 have all said it would be an extremely arduous
11 task, I personally can't see a way around a
12 randomized controlled trial. I think we talked
13 about validated measures, we talked about
14 standardization of conservative therapy, we talked

15 about the consensus issues, we talked about the
16 granularity issues. I think that one of the
17 pitfalls of the field right now is it is still a
18 maturing or dynamic field. We're going to have to
19 define what it is at some point because if the
20 target continues to move, we will never get an
21 answer on this. So we're going to have to draw a
22 line in the sand and that's what's going to be
23 used and that's what it's going to be, and that
24 will be the distribution of the trial, and not be
25 left up to the surgeons.

00259

1 I think the issue of sponsorship is
2 important. I know we're in a big trial right now
3 where the industry is donating equipment but they
4 have no role otherwise, and I think if we have an
5 industry involved in the interpretation of the
6 data and in any with the reporting of the data, it
7 is going to be a worthless study.
8 DR. JARVICK: I would completely agree
9 with that. I think just because an RCT is
10 difficult to do and is expensive and will take
11 a long time doesn't mean that it shouldn't be
12 done. I think a problem which is as critical and
13 has potentially as high an impact, not necessarily
14 talking just the Medicare population, I think, but
15 all patients with degenerative disc changes and
16 back pain, that we don't have a definitive answer
17 yet, and the best way to get the answer is an RCT.
18 DR. FLUM: I think one of the features
19 of that trial should address bias, and we all know
20 about bias, it comes in many forms. One form of
21 bias is observer bias where the doctor is a
22 cheerleader and physical therapy is used as an
23 outcome. And blind observers would be a nice way
24 and should be a key component of any kind of
25 evaluation that's done.

00260

1 The second thing that we talked about,
2 or the second bias is that patient expectation is
3 a huge driver of outcomes. Let's go back to the
4 European studies where both the operative and
5 nonoperative groups get better, so we're talking
6 about perhaps a small difference, a small
7 comparative difference. Well, even if you have 15
8 to 20 percent placebo effect, and although the New
9 York study on arthroscopy is controversial, this
10 could be even more controversy because the spine
11 surgery is genuine for the most part. There are
12 ways to get around this, there are people working
13 on this issue, but it will be the only way to
14 disentangle the effect of the patient's
15 expectation on outcome, which we know from that
16 New York arthroscopy study is a huge driver of
17 outcome.

18 Just by way of review, in the New York
19 arthroscopy study, patients were randomized with
20 knee arthritis and had to go through arthroscopy
21 on that knee and had IV sedation and they made a
22 few cuts on the knee, and they were watching their
23 own arthroscopy being performed, whereas in the
24 other arm they came to the operating room, got the
25 IV, got a few cuts on their knee, and were

00261

1 watching somebody else's arthroscopy being
2 performed, they simply got the three cuts on their
3 knee. The outcomes in both groups were identical
4 at every time point after the surgery. It's very
5 telling about the role of the operation and the
6 patient's expectations about the operation. I
7 think that should at least be a component of the
8 discussion as we move forward.
9 DR. KIRKPATRICK: I agree with the
10 spirit of an RCT. I think the selection criteria
11 and crossover issues, the nature of nonoperative
12 treatment issues, as well as the clarification of
13 outcome issues that have already been discussed
14 make that very complicated. So I would ask you to
15 rephrase the question, do you mean tomorrow or do
16 you mean in five years? Because if you're talking
17 about five years out, could we develop a
18 reasonably good randomized clinical trial, I think
19 in the meantime we could do some very good
20 longitudinal follow-up on prospectively enrolled
21 patients to be able to define some of the other
22 issues that have been raised, like complication
23 rates, comorbidity issues.
24 DR. ONDRA: I agree that I would do
25 both, and some of these issues would be a tough

00262

1 sell for a first line surgery.
2 DR. FACISZEWSKI: The randomized
3 controlled trial should be designed with the
4 outcome of surgery (inaudible) United States. And
5 it's industry-sponsored with limitations, but they
6 were prospective consecutive series of cases, and
7 actually they're a very good consecutive series,
8 and it gives us a benchmark for use in the future.
9 And I agree with the comments about some
10 limitations in a randomized trial. As a surgeon,
11 it's impossible to keep patients from being
12 operated on for a year and not working, they'll go
13 to another expert for the surgery. Long-term
14 perhaps, but short-term I think we need to at
15 least look at the prospective series.
16 Lastly, I think we need to know what
17 effects, if any (inaudible). When we looked at
18 the nonoperative treatments, they weren't
19 consistent either. The question is what power did
20 they have or what effect, and I think we spoke

21 about this earlier, but I think this is the place
22 to actually make a statement about that as well,
23 because the fusion patients, as they were compared
24 to the nonoperative group, they weren't compared
25 to no treatment at all, and where I think we're

00263

1 giving credit for nonoperative care, it may not be
2 any, I'm not sure what that effect is yet. I
3 think we need to study it.
4 DR. JARVICK: And I think we talked
5 about the problem with a case series with
6 uncontrolled data, and while it's very good and
7 very useful for complication risks, for looking at
8 outcomes, comparing one group to another, it's
9 totally, I wouldn't say totally useless, but it
10 definitely has its limitations. Getting back to
11 the issue of a sham that was mentioned, there may
12 be some compromise ground that one could take. We
13 may potentially be able to bring them into an
14 angio suite, what we talked about earlier, having
15 some sort of needle intervention, give them
16 anesthesia so they don't really remember what
17 happened, and drape them and prepare them, and
18 then make the intervention sort of as sexy as
19 possible, make them think they're having something
20 done, and it may have a benefit on those patients,
21 and we don't really know at this point. So I
22 agree that placebo effect is potentially important
23 and that is something we should try and get at
24 somehow.
25 DR. KRIST: I think we have gotten a

00264

1 lot of good information for all the spine surgeons
2 in this room, so why don't we move on to Question
3 Number 4, and I'm going to try to go quickly on
4 this.
5 DR. BURCHIEL: Before we start, I
6 looked at this form and I'm a little puzzled
7 because if I look at B, C and D, the without
8 instrumentation doesn't make sense, so I would
9 throw that back to the spine surgeons.
10 DR. KIRKPATRICK: Gutter fusion is
11 appropriate to have both columns, because the
12 gutter could have a noninstrumented posterolateral
13 fusion in it. As far as posterior lumbar
14 interbody and transforaminal interbody, some
15 people will do a posterior lumbar interbody
16 without instrumentation, some people -- I know few
17 people would do a transforaminal without
18 instrumentation, but some people do, so those are
19 relevant, but they weren't really separated out
20 well for us today. Anterior lumbar interbody, I
21 agree with you. My interpretation is going to be
22 that, you know, the with instrumentation is
23 actually the 360, that's how I would view an

24 anterior lumbar interbody fusion with
25 instrumentation, because I don't know that's there

00265

1 enough data or I've seen enough people put plates
2 across an anterior lumbar interbody fusion, so
3 that would be the with instrumentation category.
4 So that's how I would look at it. I hope that's
5 reasonable.

6 DR. KRIST: So you would have with
7 instrumentation, and C would not have with
8 instrumentation?

9 DR. KIRKPATRICK: In other words, C, I
10 was going to leave out the with instrumentation,
11 and then still have all the others to vote on.

12 DR. JARVICK: Alex, I just have a
13 clarification. I know we discussed this already
14 but I wasn't quite sure what your answer was.

15 When we talk about improved health outcomes for
16 lumbar degenerative disc disease, is that in
17 comparison to nonoperative care or not?

18 DR. KRIST: Yes, I think it's overall.
19 I know that's difficult, but we're looking at it
20 overall, and so I'm not sure you can compare one
21 to just the other.

22 DR. FLUM: I read this too as efficacy
23 of data, in other words, all the observational and
24 other series are going to apply, and is there
25 evidence that these things improve health

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1 outcomes.

2 DR. KRIST: Yes.

3 MR. QUEENAN: In contrast to
4 Question 3, this is not compared to conservative
5 care.

6 DR. KRIST: Well, no, I think for both
7 of them, I think some of the interpretation has to
8 be the quality of the evidence, and just if you
9 believe that the time period, that they improve
10 over time, I think they're looking to see if it's
11 the procedure that's resulting in their
12 improvement, and not just do they improve. They
13 could be subject to all the biases that we talked
14 about. I think the purpose of Question 4 is does
15 this procedure itself result in the improvement.

16 DR. JARVICK: So if our answer to
17 Question Number 3 was we didn't think there was
18 good evidence overall, then --

19 DR. KIRKPATRICK: Question 4 should be
20 the same. Question 4 is stratifying Question 3.

21 DR. KRIST: Yes, for each specific
22 procedure compared to -- so yes, if you put it in
23 the context, if you didn't think that 3 was
24 particularly helpful, then your vote should mirror
25 that on some level in 4. Is that what you're

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1 looking for, Steve?
2 DR. PHURROUGH: Yes, although you could
3 find that there was a lot of evidence for one.
4 DR. KRIST: So you might say one of
5 these is particularly good, so maybe one would get
6 a five, and the other three wouldn't be overall.
7 Is everyone clear on this now, before we move
8 forward?
9 DR. LURIE: Because I didn't understand
10 what the answer was, is with instrumentation as
11 compared to the same thing without
12 instrumentation, or is with instrumentation and
13 incremental benefit to without instrumentation,
14 which one?
15 DR. KRIST: I think the premise, the
16 concept --
17 DR. LURIE: If you have posterolateral
18 fusion without instrumentation or posterolateral
19 fusion with, you want us to somehow vote on these
20 two things, right? The question is if we're
21 comparing, I think I just hear we're comparing
22 posterolateral fusion without instrumentation to
23 conservative care. Then when you say with
24 instrumentation, are we considering the
25 incremental benefit of adding instrumentation to

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1 the posterolateral fusion, comparing with or
2 without instrumentation, the way most of the
3 studies do, or are we comparing with
4 instrumentation to conservative care?
5 DR. KRIST: To complete things here,
6 what we're asking you to vote on is not
7 necessarily what we have evidence on, okay? So
8 think about it from the standpoint, I'll just use
9 concrete, and I'm going to make the scenario, if
10 you think that gutter fusion without
11 instrumentation is slightly effective, but with
12 instrumentation is more effective, you might say
13 three for one and four for the other. But it
14 doesn't necessarily mimic what we have evidence
15 on. It's, does this procedure improve outcomes,
16 and so it would be does the procedure with
17 instrumentation improve outcomes, and it would be
18 does the procedure without instrumentation improve
19 outcomes, not necessarily the relative, although
20 the difference between the two will tell us that.
21 MR. QUEENAN: Both compared to
22 conservative care.
23 DR. KIRKPATRICK: But I thought what
24 you said was if I felt that the efficacy was
25 better, not the evidence, and I thought what CMS

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1 was asking for was the evidence.
2 DR. KRIST: No, it is the evidence, and

3 I apologize for saying efficacy. It's the
4 evidence, okay? All right. Let's go through
5 with 4. Under short-term, and I'm going to do
6 without instrumentation first and then with
7 instrumentation. So we'll look at posterolateral
8 gutter fusion without instrumentation, so you can
9 vote on that one first.
10 MR. QUEENAN: Alex, I apologize. This
11 is based on the evidence, what we think the
12 evidence is, not a judgment on the evidence
13 itself.
14 DR. KRIST: Correct, based on the
15 evidence.
16 DR. KIRKPATRICK: Accepting that it may
17 not be great.
18 DR. KRIST: Right. So for 4.A,
19 posterolateral gutter fusion without
20 instrumentation.
21 (Panelists voted.)
22 DR. KRIST: Now posterolateral gutter
23 fusion with instrumentation.
24 (Panelists voted.)
25 DR. KRIST: Now for posterior lumbar

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1 interbody/transforaminal interbody without
2 instrumentation.
3 (Panelists voted.)
4 DR. KRIST: And now with
5 instrumentation.
6 (Panelists voted.)
7 DR. KRIST: Now anterior lumbar
8 interbody without instrumentation.
9 (Panelists voted.)
10 DR. KRIST: Now anterior/posterior
11 combined without instrumentation.
12 (Panelists voted.)
13 DR. KRIST: And now anterior/posterior
14 combined with instrumentation.
15 (Panelists voted.)
16 DR. KRIST: Now we'll move to
17 long-term, meaning more than two years post fusion
18 surgery. So posterolateral gutter fusion without
19 instrumentation.
20 (Panelists voted.)
21 DR. KRIST: Okay. Now with
22 instrumentation.
23 (Panelists voted.)
24 DR. KRIST: And now for long-term
25 posterior lumbar interbody/transforaminal

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1 interbody without instrumentation.
2 (Panelists voted.)
3 DR. KRIST: And with instrumentation.
4 (Panelists voted.)
5 DR. KRIST: Okay. And anterior lumbar

6 interbody without instrumentation.
7 (Panelists voted.)
8 DR. KRIST: And anterior/posterior
9 combined without instrumentation.
10 (Panelists voted.)
11 DR. KRIST: And anterior/posterior
12 combined with instrumentation.
13 (Panelists voted.)
14 DR. KRIST: Okay, good job. Does
15 anyone have anything unique about the discussion
16 point on 4? It's similar to 3 but specific to
17 procedures. I'm assuming we can move on to 5.
18 DR. KIRKPATRICK: If I could suggest, a
19 refinement of the indications for each should be
20 explored. In other words, if there is a benefit
21 to doing one of these techniques in certain
22 (inaudible). Maybe one with degenerative disc
23 disease and facet arthropathy needs a 360, whereas
24 if it's just degenerative disc disease, a
25 (inaudible) some sort of project looking at that

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1 sort of question would be the ideal thing.
2 DR. KRIST: Okay. Question Number 5,
3 what level of confidence does the evidence provide
4 that radiographic interpretations are correlated
5 with clinical outcomes of lumbar spinal fusion due
6 to lumbar degenerative disc disease?
7 (Panelists voted.)
8 DR. KRIST: And then the discussion
9 question, is there uniform agreement regarding
10 terminology for radiographic interpretations? And
11 I mostly saw ones and twos, so I doubt that there
12 is much of a discussion with that.
13 DR. JARVICK: Actually, I think the
14 fact that there were ones and twos is because the
15 studies don't easily correlate the outcome after
16 spinal fusion isn't the same as is there a
17 standardized nomenclature. There in fact is a
18 reasonably standard nomenclature for describing
19 degenerative disc changes that all the major
20 societies have signed on to, this was published
21 four or five years ago. I mean, there is a
22 standardized nomenclature, but how well it
23 predicts or correlates is a whole other issue.
24 DR. FACISZEWSKI: As one of the
25 co-authors of that paper, not many people use

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1 those terms.
2 DR. KIRKPATRICK: So my suggestion on
3 is there agreement, no, because many clinicians
4 don't agree.
5 DR. BOYAN: I'm saying it's so bad that
6 every time there's an FDA panel, they have to
7 bring in an imaging expert to explain it to
8 everybody in the room.

9 DR. JARVICK: Fair enough. You know,
10 people should be using these terms, put it that
11 way.
12 DR. KRIST: It will probably support
13 their use if it's linked to clinical outcome, then
14 there would be a motivation.
15 DR. FACISZEWSKI: There is a great deal
16 of misconception, and I think that's why, part of
17 the reason we're here is because people are
18 talking about degenerative disease and low back
19 pain, and pretty soon everyone thinks it's a huge
20 problem, and I'm not sure that's the case.
21 DR. JARVICK: Well, until people do
22 start using the standardized nomenclature, it
23 makes the research very hard to do and the patient
24 selection classification hard to do. So again, I
25 think the nomenclature is there and should be

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1 used.
2 DR. KRIST: It probably goes beyond
3 just the radiographic nomenclature to the
4 diagnostic nomenclature as well.
5 All right, Question 6. Based on the
6 evidence presented, how likely is it that the
7 results generalize to the Medicare population, and
8 then for A, relief of pain?
9 (Panelists voted.)
10 DR. KRIST: Okay. And then B, for
11 complications, adverse events and harm?
12 (Panelists voted.)
13 DR. KRIST: And the discussion point
14 here is, do studies need to be done in the
15 Medicare population to strengthen the conclusions,
16 and what is the impact of age and comorbidities?
17 DR. BOYAN: I have been waiting calmly,
18 because obviously I think you have to do studies
19 in the Medicare population, but I think there are
20 things that need to be said to people here. And
21 that is even though old people do heal, they don't
22 heal the same as younger people do. They heal
23 more slowly because they have issues related to
24 age that are not, I wouldn't call them
25 comorbidities, it's just the fact that they're

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1 older. They have fewer defensible stem cells,
2 they heal more slowly, they may have other defects
3 that are not the same as young adults. So you
4 can't just assume that if something is working one
5 way in a younger population, that it's going to be
6 working as well in an older population. So we
7 have no question that it has to be effective for
8 the Medicare population. And then when we get to
9 the comorbidities, obviously the incidence of
10 disease is greater, and these are also true for
11 chronic diseases, autoimmune issues, and those

12 things are all going to impact the outcome, so it
13 has to happen.
14 DR. KIRKPATRICK: With all due respect
15 to Barbara, I agree with her on a basic science
16 level. There are clearly differences among ages.
17 However, my concern is that the expense and
18 logistical complications of trying to do such a
19 study in an over 65 group may not be enough
20 benefit to warrant those hassles. And so, you
21 know, that's my major concern.
22 I do think that we need to bring up the
23 issue of physiologic age as opposed to arbitrary
24 chronologic age, because it does appear that many
25 of our population is maintaining their health

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1 longer now, as we see by the rising mortality
2 ages, things like that. They're more active and
3 this all may translate into changes in the way
4 that you in fact heal. So I think that's another
5 concern to bring up. And I think another key
6 thing with comorbidities, we just don't know how
7 much that affects with the results and that would
8 be a better concentrated effort on comorbidities
9 than on the age factor.
10 DR. FACISZEWSKI: If I could just add
11 that my understanding is that not all Medicare
12 patients are over age 65, some are actually in the
13 disabled group, some of which may have disabling
14 back pain and be under age 65, and therefore may
15 reflect more equality with the cohorts that were
16 presented in the research. So my vote was related
17 to the over 65, and I'm assuming the question was
18 related largely to over 65 in a percentage basis,
19 but certainly not to diminish the Medicare
20 patients who are under age 65, and I would be very
21 happy to learn about that component of the
22 Medicare population.
23 DR. FLUM: I would like to add to that,
24 because specifically the point that's been raised
25 about the lack of nonoperative interventions in

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1 the United States, I think it would be very hard
2 to imagine the randomized trials from Europe would
3 have similar results in the United States when
4 comparing usual care and nonoperative care. But
5 in the absence of a designed and well reimbursed
6 nonoperative intervention, how likely it is
7 generalized to this population here, I think
8 that's problematic.
9 DR. KRIST: Okay. Now one of the
10 things we'll do is go down the table and have
11 folks make comments and sum things up, but we've
12 done a lot of talking as we've gone through these
13 questions, so maybe I will end with that, and if
14 anyone feels like they have anything to say on

15 this topic that they haven't had a chance to say
16 already.
17 DR. JARVICK: I would like to make one
18 comment, that I think there is a real opportunity
19 here for CMS to play an active role in helping to
20 gather the evidence that seems to be lacking. And
21 I think we talked about the hurdles of doing
22 randomized trials in this country, a lot of which
23 center around incentive for patients to enroll and
24 paying for the procedure, and production of
25 trials, and CMS could play a vital role in that.

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1 DR. FLUM: And just to build on that
2 point, if we are going to change the way we
3 reimburse for surgery, I think it's a great
4 opportunity.
5 DR. BURCHIEL: I think there is one
6 thing we haven't talked about, or indirectly, that
7 the bulk of the patients who get the surgery are
8 not in the Medicare age range or beneficiaries,
9 but insurance companies look to CMS for
10 leadership, I think that's why everyone is here,
11 because what happens here has import across the
12 board in the marketplace. So I for one don't
13 understand why CMS or NIH has the awesome
14 responsibility for a study that's going to be very
15 difficult and expensive, and largely relevant to
16 patients outside the Medicare population. I think
17 it's a broader issue because we talked about
18 consortium that might include industry. This is a
19 massive issue not just for CMS.
20 DR. KRIST: We appreciate all the
21 expertise in this room and thank you for taking
22 the time today to come here.
23 DR. MANCHIKANTI: I think in the
24 elderly population, we are missing a point. If
25 you look at the diagnosis, many of them have facet

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1 joint pain, but probably one of the things we can
2 do is eliminate the facet joint pain before going
3 to fusion, and that would be the proper case.
4 DR. KRIST: Thank you.
5 DR. PHURROUGH: All right. Thank you
6 all, particularly the panel for your time and
7 effort. This is a lot of work, a lot of stuff to
8 read and do. Many of you will want to know what
9 our next steps are. I lied, and we are going to
10 do an NCD.
11 (Laughter.)
12 No. We will produce a fairly
13 substantial set of minutes from this discussion.
14 We are interested in proceeding with sort of
15 outlining the data selection that needs to occur
16 both in terms of a long-term discussion around
17 what a good trial should look like versus some

18 ongoing data collection observational type of
19 data, what can we as an agency do to assist with
20 that, are there coding or claims issues we can
21 work on to assist with that.
22 And we have taken, as you've heard
23 today, taken the opportunity over the last couple
24 of years to use different tools and techniques to
25 stimulate data collection, and we would like to

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1 have continuing discussions around how we can best
2 utilize those tools in this particular arena. I
3 don't think we will mimic LDRS where we were
4 concerned with 18 percent of mortality where we
5 stopped covering the surgery and required it only
6 in a trial. I think we would have a difficult
7 time to say we're no longer going to pay for
8 fusions, that would be a challenge. But we are
9 interested in continuing interaction that will not
10 stop here today, but will assist the community,
11 you, the providers and patients in understanding
12 what are the best treatment for low back pain.
13 So thank you, panel, again, and the
14 audience for assisting us today. The meeting is
15 adjourned.
16 (Whereupon, the meeting adjourned at
17 2:54 p.m.)

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