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CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Coverage Advisory Committee

January 25, 2005

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

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Panelists

Chairperson
Ronald M. Davis, M.D.

Voting Members
Rita F. Redberg, M.D., M.Sc.
Clifford Goodman, Ph.D.
Anne B. Curtis, M.D.
Tracy R. Gordy, M.D.
Paul H. Barrett, Jr.
Tammy L. Born, D.O.
Mary W.L. Lee, Pharm.D.
William F. Owen, Jr., M.D.
Mark Slaughter, M.D.

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

Industry Representative
Patricia L. Garvey, Ph.D.

Consumer Representative
Charles J. Queenan, III

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Panelists (Continued)

Non-Voting Guest Panelists

Christina Biesemeier, M.S., R.D.
William H. Herman, M.D., M.P.H.
Pamela Snider, N.D.

Executive Secretary
Michelle Atkinson

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PANEL PROCEEDINGS

(The meeting was called to order at 8:25 a.m., Tuesday, January 25, 2005.)

MS. ATKINSON: Good morning and welcome, committee chairperson, members and guests. I am Michelle Atkinson, an executive secretary for the Medicare Coverage Advisory Committee. The committee is here today to discuss the evidence, hear presentations and public comment, and to make recommendations regarding physician-supervised health enhancement program

for symptomatic coronary artery disease. The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record. The conflict of interest statute prohibits special government employees from participating in matters that could affect their or their employer's financial interests. To determine if any conflict existed, the Agency reviewed all financial interests disclosed by the committee participants. The Agency has determined that all members may participate in the matters before the committee today. With respect to all other participants,

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we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any physician-supervised health enhancement program for symptomatic coronary artery disease. This includes direct financial investments, consulting fees, and significant institutional support. If you haven't already received a disclosure statement, they are available at the table outside this room. We ask that all presenters adhere to their time limits. We have a large number of presenters to hear from today and a rather tight agenda, and therefore can't allow extra time. There is a timer at the podium that you should follow. And panel members, we're sharing mikes today so you might have to move them around, just to let you know. I would now like to turn the meeting over to Dr. Steve Phurrough.

DR. PHURROUGH: Thank you, Michelle. I am Steve Phurrough, director of the Coverage and Analysis Group. I want to welcome you here today. Particular thanks to the panel members for braving the weather. There were a few who were unable to

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get out of the northeast, a couple folks snowed in at Boston and Cape Cod. If you've got to be snowed in, I guess there are worse places to be at, but we do appreciate you being here. Let me just review for those who perhaps may be new to the process, our goals today. In general, we've had these MCACs in the past around some of our national coverage determination processes. However, in the last year we have begun having these MCACs in preparation for a potential coverage decision. Particularly because of some of the tight time lines we have with our NCD, we not uncommonly have, and will begin to ask these questions of what the evidence demonstrates as we are

considering NCDs in the future. The goal here today is to get recommendations from the panel on what they believe about the evidence. Their goal is not to tell us that we should pay for something, those are decisions that are made internally within the Agency with additional public input, but to tell us what they believe that the evidence demonstrates about the ability of these particular programs to offer benefit to our patient population. We look forward to a very

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informative and spirited discussion, and will encourage those of you who are both scheduled and not scheduled commenters to join us in this particular discussion.

I must apologize. I will be needing to step out on a couple occasions. We have a couple of fairly major issues that are being decided this week in the coverage arena, and I will be stepping out, and Dr. Saliz will be filling in while I'm out. I apologize, and hopefully that will not be distracting. With that, I turn it over to Dr. Davis.

DR. DAVIS: Thank you very much, Steve and Michelle. My main task today is to keep us on track, and I'll do the best I can. If any members of the panel have any questions about the process, please feel free to ask during a break and I will do what I can to answer and to keep things running smoothly.

The first thing we need to do is to introduce ourselves and to make any disclosures of conflict of interest. As Michelle mentioned, the priority would be to focus on any financial conflicts of interest, but certainly I think we ought to err on the side of caution if there is

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any potential conflict of interest, financial or otherwise, so I would like to ask the members of the panel to please disclose it as we do introductions.

So, I will begin. I'm Ron Davis, I am chair of the MCAC and a preventive medicine physician at the Henry Ford Health System in Detroit. Another hat that I wear is as a member of the board of trustees of the American Medical Association, but I'm not representing the AMA in any official capacity here today and I have no conflict of interest disclosures to make. Rita.

DR. REDBERG: I'm Rita Redberg, a cardiologist and professor of medicine at the University of California, San Francisco, and I have no disclosures.

DR. GOODMAN: Cliff Goodman, with the Lewin Group, a consulting firm. I have no financial conflicts of interest on this matter.

DR. CURTIS: Anne Curtis, professor of medicine and Director of Electrophysiology at the University of Florida, and I am president elect of the Heart Health Society, and I have no conflicts of interest to disclose.
DR. GORDY: I'm Tracy Gordy, I'm a

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psychiatrist. I consult for JCR, I'm the chair of the AMA CPT panel, but I'm not representing either of these organizations here today, and have no conflict of interest.
DR. BARRETT: I'm Paul Barrett, Director of Research for the Colorado Region of Kaiser Permanente. I have no financial disclosures today.
DR. BORN: My name is Tammy Born. I'm a general practitioner at the Born Preventive Healthcare Clinic, and I have no financial disclosures.
DR. LEE: My name is Mary Lee, I'm a professor at the Chicago College of Pharmacy and I have no financial conflicts of interest.
DR. OWEN: Good morning. I'm Bill Owen, I'm a senior scholar and professor of medicine at Duke University. I have no conflicts of interest.
DR. SLAUGHTER: I'm Mark Slaughter, a cardiac surgeon and director of cardiac surgery and research at Advocate Christ Medical Center in Chicago, and I have no conflicts of interest.
DR. GARVEY: I'm Patricia Garvey, I'm an employee of Edwards Lifesciences, but I have no

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conflicts of interest to disclose today.
MR. QUEENAN: I'm Charlie Queenan, I'm the consumer representative. I'm also a member of the board of the Juvenile Diabetes Research Foundation, and I have no conflicts of interest to disclose.
MS. BIESEMEIER: I am Chris Biesemeier, I am assistant director of nutrition services at Vanderbilt University Medical Center and also am on several focus analysis work groups for the American Dietetic Association, and author of an evidence-based guide for the ADA, and I have no financial interests to disclose.
DR. HERMAN: I am Bill Herman. I'm an endocrinologist and professor of internal medicine and epidemiology at the University of Michigan. I also direct the Michigan Diabetes Research and Training Center and serve as associate medical director of the university's HMO. I have no financial conflicts of interest to disclose.
DR. SNIDER: My name is Pam Snider. I'm a naturopathic physician. I'm on the faculty of Bastyr University, teaching and doing research.

I am also an investigator with NIH public medical research, which I'm doing with the NIH Center for
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CAM. And I am the director of the Academic Consortium for Complementary Health Care. I have no conflicts of interest to report.
DR. DAVIS: Thank you very much. And just a friendly reminder to members of the panel and also members of the audience that this session is being recorded and our friendly transcriber Paul is going to do his best to take down all of the comments to help CMS compile minutes after the meeting is over, which will in turn go on the Agency's web site.
So thank you for those introductions and disclosures, and we'll just in the interest of time press ahead with the agenda which, as Michelle mentioned, is a heavy one today, and we will do our best to stay on track and get everyone out on time so that they can get to the airport and catch their flights back home.
So, the next item on the agenda is the presentation of the voting questions by Clay Farris.
MR. FARRIS: Good morning. These are the questions we ask you to consider as you hear today's presentations and that we will ask you to evaluate the evidence of at the end of the day.
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Number one: How well does the evidence address the effectiveness of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease as compared to usual medical and surgical management?
Two: How confident are you in the validity of the scientific data on the following outcomes with respect to physician-supervised behavioral interventions for patients with symptomatic coronary artery disease? Cardiac events including angina. Long-term survival. Short-term survival. And, quality of life.
Three: How likely is it that physician-supervised behavioral interventions for patients with symptomatic coronary artery disease will positively affect the following outcomes when compared to usual medical and surgical management? Cardiac events including angina. Long-term survival. Short-term survival. And, quality of life.
Four: How confident are you that physician-supervised behavioral interventions will produce a clinically important net health benefit in the treatment of patients with symptomatic coronary artery disease?
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Five: Based on the scientific evidence

presented, how likely is it that the results of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease can be generalized to: The Medicare population aged 65 and up, and providers, facilities and physicians, in community practice?
DR. DAVIS: Thank you very much. Any questions or comments? Yes, Anne.
DR. CURTIS: I just want to make sure I understand these as we go through them, because it seems to me that one and two address, do we have enough data to figure out the answer, and number three is, is the answer yes or no? I mean, is that boiling it down to what we're trying to do here? You get what I mean? I mean, number one says how well does the evidence address, and I assume that means do I have the data to be able to make a decision, and if those studies being presented today aren't very good, then I don't have the data, and then the same thing for number two, and then number three asks me to say what I think is a positive or negative. Is that fair?
DR. DAVIS: That's correct. Any other questions or comments about the questions

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themselves? If not, we'll move ahead to the presentation of the technology assessment, with Dr. Alex Clark from the University of Alberta Evidence-Based Practice Center.
DR. CLARK: Good morning. Members of the committee, ladies and gentlemen, it's a pleasure and a privilege to be here this morning to present findings of this technology assessment entitled Randomized Control Trials for Secondary Prevention Programs in Coronary Heart Disease, a Systematic Review.
My name, as Dr. Davis said, is Alex Clark. I am with the Evidence-Based Practice Center at the University of Alberta. I consult to the Scottish National Heart Disease Demonstration Project and am presenting today also on behalf of my colleagues at the university, Lisa Hartling, Ben VanderMeer, and Dr. Finlay McAlister.
A brief background, then. Where are we coming from here? There is an enormous cost and burden in the United States of America, and it started quite contemporaneously. Cardiovascular disease each year has been the single biggest cause of death in the United States since 1900, with the exception of one year. It accounts for

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38 percent of all deaths of Americans. The cost both direct and indirect on the U.S. society are extensive, estimated by the American Heart Association to be $393 billion this year.
70 million Americans have known

cardiovascular disease. 27 million of these patients are over 65 years of age. 13 million Americans have diagnosed coronary artery disease. Around about 7 million of these people have MI heart attack, and about 6.5 million have diagnosed angina.

How are these constants going to be changed in the future? Well, the signs are grave. Obesity rates have risen 75 percent in the United States since 1991. 40 percent of the American population are sedentaric, and the proportion of Americans who have two or more risk factors for heart disease has increased by 4.5 percent in the nine years, the last nine years, and around 30 percent of Americans now have two or more risk factors.

What can we do to reduce this burden? Well, recent findings and findings historically epidemiologically would indicate that we need to target at least nine modifiable risk factors,

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these risk factors being abnormally high lipid levels, smoking, hypertension, diabetes, obesity, psychosocial factors, consumption of alcohol, fruits, vegetables, and physical activity levels. And these risk factors are not just linked to heart disease, they're also linked to diabetes and they're also linked to cancer as well.

And this has resulted last year in a joint statement by the main American societies for diabetes, cancer and heart disease coming together for a consensus statement on these risk factors in relation to these three conditions which affect billions of people all over the world.

So we need to talk of the risk factors. We also need to stop people from developing coronary heart disease in the first place, a strategy known as primary prevention, through initiatives in the schools, for example, so we target people who may develop coronary heart disease in future generations.

Many people, though, have coronary artery disease already and we need to delay or prevent further worsening of that disease, and this is the secondary prevention technique here for the heart disease population. We also need to

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promote evidence-based care in relation to lifestyle change and pharmacological therapies. There are studies in both America and in Europe that highlight that people often don't get the right services and often don't get the right medications they need to make the changes that they can make to their respective profiles.

And the reason for this is because we're not utilizing what we do know about health behaviors

and what we do know about pharmacological strategies so as to get health professionals to practice evidence-based health care. The latest findings suggest that around 40 percent of patients with heart disease get the medication and support that they should get. With the wealth of evidence supporting these interventions, this prevalence is better than it was 10 years ago, but arguably still not good enough.

The programs that we're going to look at today target three of these strategies. They address risk factors through promoting evidence-based care in a population with coronary heart disease. Now, what's the point, you may say. Surely from the meta-analyses that have been

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done previously in the 1980s and 1990s, there is good evidence to the benefit, for example, of exercise as rehabilitation. The works in this area by the likes of Algens or Conner, well, yes, that work was useful, but guidelines now recommend that we need to address not just one risk factor but a range of risk factors for cardiovascular disease.

And this brings us to what we are considering today, physician-supervised behavioral interventions for symptomatic heart disease. Now I appreciate the issues with perhaps defining what we actually mean by this. Well, in the review that we're going to present today, we categorized three types of programs as falling beneath this general rubric. These programs are comprehensive cardiac rehabilitation programs, which are group-based exercise programs plus education and counseling on the range of cardiovascular risk factors. The second type of program are cardiac rehabilitation programs which contain group education and counseling on risk factors, but with no structured exercise conformance. And also, we're going to be looking at individual counseling programs which tend not to be group-based but

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involve individual-provided education, counseling and follow-up around risk factors. And we're going to be making distinctions between these three different types of physician-supervised programs throughout the presentation.

What are the common characteristics of these programs? Well, they tend to be comprehensive as I have indicated, addressing a range of cardiovascular risk factors. They are often directly or indirectly supervised by physicians but care is actually provided by members of a multidisciplinary health care team, most frequently nurses or physiotherapists,

supplemented by other parts of the intervention by psychologists, dietitians and cardiologists as well.

The programs tend to include patient education elements, health promotion initiatives where people are given information about the causes of cardiovascular disease and what they can do to change them. Often, the interventions involve risk factor intervention such as smoking cessation interventions or interventions that promote physical activity. The programs quite often provide the use of guidelines, be it

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relating to medications or content, the core components, if you like, of the program. Programs tend to involve some form of assessment and consultation where a health professional comes face to face with an individual or a group and assesses their needs and provides them a package of care or services based on those needs and discussions.

And finally, the programs often involve some assessment of drug therapies. Are the patients seen in the programs getting the right services and the right medications. The programs make sure they are getting the right medications and the right dosages, and are referred to the right services.

So with that said, the aim of our review is to determine whether these programs for patients with established coronary artery disease improve health outcomes. We will be presenting what's called the systematic review or meta-analysis where we looked at rigorous randomized control trials in these programs to look at their effects compared to usual care.

Methodologically, what did we do?

Well, we searched all the usual suspects,

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databases. We searched the bases to include lists of previous research done in this area, and it gives detailed descriptions of these research studies. And we supplemented this search with a review of PubMed for more recent publications, cited references in World of Science, some of which we also found through the search engines. And we also conducted a hand search and author contact as well.

Methodologically, myself and Dr. McAlister independently reviewed the titles and abstracts of relevant studies, and from the full texts we screened the eligibility criteria which I will detail in one moment, to identify those studies which were most rigorous. We then extracted outcomes from these papers and these were double checked by a member of the team, Ben

VanderMeer. If important data were missing, where possible we tried to contact the original investigator to get some form of clarification or information on data that we were missing. Finally, Dr. McAlister and myself also independently assigned each program to one of the three groups, comprehensive cardiac rehabilitation, contact rehabilitation, or

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individualized counseling group. What exclusion criteria did we use to screen the programs? Following conventional hierarchies of evidence as in previous reviews that were undertaken in 1999, we excluded studies that were not randomized. This most often involved demonstration projects and case control studies. We excluded studies that did not contain any patients with heart disease, that is, studies which focused on interventions dealing with primary prevention. We excluded studies that only focused on one particular risk factor, what we call single modality interventions, such as an intervention for physical activity only or diet only. We also excluded studies that had no outpatient component. This would be studies that contained interventions that were provided before a patient was discharged from hospital with coronary artery disease. We excluded studies that had no usual care arm, because only with a usual care arm in place could you then compare how the programs perform against what the patients would usually

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get. We excluded studies of interventions not provided by health professionals. This would be self-directed interventions, where patients do the intervention themselves effectively, or an intervention that involves no face-to-face contact with a health professional. Also, we excluded studies which included outcomes data for less than 50 patients. This was done to avoid type one and type two statistical errors which often can contribute effect to an intervention, and reflects conventional levels of evidence in hierarchies of evidence used in reviews of this kind. Now we're not stating that no useful studies exist with these criteria, nor are we saying that these criteria are not debatable, but these criteria do define guidelines for use of this type, guidelines of cardiovascular treatment, and also the questions set by the committee and how we can best answer those questions.

So what did we actually do in terms of reviewing papers? Well, for our study, we identified over 6,300 potential studies. Both McAlister and myself independently reviewed the

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abstracts of these studies which are short descriptions of the studies, and we identified 231 for potential inclusion. Many of these were not relevant for one reason or another and we describe the reasons here. Eventually this led to 51 studies being identified. However, ten of these studies contained findings that were reported in more than one paper, so there were really only 41 original studies within this group of 51.

How did these numbers compare to previous systematic reviews? Well, we introduced 29 more studies than were in the previous review by Dr. McAlister in 1999, only including studies up to that time point, but we also included 22 more studies that were included in the recent Exercise-Based Cardiac Rehabilitation Guidelines by Cochran in the United Kingdom.

A little side note here: That Cochran review included the WHO standard trials as separate trials. We grouped those trials together in one trial and we tested the statistical acceptability of that and that was found to be acceptable. So these numbers in themselves further point to the effectiveness of our review here.

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Our primary outcome was looking at mortality. Did the programs help patients live longer. Second, we had an interest in recurring MI; did the programs help prevent patients getting heart attacks? We also looked at hospitalizations; do the programs help avoid hospitalizations to do with heart attacks? And we also looked at quality of life, effect on risk factors, effects on increased use of statins, and finally, effects of patient functional status, reflecting what they could do day-to-day in their lives. All these comparisons were made comparing the programs to usual care, and the statistics were performed using Revman 4.2.

Okay, what did we find? Well, in isolation, one out of the 27 trials reported a significant survival benefit at 12 months. This represents an 11 percent mortality benefit. However, it was not quite enough to reach statistical significance. There is still some doubt here about whether these programs effectively reduce mortality at a 95 percent level. It's very close based on this number, but not quite, and this is based on a very large cohort of patients.

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Systematically by program, this is comprehensive contact rehabilitation here, 14 percent reduction; again, very very close to reaching a statistical significance here, just shading the data to one side, and that is based on 3,254 patients. Cardiac rehab, a small amount of studies so therefore, not quite the same confidence interval, but similar results. And also close here, the individual counseling here, 10 percent reduction, also just short of statistical significance. And you can see across these three slides there are some programs here that show benefits, there are some that are not quite as effective, but the pool results show some effect. That was at 12 months or the point closest to 12 months. Let's examine the short versus long-term mortalities and here we do see an effect. Now I will just explain here, these studies here also contain four studies that examined outcomes at 24 months. Here we see a very marked reduction in mortality, a 47 percent mortality reduction. This means that the patient's risk of death was almost half, and from
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a health services point of view, we would need to treat 39 patients to save one life. The level for most medications is around 30 to 35, pretty similar, and we can be satisfied at a 95 percent level that the secondary prevention programs save lives at two years and five years, based on data contained in a fairly large number of patients and confidence intervals that are satisfactory. What about reinfarction rates, do these programs stop people from suffering more heart attacks? Well, one out of six in trials in isolation reported a significant difference in event rates. At 12 months, again, there was a very close but insignificant reduction of 11 percent in risk for MI, close again. Now similar results here between the comprehensive contact rehab programs, cardiac rehab programs, and the individual counseling programs. Hospitalization rates, do the programs prevent or reduce risk of hospitalizations? 13 studies reported outcomes on that. Firstly talking about cardiac and all-cause hospitalizations, and we defined hospitalizations as the number of times a patient was hospitalized at least once, so for each patient there is only
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one event. There was a significant reduction in hospitalization rates at 12 months, 50, 60, 24, all at statistically significant levels and all

based on large patient cohorts. This is for the all-cause and cardiovascular mortality, which suggests that we need to treat 21 patients to prevent one hospitalization. We do follow up the studies for the past 12 months. And you can see here the trends here for all-cause and cardiovascular hospitalization; virtually all the programs there show some positive effect with very few having less effect than usual care, and you see the levels of confidence down there.

Other end points. Quality of life and functional status, we had to pool these two together because actual data was very heterogeneous in terms of the measurement tools used. There was lots of variability here, but beyond that variability we identified 14 out of the 26 trials reported significant improvement in quality of life or functional status. But we need to qualify that with the statement that the measurements were very heterogeneous and this prevented us from pooling the data.

As far as cholesterol was concerned, 20

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of the 24 studies reported improvement in profiles, and within these 20 studies, 12 showed significant, statistically significant improvement. If you look at Table 3 in the report that we submitted, it indicates that effects were small to moderate.

How about the use of application of medication? Well, eight out of 20 of the studies showed significant application of at least one therapy in the program groups. Two of the programs showed a nonsignificant difference in prescribing rates, and ten programs showed no statistical significance whatsoever.

Now, I'll just qualify this with a comment. If one looks at the large studies on evidence-based care in America and also in Europe, one finds that the prevalence of application therapies in the usual care arm is uncharacteristically high compared to what one would normally expect in routine clinical practice and if anything, this has reduced the difference between the programs and the usual care, and I'll touch upon that issue when it comes to conclusions.

What are our conclusions? Well, in

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patients with coronary artery disease, the programs reviewed reduced long-term mortality. They showed a nonstatistically significant effect on short-term mortality. It was an effect that was very very, almost at statistical significance. What is noteworthy, in the two studies that looked at biological process they identified that there

were significant regressions of coronary atherosclerotic lesions in compliant patients at 12 months, but even with these regressions, there were no changes if you like hard outcomes at this point. So it would appear that the foundation for change and biological changes are happening at 12 months, but not quite at a level that is sufficient enough to show effect or significant effect to the hard outcomes. If we did more studies in future years, that may well change because we were so very very close.
The studies reported a significant reduction in hospitalizations, all-cause and cardiovascular only.
The studies clearly improve process of care, but we could not synthesize outcomes because of the heterogeneity of the measurements.
This study showed some reduction in

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health care costs. Let me just go back here just to reiterate on that. Six out of the 41 studies reported costs. However, only three reported or implied the interventions with cost savings with no data on that. One of the reports reported, through contact with an author, some cost saving.
Often these six out of 41 really didn't do any cost saving analysis, so it's really difficult for us to conclude beyond the fact that this may reduce health care costs.
Now with these trends in mind, I would like to propose some issues for consideration. We need to consider particularly the inconsistencies and effectiveness of the programs. Clearly some programs are more effective than others and we need to identify why that might be, why do some programs seem to perform better than others. The studies collectively give a little understanding of what we call the black box of the intervention, they don't really address at all which components or dimensions of the intervention really do promote the changes that we see. They don't discuss the specific mechanism that is in fact the intervention, or identify how these studies influence the willingness capacity in patients for

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the risk factor changes that we hear.
We also need to consider the generalizability of the findings to older patients in particular. We know that 38.5 percent of patients with coronary artery disease in America are over 65. However, 18 of the studies excluded patients based on age: The research in this area suggests that age is no barrier to risk factor change or benefit from these types of programs.
So although the studies didn't include, perhaps, a sufficient proportion of older patients as we

would like, there is good evidence there that benefits reflected in this younger population will be transferred to a more representative or older population.

What about generalizability to women? Well, it's perhaps an indictment on researchers that seven of the studies included no women at all, and 33 of the 41 studies had proportions less than 25 percent female participants. There may be reasons for that such as time commitment involved in participation or women's social support, particularly after hospitalization. There is no theoretical reason why the benefits will not be extended to women. More recently, specific

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guidelines have been published on health care for women. Women have particular social issues, particularly after MI, but there is no reasons why the physiological benefits of these programs cannot be transferred to women.

We also need to reflect on the transferability of these findings to the real world where patient compliance can be slightly lower than perhaps one finds in clinical trials, or self-commitment to the program may also be lowered.

Methodologically, we need to be very cognizant of the atypicality of the optimal care identified in the usual care groups. This does not reflect the very large studies of optimal care carried out in the United States and Europe, and this would have reduced the effectiveness of the programs compared to usual care. So if anything, these studies underestimate the differences that will be made in the real world where we know that usual care may be lower.

We also need to consider the effect of unpublished studies. This is a perennial problem with meta-analyses, that studies may be being carried out for one reason or another, or they

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have been unable to publish those studies. And we have been unable obviously, since we don't know about them, to include them in our analysis. We did carry out some analysis of any publication bias in our research, which we cover in the report, and we found that there was no change in terms of years and the general effectiveness of the studies compared to usual care.

Other observations: There was certainly a lack of detailed program descriptions, for instance examining underlying themes or pretty much guiding the interventions, and it was difficult to gain any insight into that based on the information in the studies. There was little analysis in the literature of the specific impact

of a particular component on outcomes, which elements or dimensions of the studies have the most impact on the risk factor change? There was lack of double blinding in the randomized trials that we looked at. This reflects the challenges of doing research of this type; it's slightly different than doing research pharmacologically. A few studies contained details regarding randomization concealment, and collectively these resulted in fairly large questions as to the

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quality of the studies that we reviewed. So, we both have conclusions and caveats in mind. I thank you for your attention.

(Applause.)

DR. DAVIS: Thank you very much, Dr. Clark. Perhaps members of the committee might have questions or comments. Yes please, Bill?

DR. OWEN: Dr. Clark, great work in a very short period of time. Actually, relevant to the last slide which they just took off, where you don't have much transparency to the interventions themselves, do you have a subjective impression as to whether or not there was an effect of the intensity of the intervention? In other words, the harder they work at a particular intervention or interventions, there was improvement in the effect?

DR. CLARK: That's a really interesting question. I would state my subjective impression is that because of the vagueness of the descriptions, the lack of detail, it was difficult to get a sense of that. I think studies that had carefully targeted populations and had commitments of local stakeholders were important. Multidisciplinary involvement was important,

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involving not just nurses but other members of the health care team. This is an issue of, you know, what explains the differences between the programs. I have looked at this issue in relation to my other research. Staff commitment to the program and the dynamics between the patients and the staff can be very important. An underlying theme guiding the program is also important, and determinants of health, an acknowledgment that it's not just about willingness to participate but also willingness to change risk factors is important. Often programs similar to this in Europe don't have strong links with the community, and have fairly short term, so I think providing longer term support or agreed-to links to the community is very important, because the change in cardiovascular risks is really long-term. We see them in the short-term and as I pointed out, they're almost there, but this has to be a

life-long change, and I think programs that can facilitate that are the most effective.
DR. OWEN: Thank you.
DR. DAVIS: Yes, please, Paul.
DR. BARRETT: This is Paul Barrett.
Dr. Clark, you mentioned that there were some
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regression of angiographic lesions in compliant patients?
DR. CLARK: Yes.
DR. BARRETT: I know that many of these programs have fairly high dropout rates, so I'm wondering if you could address the issue of whether regression of angiographic lesions would be expected for the entire cohort.
DR. CLARK: I think the crucial caveat of that is compliant patients, and the short-term progress that one can make with a general group of patients depends on their commitment to behavioral change and their attendance in the program. One cannot assume simply that patients who are not attending are not addressing risk factor change. However, attendance and participation in programs is a key aspect. If you look at the work done in the United States by Thomas a couple years ago and also more recently by Cooper, attendance in these programs is an international problem. We need to make it easier for patients and make it more appealing to patients' prospects because they are engaging in future risk factor change.
Why patients get attracted to programs, why they stay on them has remained an unresearched
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area traditionally. We do know that women are less likely to attend, older patients are less likely to attend, people from low incomes are less likely to attend, and minorities are less likely to attend. Traditionally, these are all groups that tend to have more risk factors. They tend to have less, often less social support, particularly with older patients more comorbidity, and more limiting factors culturally and in their environments. And transferability of the benefits of these programs' access to patients and participation and outcomes is a key issue, and programs need to address that.
DR. DAVIS: Dr. Slaughter.
DR. SLAUGHTER: Similar type question, but presuming that coronary disease is a progressive disease if under or poorly treated. At 12 months there is no difference in reinfarction rate, so there would certainly be no difference in mortality at 12 months. And then the four studies where there was a reduction in mortality at 24 months or five years, was there also a concomitant reduction in reinfarction rate

in those studies and if not, then what is the explanation for decreased mortality, because
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presumably these patients are dying of reinfarct and heart attacks.
DR. CLARK: Yes. Sadly, that association would be there, and I think tackling the specific prevention of MI head on would be a main priority, yes. So I mean, those trends do correlate. So yes, the trends do correlate between the MI prevention and the mortality benefit. The issue, I think as well as the lack of long-term follow-up in the vast majority of the studies that said, the four studies that followed up at 24 and 60 months had fairly large numbers of patients, so even though it's lacking as to specific mechanisms, there definitely is an association between prevention of MI and mortality benefit with large numbers of patients, that seems to be fairly standard, but as with all studies, I think they should try to address the mechanisms.
DR. SLAUGHTER: As I recall reading specifically in those four studies, though, the reinfarction rate was not necessarily addressed at 24 months and 60 months.
DR. CLARK: We need to check our data. I can just probably do that just now.
DR. SLAUGHTER: I don't remember
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specifically.
DR. CLARK: Four of the follow-up studies, I've just got the profiles of the patients involved in them, the four studies that show the differences at 24 and 60 months contain typical patient profiles. One of the things that we could do perhaps for the final analysis report would be to pull out data in more detail for each of those four studies and that might provide more information on these issues.
DR. DAVIS: Cliff.
DR. GOODMAN: Another question about compliance. I notice that you assigned outcomes using an intention to treat analysis, which to me would mean that to the extent that you did have defined positive outcomes, that is statistically significant findings, those were found despite the fact that there must have been dropouts. And I wanted to confirm that, number one.
And then number two, compliance was not one of the outcomes that you measured, and I am curious, although we might recognize that enrollees in RCTs are more likely overall to be compliant, that said, did you happen to observe any compliance rates that you could report to us
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in general, any observations even in these special

circumstances?
DR. CLARK: Just to address the first point, there was certainly, and it was challenging to review these studies, because often outcomes data and the actual population size at the start were quite different. And for example, there might have been outcome studies that contained at the beginning more than 50 patients but by the beginning of the outcomes data, there was less than 50 patients, and so it involved a lot of reading, and that was a common issue. So clearly, there was a marked trend toward patients having some sort of baseline data at the beginning of the program and then dropping out for whatever reason later and not being available. All the outcomes data we present is obviously from the patients in terms of the longer-term outcomes. Does that answer your first question?
DR. GOODMAN: Right. To the extent you have statistically significant findings for those outcomes such as long-term mortality, those, if you will, prevail despite the fact that there must have been dropouts, because you're using an intention to treat analysis.

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DR. CLARK: Yes.
DR. GOODMAN: Which might suggest a more robust effect, so that was, I wanted to confirm that.
But the second point was, did you happen to notice compliance rates that you might share with us?
DR. CLARK: Sure. The compliance rate, I would just, purely anecdotally as a judgment reading through the whole cohort of the studies, once you get patients onto programs, and I think this is a key area, there may be a dropout or attrition rate of say 20 percent. But what one doesn't know really is the cohort from which patients would be referred to the programs, and from that real world contact data you tend to have programs on patients who are eligible. You later have data on patients who participate at the beginning and then you have data on the patients who drop out, and at every stage along the way there is potential for dropout. And the key elements, key issue is to provide sufficient support or maintenance to facilitate the health services usage along throughout these key points, referral, attendance, participation, and then

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longer-term participation in the community.
DR. GOODMAN: And these, of course, are all in the context of RCTs.
DR. CLARK: Exactly, yes.
DR. DAVIS: Yes, Anne.

DR. CURTIS: I wanted to make a quick comment. You said that a lot of studies had men only and then there were other ones where they were included but they were a minority of the patients. So none of these studies that you talk about were women only?
DR. CLARK: Correct.
DR. CURTIS: Because I just, I think in a situation where a minority of participants are women, that might be harder for them to keep going back to a situation that is mostly male, just as I would suspect that if you had a program that was 80 percent women and a token number were men, they might not want to keep coming back either, and so I really don't know what the outcomes would be under a different kind of circumstance.
DR. CLARK: Yeah. I can give you some interesting information on that. Previous work I have done in the United Kingdom on really the mechanisms of failure, why people attend

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rehabilitation, highlights the specific embarrassment that exercising in public is such a big issue, particularly for women, and it's not been found in any other research in the contact area, just the theme of exercising in public. These people are often exercising in public for the first time, either in the rehab center or in local fitness facilities, but older people who exercise in these fitness facilities are fit people, and it would be different to me. And coming over to North America about 19 months ago, I'm really interested to see that you have women-only gymnasiums, and I think if they were in place in the United Kingdom, there would be far more willingness to use them, because these factors, as you say, are just so important. There are similarities in the practice, but they are the things that really influence patients' decisions and we need to address them.
DR. DAVIS: Dr. Clark, can you speak to the diseases that were addressed in these studies? The title of the meeting and your tech assessment includes a reference to coronary heart disease or coronary artery disease, yet I believe some of the studies looked more broadly at other types of

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heart disease or cardiovascular disease. Can you comment on that?
DR. CLARK: There wasn't enough consistency in terms of data for the other variations of heart disease such as angina or heart failure to present anything useful in the sense of synthesized data such as, you know, if you like prevention of bypass, you start by preventing angina leading to bypass. Anecdotally,

it's difficult, I would say it's difficult to comment. The focus of all of the papers tended to be on preventing MI and issues related to MI, so it's difficult to conclude based on the data reported.

DR. DAVIS: The reason why I'm asking, and I know we're not supposed to get into coverage issues much in this committee, but before I came to the meeting, a colleague of mine at Henry Ford Health System who works in cardiac rehab pointed out to me, and I haven't verified this independently, but he pointed out to me that Medicare covers cardiac rehab for patients who are post MI or who have angina or who have undergone coronary artery bypass, but that Medicare does not cover cardiac rehab for patients who have heart

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failure or who have undergone angioplasty. So it's important, I think, to collect data and examine the data according to disease category as much as possible.

DR. CLARK: Can I just come back on that?

DR. DAVIS: Yes.

DR. CLARK: Heart failure is still very much in discussion all over the world as to whether those patients should be included in rehab programs. Yes, they can exercise. I think the issue in most programs is that the health care systems are stretched, and with the prevalence of heart failure being one to two percent of the general population and six to ten percent of the over 65s, there are real issues of whether these types of services are appropriate for cardiac rehab patients in a nurse-led prevention clinic, or whether home-based or hospital-based. PTCA has only two requirements in terms of the British guidelines as meeting inclusion criteria for rehab services, and a lot of that is being driven between ourselves, so a lot of the outcomes data doesn't deal with PTCA, so you will see both those types of patients which you will

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see in Table 1, but there wasn't sufficient data to evaluate the outcomes.

DR. DAVIS: Thank you. We'll take one more question and then move on. And I would point out in regards to the agenda that we have a portion of time later this morning, namely 10:50 to 11:30, although we're a little bit behind schedule, for questions to any of the morning presenters. So even if we don't get all the questions in right now, we can come back and ask more questions of any of the presenters later this morning. And Dr. Clark, are you able to stay with us for the rest of the morning or rest of the day?

DR. CLARK: Yes.
DR. DAVIS: Good, thank you. Yes, please.
DR. GARVEY: Yes. Dr. Clark, if I understood the articles correctly, there wasn't a good description of who paid for the intervention program and the figure of $7,000 came up a few times. Now, was that cost borne by the patient or was that part of the study cost? And what the patient did pay, to what extent do you think that influenced a willingness to participate or then to continue in the program once it started?

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DR. CLARK: The vast majority of these studies were carried out in the United Kingdom, Europe, particularly Scandinavia, where health care access is free. I recall the studies from the U.S. did report, indicated that the costs were covered by the intervention. So there were very few patients who were actually paying either through insurance or paying directly to the program.
The question that I think you alluded to is the fact that, will this affect motivation? Based on the previous research I have done with heart disease patients, yes, I think it would, but those who can least afford to pay that are probably those who are most in need of risk reduction and to attend programs, so widening access is a crucial topic for excluding groups who might not be able to attend these programs using conventional insurance.
DR. DAVIS: Dr. Clark, thank you very much.
DR. CLARK: Thank you.
DR. DAVIS: And we started out this morning about 15 minutes late and I believe that we're now about 25 minutes behind schedule now,

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according to my watch. However, I'm confident we will be able to make up time later on in the day without short-changing Dr. Ornish. So with that segue, Dr. Dean Ornish, thank you for joining us today.
DR. ORNISH: Thank you. I tend to be a little soft spoken so I'm going to use this mike so you can hear. I appreciate so much the chance to be here today. I'm deeply grateful to all of you on the committee and to Doctors Martha Collins, Sean Tunis, Steve Phurrough, Michelle, and to Dr. Davis for chairing the committee.
I'm really passionate about doing this work because I have been doing it for 28 years or so. And having seen the powerful results that changes in diet and lifestyle can make, it's to me historic to have even the possibility that

Medicare may provide reimbursement for this. I used to think that it was just good science that would change medical practice, and I think that was a little naive, and while good science is clearly important, reimbursement I think also plays a very important role.
I have no conflicts of interest either.
My goal here is ultimately to get reimbursement

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not for our branded proprietary Dean Ornish type program, but for anyone who has evidence showing that a program is safe and effective in treating people with coronary heart disease. I've been in discussions with Dr. Mike Holt from the American College of Cardiology and with Dr. Bob Evans from the American Heart Association, and our goal has really never been to give programs like this away, but to make them available to people who can benefit from them.
And there are a spectrum of programs that have been shown to affect progression of coronary heart disease, ranging from traditional cardiac rehab that Dr. Clark very eloquently summarized, to the programs like Dr. Benson at the Mind-Body Institute, to programs like what we have been doing that are much more intensive. And there is a spectrum because different people want different types of programs. There is a gain that comes by making more intensive changes and one of the points that I want to make is that when you make bigger changes you get better outcomes. And yes, it's more difficult to do, it's harder to recruit patients, but those patients who do enroll do very well. And it requires more intensive

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changes to reverse the progression of coronary heart disease than just to do traditional cardiac rehab, you don't get something for nothing. And yes, I think all of these programs should be reimbursed because they have different goals and different purposes.
I also am going to present data from three demonstrations that we've done. One is the data from the Medicare demonstration program that we've done so far, but also two earlier demonstration projects that we've done, one that was sponsored by Mutual of Omaha and one by Highmark Blue Cross Blue Shield. And I'm going to show a lot of slides because, you know, this is an evidence-based panel, but I want to make the point that the data that is shown in our two earlier demonstration projects with more than 2,000 patients now are almost identical to the data that we're finding in a much smaller number of patients in the Medicare demo. Therefore, it's appropriate to pool these data and look at the patients in

aggregate rather than focusing only on the patients in the Medicare demo. So we have data on more than 2,000 patients. We find that older people do just as well as younger people. We find

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that women do just as well as men.
So with that, let me go through this.
As the cartoon says, I can operate or you can go on a strict diet, and the patient says, you'd better operate, because my insurance doesn't cover a strict diet. And that's been the paradox, because insurance and Medicare will pay for bypass surgery, they'll pay for angioplasty, they will soon be paying for medication, but for diet and lifestyle intervention, even for a registered dietitian, Medicare generally doesn't pay for it except for, you know, renal dialysis patients, rather than working on the other end.
And let me state again, we're not just talking about prevention here. We're talking about something very narrowly focused either as an adjunct or an alternative treatment for people with documented coronary heart disease. This is a metaphor that we work under, we spend so much time in medicine mopping up the floor around the sink that's overflowing without also turning off the faucet. What we're finding is that the body has a remarkable capacity to begin healing itself when you have coronary heart disease in most cases if you make big enough changes, and that we can use

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very high-tech state-of-the-art measures to prove the effectiveness of a low tech and low cost intervention.
It's a multifactorial intervention that includes diet, stress management training, moderate exercise, and psychosocial support groups. The diet gets about 10 percent of its calories of fat, it's much lower in fat than a typical cardiac rehab or AHA diet. It's predominantly complex carbohydrates, whole foods, fruits, vegetables, legumes, soy products, plant based. And they do stretching, breathing, and other stress management exercises, half an hour of moderate exercise, and a support group.
The first study was done in 1978 with medical students. We only had ten patients, men and women, no control group, with a 30-day residential intervention, and what we were struck by was how quickly people improved and how they felt. We found a 91 percent reduction in the frequency of angina in just a few weeks. But they not only felt better, in most cases they were better in ways we could measure, and we found that eight of the ten patients showed improvement in myocardial ischemia as evidenced by thallium scan,

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and we published this in the Journal of Clinical Research. This is one of the patients, a representative patient. You can see the perfusion is the white area, the black area is not getting much blood, and a month later it was clearly improved. But we had no control group. So in 1980 after finishing medical school we did a second study which was a randomized control trial. And we had 48 patients who were randomly assigned, and once again, we found a 90 percent reduction in frequency of angina, and in the experimental group the ejection fraction response to the measure of blood flow improved in the experimental group, it got a little worse in the control group, the difference between groups were highly significant, and we published that in JAMA in 1983. After finishing training in Boston, I moved to San Francisco and began my third study called Lifestyle Heart Trial, also with 48 patients. It was originally a one-year study and after the results at one year, we got support from the NIH for four more years for a total of five years. The primary end point measures were quantitative arteriography and cardiac PET scans,
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as well as cardiac events. And the one-year data we published in JAMA, or excuse me, in the Lancet, we found there was, again, a 91 percent reduction in frequency of angina in the experimental group, whereas the control group increased by 165 percent. There was significant regression in coronary atherosclerosis, even when evaluating blind results at different institutions. And there was a 40 percent reduction in LDL. None of these patients were on any lipid-lowering medications; this was a free-living group of men and women over a year-long period of time. After five years, we found that there was still a 72 percent reduction in the frequency of angina. There was a continued regression, there was more regression after five years than after one year, and you can see here in a typical patient using quantitative arteriography, where the lesion here, its minimum diameter is wider a year later, not dramatic, but it's fairly significant. And since perfusion is a fourth power function of the diameter, there was a 300 percent improvement in blood flow. And the PET scans in these patients, blue and black is no
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blood flow and a year later orange and white is maximum blood flow. Clinically these are patients who

showed dramatic improvement in their symptoms and quality of life as well as in their underlying disease progression. And if you had to look at all these patients, they are comparable to baseline, and the progression after five years shows even more progression. This is in part due to the natural history of heart disease, which is it gets worse, but we found in fact there was some regression after one year and even more regression after five years. So instead of getting worse and worse, patients on average got better and better. Not every lesion got better, not every patient got better, but if you look at all lesions and all patients, that's what we found. We published that in JAMA in 1998. 99 percent of the patients were able to stop or reverse the progression of their heart disease by cardiac PET scan, also conducted by blinded people who were not part of the study. Well, you say 48 patients, what does that really say? I mean, how does that compare to studies that have thousands of patients. And Attilio Maseri, who discovered coronary statin, I

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think said it best. He said, you know, if you need a lot of patients to show a statistical significance, the intervention must not be that strong. Or put another way, if you can show a statistical significance with a smaller group of people, then the intervention must be really powerful. And of course that's really the bottom line in science, what is the likelihood that these findings are due to chance? It's harder to do that, particularly difficult when using a smaller sample size, but we show that after one year and also after five years.

One of the interesting findings is I thought the younger patients with milder disease would be more likely to show improvement but I was wrong. The primary determinant was neither age nor disease severity, but it was adherence, and we found that at one year and at five years. Across both groups, the more people changed, the better they got. And the older patients improved just as much as the younger ones.

In fact, one of the patients who will be testifying later today was 90 when his trouble started, and he showed more reversal than anyone, and I think he was more compliant than anyone. I

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got this actually in a Christmas card a couple years ago from two patients in a hospital in New York. The younger brother is 86 and the older one is 95, and they wanted to show me how much more flexible, and the next year they sent me this one which is kind of funny. You never know how much better people can get.

(Laughter.)
So then I thought, well, having published these data, this will become the standard of care and again, I was wrong. I realized that people would say well, you know, we live in California, it's an altered state, people do things there, it will never play in Peoria. So we began training through our nonprofit institute, initially hospitals in other regions. And the questions were, can we train other physicians and health professionals to do this in other parts of the country, can people in Omaha do it as well as in San Francisco? It's cost effective as well as medically effective, but can payment mechanisms be developed to help prevent fraud and abuse?
We've done, as I mentioned, three demonstration projects on more than 2,000 patients. And we've shown on average greater

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changes in diet and lifestyle, better clinical outcomes, and more cost savings than what other programs have shown, because people are making bigger changes, and when you make bigger changes you get bigger benefits, in simple terms.
It's a physician-supervised team that includes a nurse case manager, a registered dietitian, a clinical psychologist, an exercise physiologist, a stress management instructor and a program director. The patients meet twice a week during the first three months for four hours at a time, it's a big time commitment. They have an hour of exercise, an hour of stress management, an hour of support group, and an hour for group lecture and a meal. Then they meet once a week for the remaining nine months for four hours.
The first demonstration project was funded by Mutual of Omaha. Our data coordinating center was at Mass General Hospital and Harvard. It was a one-year intervention but we followed patients for a total of three years. We had 194 patients in the seminal group and they were matched for disease severity, ejection fraction, age and gender with 139 patients in the control group. It was a very good cross-section of public

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and private hospitals that participated.
What we found was that after three years, 77 percent of the patients who were eligible for a bypass or angioplasty were able to safely avoid it and as a result, Mutual of Omaha saved almost $30,000 per patient. And we published that in the American Journal of Cardiology in both 1998 and 2003.
The second demonstration project was sponsored by Highmark Blue Cross Blue Shield of Pennsylvania, but they had two companies

reimbursing the program that had such good outcomes they decided to provide it to two sites, in Pittsburgh and one in Johnstown, Pennsylvania, a blue collar steel mill community. And they had 75 patients in the experimental group that they matched to 75 in the control group, and again, it was a one-year intervention with a three-year follow-up. And what they found was that event rates came down, heart attacks, angioplasty, bypass and angina in the experimental group, whereas they tended to either go up or not to go down as much in the control group. The emergency room visits, hospital visits and so on also were much lower,

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and as a result, they saved a lot of money. I know that money isn't the primary goal here, but I just want to mention that at baseline they were comparable, but they cost their costs nearly in half the first year, and there were continued cost savings in years two and three, so that there was a net 8.7 decrease in cost in the experimental group and a net 47 percent increase in cost in the control group. So even factoring in the cost of the program, they still saved money. And the control group patients were also motivated to change their lifestyle. They were given a book, they were interested in being in the experimental group but they were kept in the control group. And to illustrate, one of the questions is, why should Medicare pay for this, isn't it all just personal responsibility? And the answer is sure, in theory it's personal responsibility, but it's hard to make these kinds of changes on their own, in the same sense that Medicare now pays for smoking cessation. These were motivated patients but without the support, most of them weren't able to do it on their own but with the support, they were.

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And we've had a review of our data done by Dr. David Eddy, and he says, all the available evidence suggests that this program is highly likely to be cost-saving. And Dr. Alan Garber, who also conducted a review of the data, says that he concurs with Dr. Eddy's analyses and conclusions. Guy King was the chief actuary of then HCFA and now CMS for 16 years, and he said that, you know, he also concluded that, and he told me privately that other than childhood vaccinations, that this type of program was the only one he thought would actually save money, even under a more pessimistic set of assumptions than what we were actually doing. And he said one of the

biggest concerns was that the program might get abused, you know, there was fraud and everybody's going to want to get covered. And he said that he doesn't think that's likely. He said, I believe that the Medicare demonstration project as well as the experience of health insurers such as Highmark has already proven that concern to be unfounded. The third study, of course, was the Medicare Lifestyle Modification Program Demonstration. And I want to emphasize that this

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was really set up as a payment demonstration project, there were legitimate concerns about setting up benefit categories, about potential for fraud and abuse. The assumption, and we had many discussions about this at the time, was that diet and lifestyle changes had already been proven in our earlier randomized trials as well as in other studies that Dr. Clark has already summarized. So it was really not, that's why there's no cardiac end point measurements in this demonstration, there aren't thallium scans in there, there aren't angiograms, there aren't PET scans. It was really designed to set up patient selection criteria, could they control fraud and abuse, and that's been done. That's why I think it's appropriate to go ahead and move forward with the coverage decision.

As I mentioned, older patients improved as much as the younger ones, both in the earlier randomized trials as well as the Medicare demonstration project. I think it's appropriate to pool these data, so that we really have data on more than 2,000 patients, and I'm going to just run through a lot of slides fairly quickly to give you a gestalt of that. And I think this is

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particularly important because the risks of bypass surgery and angioplasty increase with age, but the benefits of diet and lifestyle occur as much at 90 as at 40, and I think this is of particular benefit to patients in the Medicare population. And again, I'm not saying that people shouldn't have bypasses and angioplasties. For some people they are certainly valid, but even then I think that people need to change their diet and lifestyle to reduce the likelihood of needing more than one. So let me just go through, and all these slides, the machinations are categorized into all of the participants in all three demos, those who were 65 and over in all three demos, and those just in the Medicare demo, okay? And this is all the patients we had data on so the ends are not comparable, but I have a second set of slides I'm going to show you where the ends are the same in all three studies.

And what you're looking at is baseline, 12 weeks, one year in each of these categories. And what I'm really trying to show you is not only the changes in each of these parameters, but the fact that the pattern of change you see in almost every slide, you could almost overlap these two

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slides. So patients lose weight after 12 weeks, they lose even more weight after a year. Just on weight loss alone, I think a program like this would be beneficial. Here you see the same thing in those 65 and over and you see the same pattern with those in the Medicare demo. The same pattern with BMI. The same pattern with systolic blood pressure. It does go down, there is some rebound after a year but it's still lower than baseline, although the Medicare patients, it showed significant improvement. Diastolic blood pressure, you find the same pattern. Functional capacity, the ability to exercise on a treadmill increased at 12 weeks, increases more after a year. Total cholesterol came down. There's some rebound after a year, but these patients still showed improvement, and it's important to point out that unlike our earlier studies where none of the patients were on lipid-lowering drugs, it showed a 40 percent reduction in LDL. Most of these patients are on statins, 87 percent of the

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Medicare patients are on statins at baseline. So when you look at their LDL for example, they're already below 90 when they started, so these were additional changes that we see. HDL does come down, not a lot, but by the time the year comes around, most of that fall has been recovered. Triglycerides show continued improvement. Angina shows marked improvements, as we found earlier. This is a very conservative measure. These are people who had angina at baseline, who had no angina at all for at least 30 days prior to testing. And so even if you went from ten episodes to one episode, it wouldn't even show up on this data. These are people who were truly angina-free. And that's part of the reason that we get such high levels of adherence, because when you make these changes you feel so much better, it makes the choices much clearer for people. It's not about risk factor modification or prevention; what's really worrisome to people is feeling better. People say yeah, I like doing

these things. You will hear stories from some of these patients later that talk about some of the
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dramatic improvement in quality of life. And speaking of quality of life, the SF-36 is a standard measure of quality of life, and you can look at each of these measures. Physical function shows marked improvements; whole physical shows marked improvement; bodily pain, marked improvement; general health, marked improvement. So again, I would just like to point out again, you see the same pattern of improvement in the 2,000 patients, and it's kind of remarkable, especially with self-reported data, how consistent they are and therefore, how appropriate it is to look at these in the aggregate. Vitality, how energetic people feel, it went way up, continues to go up. Social functioning improves, again, across all three groups. Role emotional improves. Mental health improves, people feeling happier, talking to more people. Depression came down markedly, and there's a lot about that later. Depression and hostility are the two psychosocial measures that are most firmly linked with heart disease, and this is accomplished without antidepressant drugs.
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Hostility came way down and stayed down, again, same pattern. Stress level came down and stayed down. Dietary fat, which was already low, you know, there were a lot of people at 22 percent or 25 percent fat diets at baseline, so these are additional changes, additional reductions, additional improvements you get by making more intensive changes. And these are the kinds of fat levels you expect to see after a cardiac rehab program, and this is where people came in at baseline. Minutes of exercise per week more than doubled in these patients. And minutes of stress management, you know, went way up because most people weren't doing anything for it. And now just to show you the same parameters in people who have the same end at baseline, 12 weeks and one year, to address the concern of well, maybe people who didn't improve as much dropped out, and what you find are the same patterns, and I'll just run through them quickly in the interest of time. People lost weight, they kept it off, they continued to lose weight over the year, and
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you see the same pattern. If anything, they are

not quite as heavy as when they entered, but again, the same pattern of reduction. Same with BMI, same with blood pressure, systolic, same with diastolic blood pressure, same with functional capacity, same with total cholesterol, same with LDL. And again, these are people, 87 percent of these Medicare patients are on statins at baseline, they already have an LDL of 95 when they started but they still show additional reduction with diet and lifestyle. And by the way, some of these patients actually had their statin stopped, and so we still have to show the reduction. HDL, again, same pattern. Triglycerides, continued reductions. And angina, marked reductions and again, it's the same across all three groups across all three time periods. Physical function, all of these quality of life measures, marked improvements. Physical, bodily pain, general health, vitality.

Again, I know I sound like a broken record but if you compare the data for the Medicare patients with the much larger group of patients in the earlier demos, they are almost superimposable. Vitality, social functioning

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improved. Role emotional improved. Mental health improved. Depression, marked reductions. Hostility, marked reductions that were sustained over the course of the year. Stress levels went way down.

You know the old joke, am I going to live longer or is it just going to seem longer if I make these changes in diet and lifestyle, and these are people who are sustaining it because the quality of their life is so much greatly enhanced. Dietary fat went way down. Minutes of exercise per week went way up. Stress management went way way up.

It's interesting, these are people who started with a systolic pressure of 150 at baseline and went down to about 135 after a year, or excuse me, after 12 weeks, and went down to levels of 128 or so after a year. For many people, that's the difference between being on a lifetime of medications or not. Diastolic blood pressure, the same thing. Diastolic of close to 86 when they started down to 76 by the end of the year. This is important when we talk about interpolating these findings to mortality and morbidity.

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Diabetes is a major epidemic, as Dr. Clark alluded to. Diabetes has increased 70 percent in teenagers in the last decade and is a time bomb waiting to happen. And so people don't really want to see just an average HbA1c, and it

shows reduction, and while it shows some rebound, it still shows a clear reduction after a year. Fasting blood sugar shows a similar pattern as well. And so keeping the sample size the same at baseline, 12 weeks and one year shows that these changes were real, they weren't artifacts of people dropping out because they didn't finish a year, or we didn't have data on them. We're presenting an abstract of these findings that has been accepted at the Society of Behavioral Medicine annual meeting, and the answer is yes, older patients do improve as much as younger patients, and women improve as much as men. I'm just going to skip that. So, let's look at that question. Do women improve as much as men by gender? And again, if you look at men versus women, you find the same patterns. Reduction in body weight, in BMI, in blood pressure, and again, these patterns

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are superimposable with men as well. Diastolic blood pressure, functional capacity, total cholesterol, LDL, HDL, triglycerides, and all these quality of life measures, and again, I'm just going to skip through these, the same patterns in women as in men. And so, I think the answer is that women do just as well as men when they make changes to diet and lifestyle. The changes in depression are, again, dramatic. Changes in hostility are, again, sustained. Their stress levels go way down, their dietary fat went down. Their ability to exercise went up, their stress management went way up, and so on. So in summary, women adhered as well as men to the comprehensive lifestyle intervention and they showed comparable improvement as men in each of these measures. Now people say, you know, that's nice, but you know, we have statins, why don't we use these statins, that's just as good. It's kind of like that scene from an Indiana Jones movie where this guy comes out and does all this kung fu, and Harrison Ford takes out a gun and shoots him. So why fool around with all those things instead of just giving him statins. Well, I guess that

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taking a statin is easy and everybody will do it, but changing diet and lifestyle is difficult and hardly anyone will do it. If you take an evidence-based approach, that is really not true, because a number of studies have shown that compliance with statins is really awful, that within the first six months to a year, two-thirds of the patients aren't taking them. And why aren't they, they have a proven

benefit. Because you're taking a pill to prevent something really awful like a heart attack or stroke from happening years down the road and people don't want to think about it. I mean, after you've had an MI, you'll do anything for about a month or two and then denial comes back. So I have found through trial and error that efforts to try to motivate people to change out of fear of dying or a heart attack or a stroke don't work that well, that it's too scary to think about, so people don't think about it in most cases. But what does work is not fear of dying, but joy of living. And when you make the paradox that small gradual changes are easy and everyone will do it, and big intensive comprehensive changes like what we're talking about are

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difficult if not impossible, it's really not true. It's counterintuitive but it sometimes turns out easier for people to make comprehensive changes than small ones, because when they make big changes they get big benefits, they feel better, they lose weight, their depression gets better, and for many people these are choices worth making. And they say things like even if I'm not going to live any longer, I would still do these things because the quality of my life is so much better, and that's ultimately what sustains these kinds of changes, as opposed to this, I give smokers a discount because there's not as much to tell. So fear of dying is not a good motivator and so, reduced angina, improved well-being, better sexual function, decreased depression, increased capacity to exercise and work and so on are really more valuable to people. For the last part of my talk, I wanted to review some of the other studies that exist. These data are not in a vacuum, they are part of a much larger group of data and to address the evaluative questions, I thought it might be helpful to interpolate our findings to the larger context of studies that are out there.

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I think Dr. Clark did a wonderful job of showing that while you don't necessarily see changes in mortality after a year, after two years or three years or five years, you do, and so it's important to look at longer-terms as well as the kinds of interventions, and the studies that were reviewed in cardiac rehab is not nearly as intensive as the kinds of changes that we have been talking about. So, in the studies that they reviewed, I'm just going to go through it quickly because he already talked about it, they looked at 12 trials with 9,800 patients, and they found that disease management programs do have benefit.

The INTERHEART study was published in Lancet last year. It was a study of 15,152 patients and almost 15,000 controls, and they looked at nine risk factors that are modifiable, which you are all familiar with. You know, daily consumption of fruits and vegetables, smoking, lipids and so on. And what they found was that if you take these nine risk factors in aggregate, it accounts for 90 percent of the population-attributable risk in men and 94 percent in women. That's a lot.

And so, I really believe that although

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coronary heart disease is still one of the leading causes of death for men and women, it's largely preventable and for those who have it, it can be treated in ways that involve diet and lifestyle, as well as drugs and surgery. Drugs and surgery are already paid for, diet and lifestyle are not, and we want to give people the whole spectrum of choice. And not everyone is going to want to change their diet and lifestyle, and that's fine, but for those who are motivated, I think it should be made available to them, because the real question to me is not how many people will do it, we find that a lot of people will, but of those who want to do it, given the proper support, how likely are they to succeed? Insurance companies don't pay for the people who don't want it. The real question is, of the people you pay for, how likely are they to do, and they do very well.

In the INTERHEART study, they found that these findings suggest that this can prevent, has the potential to prevent most premature cases of myocardial infarction. As I mentioned earlier, the complications of surgery increase with age whereas the benefits of diet and lifestyle occur up to age 90, so this has particular importance

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and relevance to Medicare patients.

Again, hospital stays. Complications and mortality caused by bypass surgery are directly related to age and you find the same thing, that it's actually five times greater in the first five days after surgery.

Same thing with angioplasty. Age was the most important correlate of death, with a 65 percent increase in hazard of death for every ten-year increase in age, so again, this is very important for Medicare patients.

You find the same with stents, you find much more mortality in people who are older than those who were younger. After angioplasty, half of the patients may have chest pain, so angioplasty actually doesn't relieve angina as much as intensive diet and lifestyle, and without

the trauma of that.
The National Cholesterol Education Program said that lifestyle modification is the nationally recognized first-line treatment of choice for primary and secondary cardiovascular risk management.
Now, again, I'm not in any way being critical of bypass or angioplasty, but I am making
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the point that if one of the questions is, does diet and lifestyle work as well, I think it's a valid question if we really want to take an evidence-based approach. My point is that intensive risk factor management is at least as good as bypass or angioplasty for people who have stable heart disease.
Now, why do I say that? Well, there's been several randomized control studies of bypass surgery. Probably the best one was the CASS study with 25,000 study patients and what they found is bypass surgery prolonged life and prevented heart attack only in a small percentage of those, those who had both left main disease and poor left ventricular function, which is only about two percent of the people who get operated on. For the rest of the patients, there really aren't any good data that bypass surgery prolongs life and prevents heart attacks. Its major value clinically is that it reduces angina but there again, you can accomplish that simply by changing diet and lifestyle if those changes are big enough.
In the AVERT study, it was one of the only randomized trials where patients would get
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angioplasty versus medical therapy, and they found that if anything, medical therapy was better. And so angioplasty has never been proven to prolong life or prevent heart attacks in a randomized trial. Again, its major benefit is that it reduces angina. And we understand the mechanisms of why that is, because it's not so much the 90 percent lesions that tend to cause the problems, it's more the 30 to 40 percent lesions that are more unstable, and those aren't the ones that are getting bypassed or angioplasties, whereas statin drugs or diet and lifestyle, or a combination of the two, affect the entire coronary tree. In fact, the AVERT study reported that there was actually 36 percent fewer ischemic events after lipid-lowering therapy than after angioplasty, and this was in the New England Journal.
The TIME trial looked at patients 75 years or older and again, they found that lipid-lowering therapy worked just as well as angioplasty, and this was published in JAMA in

2003.
What about angioplasty versus regular physical exercise? This is a study that was published in Circulation last year where they

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found that compared with angioplasty, a 12-month program of regular physical exercise resulted in superior event-free survival at lower cost because of fewer revascularizations and rehospitalizations.
So in summary, angioplasty has really never been shown to prolong life or prevent heart attack, and bypass surgery only in a small percentage, and we exclude those patients from programs like ours. So we don't include patients who, we tell them they should have a bypass if they fall into that subset.
And as I mentioned, at best, revascularization provides a temporary benefit but the lesions tend to restenose, whereas we've shown that there was even more regression after five years than after one year when people make and maintain these changes. And so, comprehensive lifestyle changes are comparable, equivalent or perhaps even superior to bypass or angioplasty, but clearly we're not saying choose one or the other; for those people who need a bypass or angioplasty, they would also benefit from making these changes.
Now, let's look at event and mortality

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reduction, and a study that was published in the Journal of the American College of Cardiology, they looked at people in three groups, those that really weren't given diet or drugs, those that were given a 30 percent fat diet without drugs, or a ten percent fat diet without drugs, or a very low fat diet and drugs. And what they found was that the optimal combination was to do both, that is, in those patients who had lipid-lowering drugs and a very low fat diet did better than those who just had lipid-lowering drugs alone. So for those who say just give people statins, that's enough, clearly there's additional benefit if the person changes diet and lifestyle as well.
What about exercise? In a study that was published in Circulation in 2003, they looked at 5,721 asymptomatic women and they followed them for eight years. And they found that for every 1-MET increase in their ability to exercise, their mortality risk decreased by 17 percent. And in men, in the New England Journal they found something similar. They found that for every 1-MET increase in exercise there was a 12 percent increase in survival.
And so if we interpolate our findings

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in terms of the increased ability to exercise in the Medicare demo and the earlier demos, we found that we can interpolate there would be a predicted mortality risk reduction of 34 percent in women and 32 percent in men. Clearly, this is not the same as having a randomized trial where you would have one group exercise and one group not, but at the same time, I think it's fair to make these kinds of interpolations.

What about depression? Depression is one of the only risk factors that has a major impact not on just quality of life but on survival. And in Circulation, they did a study that found that in 4,400 elderly Americans, again the Medicare population, who were followed for six years, who didn't have heart disease at baseline, the risk of developing heart disease increased by 40 percent and the risk of death by 60 percent in those who were most depressed. So it's an independent risk factor.

In a study that was in JAMA, they found that six months after a myocardial infarction, four percent of the nondepressed patients and 17 percent of the depressed patients had died, so a four-fold difference in mortality. And you can

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see in the graph here that six months after an MI there is greater than a four-fold increase of those risk factors. What's interesting is that's independent of their disease severity, their lipid levels and other risk factors, that's how powerful depression is, and we found that we can modify depression through change in diet and lifestyle.

In the SHEP study, they found that healthy men and women who are 60 or older had a 25 percent increased risk of death per five-minute increase in the depression score that we used in our demonstration projects. We found a four to six unit decrease in the depression score. So again, if we interpolate the reduction in depression that is measured with these kinds of studies, we found that there was a 25 percent decrease in depression-related mortality as a result of making changes in diet and lifestyle.

What about changes in lipids? Now the 4S study, as you all know, looked at more people, as well as those who were 65 and older, and found that mortality was substantially reduced from all causes as well as heart disease mortality. If we look at the changes in LDL that we found in our demonstration project, again, these are additional

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to what people got from actual statin therapy because 87 percent of the patients in the study were on statins. These additional reductions, we

found an additional predictive mortality reduction of at least 90 percent. If we look at our earlier randomized trial data where we found a 40 percent reduction in LDL, obviously these changes would be much greater.

What about the results in mortality and changing blood pressure? In the ALLHAT study, they found that it doesn't really matter how you get your blood pressure down, whether it's through drugs or lifestyle, just get it down, and people live longer. And in the six-year study, looking at 4,700 people, they found that when they got blood pressure down by ten millimeters systolic or 4.5 millimeters diastolic, there were marked reductions in stroke and cardiac heart failure, cardiac mortality. This was published in Lancet. In the STOP trial they found the same thing; if you get your blood pressure down, you get your risk way down.

So in the SHEP study, the same thing as well. Looking at a 60-year minimum, mean age 72, again, modifying risk factors in elderly patients,

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you get a lot of benefits both in cardiac morbidity and mortality. And so if we interpolate the changes in blood pressure that we mentioned in our Medicare demo with the outcomes of these studies, we found that we reduced in hypertension patients, systolic blood pressure by 19.6 millimeters, diastolic by 10 millimeters, and as a result, we should be reducing mortality at least as much as in the earlier studies.

What about losing weight? You know, the problem with cardiac rehab programs, as was alluded to earlier, is that only three percent of eligible women are getting them, whereas we found that 20 to 30 percent of eligible women were interested in programs like what we had, and we published that in the American Journal of Cardiology in 2003.

It's not surprising that 40 percent of heart patients are obese, and they're more likely to have diabetes and hypertension and all kinds of problems. And so losing weight in cardiac patients is a desirable goal, it's desirable in anybody, but particularly cardiac patients.

Studies have shown that most cardiac rehab programs don't help people to lose very much

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weight if at all, because they don't ask the people to do very much and they only focus primarily on exercise. And it's really about energy balance, you need to focus on diet as well, as well as the other kinds of behavior strategies that we have found to be so effective.

And in our program, there was a 6.2

percent weight loss, which is actually better than most weight loss programs, even though that wasn't the primary goal. If you interpolate the data from the larger studies, that represents a decrease in both stroke and heart attack rates of either one to eight percent in stroke or seven to 24 percent in coronary heart disease.

What about diabetes management? A number of studies have shown the results. In the New England Journal, a very famous study looked at diet and lifestyle versus medication, and they found that diet and lifestyle actually worked better than medication, there was a 58 percent reduction in the risk of developing Type II diabetes in the lifestyle change and only 31 percent in the medication group.

And there was a meta-analysis done of 18 randomized trials looking at the effects of

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changing cholesterol and blood pressure and also in changing diabetes. Reducing HbA1c reduces both mortality and morbidity in diabetics. What they found was that for every one percent reduction in hemoglobin A1c there was a 21 percent risk reduction in deaths from diabetes and about a 14 percent reduction in myocardial infarction, and the lower the HbA1c, the lower the risk, there was no threshold.

So we found in our demonstration that the hemoglobin A1c came down from 7.4 to 6.6 after 12 weeks and from 7.4 to 7.0, there was some rebound after a year. But even just looking at the more conservative one-year data, that would translate to a 12.6 percent decrease in risk of death due to diabetes and a 12.6 percent decreased risk of death for any end point related to diabetes, and lower complications of diabetes.

So in summary, we've covered a lot of data fairly quickly, but I guess I still have what, do I have five minutes? Yeah, five minutes. If we take a look at the evaluative questions, the first two are really, are there enough data, and I think the answer to that is yes. Now, some people might argue well, why don't

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we just continue the Medicare demo, more data is always a good thing, what's wrong with that? And the group from Brandeis I imagine will argue that. And my response to that is there are enough data. I mean, we have data on more than 2,000 patients just from our demonstration projects. We have data, randomized control trial data which is state-of-the-art measures. And even though the numbers were small, the impact was great enough to show statistical significance. The American people need this. You know, this is something

that can save money, it can improve the quality of care, and it's consistent with a wide body of data from other programs.

The other thing that the Brandeis group would like to talk about is to compare the programs that you have both in cardiac rehab and Dr. Benson's program, and they will make the point that, you know, more patients are enrolling in cardiac rehab through Dr. Benson's program and that's because it's not as hard to follow, it doesn't take as much time commitment, it doesn't ask people to make as big a change, and so it's not surprising.

But again, the question is, how well do

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people do who enroll in this program that we have and ones like it, and how many drop out, and what are the clinical outcomes? And we have shown that they achieve much better clinical outcomes, and actually regression of coronary artery disease, which you don't find in less intensive interventions. And yet, these less intensive interventions should also be covered because they have benefits as well, and not everybody wants to make changes to their lifestyle, but for those who do, it should be made available to them because they do very well, it's both medically effective and cost effective.

I think the last thing I want to talk about is a study that is really, I didn't show data on, but we're about to publish the first randomized control trial in a leading urology journal, a peer reviewed journal, that these same kinds of diet and lifestyle changes can affect the prevention of prostate cancer in men. We found that PSA levels had gone down in 70 percent in the experimental group versus only nine percent in the control group. If it's true for prostate cancer, it will likely be true for breast cancer as well.

And so, although we're focusing on coronary heart

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disease, diabetes, hypertension, obesity, probably prostate and breast cancer and a number of other illnesses will also be improved when people make changes in diet and lifestyle, and unlike most things we do, the side effects really are good ones. Thank you.

(Applause.)

DR. DAVIS: Thank you very much, Dr. Ornish. Questions from the committee members? Yes, Bill.

DR. OWEN: A lot of your data reminds me of Laura Svetkey's work on the DASH and the DASH Sodium Diet. Have you done a subgroup analysis to see if there's the same sort of differential benefit across races where she saw a

greater benefit with African Americans, which is in my mind quite germane, since we have a population that is browning as well as graying.
DR. ORNISH: Yes. We haven't found a physiological difference in African Americans than in other groups, but you know, most bypass surgery and angioplasty are done on white upper middle class men. And yet, heart disease is declining in that group while increasing in minorities and other socioeconomic groups who don't really have
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access, so it's precisely people who don't have access to conventional approaches who might benefit the most. And we have certainly found, you know, there is this kind of prevailing idea that this is the lead thing for rich white people. And we found that in our studies, we have a very wide demographic of people and that people across the spectrum seem to do just as well.
DR. DAVIS: Yes, Cliff.
DR. GOODMAN: Yes. Dr. Ornish, in looking at a lot of the bar graphs in the last part of your presentation, I notice that many of them, not all, but many show a pattern of a baseline, a 12-week effect, and some of them bounced up after one year. And not only with your program but with others, I'm very concerned, or not concerned, but wondering how much of the effect that we're observing is simply regression to the mean. I mean, a lot of the variables tend to go up and down, and whether it's weight, blood pressure, lipids, and quite a few of the ones that you cited go up and down for most of the population. And I'm wondering, and I'm sure that regression may exist in some cases, but I'm wondering given the Medicare demonstration and
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some of these other studies, whether the people who enroll in these studies tend to self-select and agree to be enrolled at a time when they tend to be at the upside of their weight, have other kind of risk factors that tend to be an upside of variables that tend to go up and down. And I'm wondering even in the control groups, let alone the intervention groups, if they are both subject to regressions to the mean and in fact, does this apply to patients in the Medicare program?
DR. ORNISH: Dr. Goodman, that's a good question and the answer is yes, in many of these measures, there was more improvement at 12 weeks than at one year. But we found there was a direct correlation between degree of adherence in the outcomes at both 12 weeks and one year. And I don't think it's surprising that the adherence is going to be higher at 12 weeks than it is at one year.

In our earlier randomized control trials, as you know, that's a control for regression to the mean, because we expect to see that in the control group as well as the experimental group, and we didn't find that. Or let's put it this way. We found that whatever

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effect regression to the mean might explain was outweighed by the intensive diet and lifestyle intervention. And so, again, the Medicare demonstration project really isn't a clinical trial, it's a payment demonstration, but these data I think are very consistent with the randomized control trial data that we did earlier which do control for the regression of the mean, as well as the larger body of controlled trials that also do. I appreciate the question.

DR. DAVIS: Tracy.

DR. GORDY: Dr. Ornish, perhaps I missed it, but did you present any data to show what the dropout rates were in the Medicare demonstration project?

DR. ORNISH: In the Medicare demonstration project, no, but I can talk about the earlier demonstration projects in which we found that even though the intervention was a year long, we followed patients for three years, and we found that 77 percent of them who were eligible and needed an angioplasty or bypass still were able to avoid it, and I think that's comparable to what we find in the Medicare demo as well.

DR. DAVIS: Bill.

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DR. HERMAN: In the bar graph data on the Medicare demonstration project particularly, I was impressed by the very high mental health and composite scores in the SF-36. At baseline the score was about 70 in the 65 or older, which would be in the Medicare population. That would be three standard deviations, two to three standard deviations above the mean for the population. Do you think there is a major selection bias in those studies?

DR. ORNISH: I appreciate your question, Dr. Herman, and there is a selection bias, but it works against us being able to show treatment effect. It's kind of like, by analogy, most of these people are already on statin drugs, so it's even harder to show continued reduction in LDL. When you're dealing with people who already are healthier, it's harder to show continued improvement. In our earlier studies and my own clinical experience, we generally find that the more severely ill the person is both physically as well as emotionally, the more room for improvement, you might say, the more we show

greater outcomes. And in fact, you know, using the point that Dr. Goodman suggested, regression

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to the mean, when you're dealing with people who are healthy, they're more likely to get sick than any better. So in that sense, regression to the mean was working against us.

DR. DAVIS: Dr. Ornish, you mentioned at the beginning of your talk that the optimal lifestyle program addresses diet, stress management, moderate exercise, psychosocial support groups. In perusing some of your papers that were included in our agenda materials, it seems to me that in some of your studies, smoking was addressed and in others it was not. Can you comment on that or correct my misimpression?

DR. ORNISH: Yes, Dr. Davis, you're absolutely right. In our earlier studies, we included smokers in the randomized trial, but it turned out that we only had one or two smokers, it didn't really affect it one way or the other. But in our earlier experience with training hospitals, we found that if someone is smoking, it's very hard, and they don't want to quit, it's very hard to get them to do anything else. And so we excluded people who were actively smoking from the intervention. We referred them to smoking cessation programs, if they wanted to quit

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smoking, then come in. Otherwise, it's very difficult for them to make any changes if they're still smoking.

DR. DAVIS: Thank you. Yes.

DR. BORN: One of the references you made was compliance to the statin medications and when you showed the bar graph showing the LDL, could that be part of the reason for that, and was that factor included when you looked at cost savings, was the use or discontinuation of the medication included with the overall cost savings?

DR. ORNISH: That's a very good question and I'm glad you raised the point because I forgot to mention it. There are two aspects there. One is that the patients who actually complied with their medications, including the statins, did much better when they made diet and lifestyle changes, and so it has an added benefit of increasing medication compliance. But under our supervision, many patients were able to reduce or discontinue statins or antihypertensive medication, beta blockers, nitrates, and so on, because they didn't need them anymore. Their blood pressures were getting too low, so they had to reduce them. We found that in the very first

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study that we did over 28 years ago. So that most

often, people are put on these medications and told you need to take this for the rest of your life, often in ever-increasing dosages. What we found is that if you turn off the faucet, so to speak, if you make big enough changes in diet and lifestyle, the need for drugs and often surgery is often greatly reduced.

DR. DAVIS: Charlie, and then Pam.

MR. QUEENAN: In your control group as I understood it, the patients were already given some information prior or contemporaneous to being randomized in either control or intervention. I guess the question I'm wondering is, did you follow up the behaviors of the control group to see whether the mere fact of giving them that information up front actually changed their behavior and if so, how did it change and how might that affect the comparison?

DR. ORNISH: It's a good question, Mr. Queenan. We did look at the control group and we found that they didn't change very much, and they didn't show much change in their behavior, they didn't show much change in their clinical outcomes. And it just to me indicated that even

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in people who are very motivated and well intentioned, giving them information in the form of a handout or a book is not sufficient. For some people it is, but for most people it isn't. And that's why when you talk about personal responsibility, we also can say that if we take motivated people and give them enough support and they can make and maintain marked changes in diet and lifestyle and get a number of desirable clinical outcomes, and save a lot of money, even when we factor in the cost of the program, that it may be worth considering.

DR. DAVIS: I have Pam, Paul and Bill on my list, and then I think we'll take a break. I'm sorry, Christina, I will get yours too. Pam.

DR. SNIDER: Thank you. Hello, Dr. Ornish.

DR. ORNISH: Hi.

DR. SNIDER: In your multicenter lifestyle demonstration project, for those patients who were eligible for revascularization and bypass surgery, was there any cost analysis which I may have missed or you may have mentioned, that differentiated between those who were actually eligible and would have been referred for

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the surgery, has any of that work been done?

DR. ORNISH: If I understand your question correctly, Dr. Snider, we chose people who were told they needed a bypass or angioplasty, and chose them because when we started talking

with insurance companies, they'd say, you know, we're not interested in diet and lifestyle, that's prevention, 30 percent of people change insurance companies every year, it might take years to see the benefit, why should we spend our money for some future benefit that chances are someone else is going to get.

So we refined it by saying look, for these select patients, this can be a safe alternative treatment, and for every man or woman who would have undergone bypass surgery who can safely avoid it by change in diet and lifestyle, then Mutual of Omaha would have to pay $30,000 immediately, you know, real dollars today, not just theoretical dollars down the road. In addition, there were other savings that came because it wasn't just the savings from avoiding the surgery, but other cost savings as well. And so we have those data, and it turns out that even if we delayed surgery for a year-and-a-half and

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had a 100 percent failure, they would still have that $30,000 invested at a ten percent return, and it would more than cover the cost of the program to cover these failures.

DR. DAVIS: Paul.

DR. BARRETT: I also have a question about dropouts and selection bias. I think you have done two randomized control trials?

DR. ORNISH: That's correct. Well, two, one of which had both a one-year and a five-year component to it.

DR. BARRETT: Right, the lifestyle and the heart trial.

DR. ORNISH: Right.

DR. BARRETT: And in that study, individuals were prerandomized to intervention or control and then consented and enrolled, and then you followed them for five years. And you randomized 53 subjects to the intervention, enrolled 28, and had 20 remaining at the end of the five years, which is a 60 percent dropout rate from randomization and about 20 or 30 percent from actual enrollment, and the controls had a similar amount of attrition. I'm most concerned about the prerandomization. Can you address that?

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DR. ORNISH: Yes. We started out doing a classical randomization. What we found was that unlike a drug study where you can give people a placebo, as you know in classical randomization, you need to tell Mr. Jones or Miss Smith in great detail what the intervention will be, and they have to then be willing to agree to make those changes if they're randomized. And what we found was that in the process of going in great detail

and people making the mental commitment, yes, if I'm randomized to the control group I will make those changes, those who were subsequently randomized to the control group, we had created a lot of contamination in that many of the people in the control group began making these changes as well.

So we consulted with Mark Allen at Harvard, who has a variant to that, which we then changed to. And the point of that was that if someone was randomized before contacting us, if they were randomized to the control group, you don't have to go into great detail about what the intervention is. And while that has its own set of potential biases, we felt very strongly that the type two error that could be resulting from

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the relation of differences between the groups, because the control group was also making intensive changes, outweighed any potential bias. We tried to control for that as much as we could by looking at all the baseline characteristics, including the baseline characteristics of those who refused to be randomized, and didn't find any differences. And so, it's not so much that there was a 60 percent dropout. Of those who actually enrolled, after five years, we ended up with 20 patients of the 28 in the experimental group. And remember, they only initially volunteered for a one-year study. We then went back and said, would you consider being in this program for four more years? It wasn't what they had originally signed up to do. And so it's probably not the best indicator, the level of dropout, I think that's where the results of the demonstration project are going to be more indicative of how many people are going to be able to stick with us. And what we've done with most people, if they're interested in doing it, given the proper support, have been able to make the changes and have shown both extraordinary medical as well as cost outcomes.

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DR. DAVIS: Bill.

DR. HERMAN: I had a couple additional questions about the economic analyses. I think you've indicated that when you consider secondary prevention of coronary heart disease, there are really three interventions that are effective. One is the comprehensive lifestyle changes which you have nicely demonstrated, the other was medical management, and finally revascularization. When you look at the economics, it's unlikely that people are going to choose one intervention exclusively over the others, people are going to get pieces of all three of the interventions,

which I think would cloud the economic findings that you presented.
The second issue is that you showed, I think very nicely, that medical management and surgical management would really produce comparable outcomes in the population that you enrolled in your studies of comprehensive lifestyle changes. Yet in the economic analysis, you assumed that everyone was having surgery, and there is of course a very high up front cost of bypass and angioplasty. Because they're equally effective, you could have in fact, assuming that

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people had all been treated, that these patients eligible for revascularization might have opted for medical treatment, and you probably as a sensitivity analysis would want to consider looking at medical management versus the comprehensive lifestyle management.
DR. ORNISH: I appreciate your questions, and let me start with the second one first. In the first study that we did with Mutual of Omaha, we assumed that the patients at this program, all of them would have had bypass or angioplasty because they were told to do it. The fact is most patients who are told to have a bypass or angioplasty usually do it, not all of them, but most of them, so I think the assumption is reasonably valid, but you're right, it may not be.
But in the Highmark Blue Cross Blue Shield demonstration, that doesn't apply. These are people who were not told you need a bypass or angioplasty, these were people who had documented coronary heart disease. They were matched for age, gender, disease severity into similar groups of people, and they were also matched for motivation. And yet, they still found -- and they

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were very skeptical when they first started, but they cut their expenses in half in the first year, and as I showed earlier, they showed continued cost savings over a three-year period, so even factoring in the cost of the program, it still saves money. So I think it's reasonable to assume that the first demonstration notwithstanding, clearly the second one does show that these kinds of intervention do save money.
The first part of your question or concern, I'm sorry, please help me.
DR. HERMAN: Again, that people are likely to choose a little bit of lifestyle and a little bit of medication, and end up with surgery.
DR. ORNISH: Well, again, these are non-exclusive interventions. For people who go through an intensive program like this, they

generally tend to follow up with the program, because there's a synergy. Many people overeat when they're stressed. When you teach them how to manage stress better, they're more compliant to their changes in diet. They may smoke. One woman told me, I've got 20 friends in this package of cigarettes, they're always there for me, nobody else is. But when they join the support group, it

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often addresses the underlying loneliness and depression and it results in a decrease in the rates of antidepressants and it makes it easier to make other changes when you do it all at the same time.

Again, we're not saying that lifestyle changes are better than angioplasty or bypass or medications. I think that the physician as a quarterback needs a full range of options so that if a patient has heart disease he can say Mr. Smith or Miss Jones, you've got heart disease and we need to do something about it. We can do bypass surgery, we can do angioplasty or stent, we can teach you how to change your diet and lifestyle, we can put you on medication, and go through the risks, the benefits, the side effects of each approach. And then I tell my own patients, I often tell my patients, I don't have an agenda to get you to do something, I just want to make sure that you know what your choices are, that you don't fool yourself into thinking that something is going to be more beneficial than you think it might be.

Then you go to the subset of people who want to make intensive lifestyle changes, and that

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should be available, so the physician as a quarterback will have a team of registered dietitians, of exercise physiologists, of clinical psychologists and so on, to work with where he or she doesn't actually have to do the intervention, but to refer the patient.

Now the reason that we're here from my standpoint is that Medicare pays or will be paying for the medications, it clearly pays for angioplasty and bypass surgery, but it doesn't pay for programs like this. And it should, so that people have real freedom of choices, and so that people who want to make these changes either as an alternative or as an adjunct to these other modalities will have the opportunity to do that.

And I would just say as a coda, it's fun practicing medicine this way. You know, it's different than just forcing doctors to see more patients in less time, so that finally all you really have time to do is listen to the heart and lungs, write a prescription for a statin, and

you're off to the next patient. That's not good medicine for the patients or doctors, and most doctors wouldn't recommend that as the way medicine should be done.

I was on the White House Commission on Complementary Alternative Medicine Policy, and more money is spent out of pocket on alternative medicine than traditional medicine even though there's so little evidence to support it, because people spend time with patients and that's something that's missing. And this is a model that we're trying to create that's a lot more caring and compassionate, but it's also more cost effective by turning off the faucet and addressing the fundamental causes of why people get sick rather than just seeing them sick and doing a bypass on them.

DR. DAVIS: Christina.

MS. BIESEMEIER: Dr. Ornish, I have two questions. First of all, I'm interested in the diet component of your intervention, and within this stringent fat limitation, cholesterol limitation, thinking of diverse populations, is their customization of that portion of the intervention by the registered dietitian for different food preferences, cultural styles of eating at your sites around the country? And then number two, just a word on the training program component, what's required for

teams to be trained in terms of time requirements and resource utilization?

DR. ORNISH: Yes. We have, although the nutritional guidelines are the same, how people fulfill them varies by culture, by region of the country. You know, we trained at Richmond Memorial Hospital in Columbia, South Carolina, and cardiologists there said taking out gravy would be a huge change in our diet. And so we found ways of working with the local culture, with the local cuisine to make it, you know, both tasty and practical and affordable. There was an article in the New York Times today actually, I was reading it on the way over here, about how in some lower economic communities they don't have access to fruits and vegetables and whole grains, so we're trying to change that.

I'm sorry, what was the other part of your question?

MS. BIESEMEIER: The training component.

DR. ORNISH: We train a team of people, a registered dietitian, an exercise physiologist, a cardiologist, usually an interventional cardiologist, a nurse case manager, a stress

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management specialist, a clinical psychologist, and a program director, and they in turn then offer the program. All of the reimbursement in the Medicare realm goes to the hospital which pays for these people, none of it goes to us. Our goal is to train, as I mentioned when I first started, other teams of people through the American College of Cardiology, American Heart Association, the American Diabetic Association, to make this available, because we are not interested in being in that business. We just want to train other trainers so they can in turn train other hospitals and physicians to do supervised interventions of this type.

And so, you know, all we're saying is of course there are methodological limitations in everything that we've talked about, but hold us to the same, and when I say us, hold Dr. Benson, hold cardiac rehab, hold us to the same standard that you would for other interventions that you already pay for like bypass, like angioplasty. Because I think if you would say, are these studies ironclad, completely free of methodological issues, of course not. I don't think any studies really are. But in view of the large body of

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evidence out there, the randomized trials that we and others have done, the epidemiological data, the demonstration projects, I think you can make a pretty good case that this is something that would benefit the American people, and like most things that we do as doctors, we only ask for reimbursement.

DR. DAVIS: Thank you again, Dr. Ornish, and we will take a ten-minute break and then we will have about an hour and 40 minutes for more Q&A and more public comments, so I think we will be able to get back on track.

(Recess.)

DR. DAVIS: Let's reconvene. We were a little more generous with the break than I had planned, but that is the reality show with MCAC, I guess.

And so, we have a list of scheduled speakers and we will begin with Dr. Richard Collins. Let me remind these speakers to please introduce themselves and say what their affiliation if any is, and whether they have any conflicts.

DR. COLLINS: Thank you. I will do that, Mr. Chairman.

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Committee members, colleagues and guests, here is sort of a map of my three-minute presentation, a brief overview of the heart

disease program, early experiences as the director of the first medical site in Omaha, Nebraska, and my personal thoughts on behavior modification. You know they say statistically that when you die, you'll stand next to someone you've never met, and the majority of you don't know who I am. I'm currently director of the heart disease prevention and wellness program at South Denver Cardiology, a practice of 14 cardiologists. It's probably a model that will be happening across the United States, an integrated center with imaging, yoga, cardiac rehab, lifestyle and nutrition center, and home of the cooking cardiologists. I was prior director of the heart disease prevention and reversal program at Alegent Health in Omaha, Nebraska. I was on the beachfront and had been there for ten years, beginning with the program in 1993, since moving to Denver in 2002. I am currently medical director of the Wellness Councils of America and clinical cardiologist at South Denver Cardiology. I was trained as an interventional cardiologist at the Mayo Clinic at

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the beginning of the program in 1993 and that's how I met Dr. Dean Ornish. Now, if it's okay with the committee, I would like to pass through quickly and actually skip the majority of the slides and go pretty much towards the end. You know the early research both in '77 and '80, and the lifestyle heart trial that Dean explained to you, and the one-year and five-year data. I became involved in the program in 1993. Part of that was the Mutual of Omaha experience. At that time an insurance company decided to pay for a lifestyle intervention program and I met Dean for the first time. And the biggest question was, could they save some money if they entered their patients in a program such as this. We sat at the table and we made one decision with Mutual of Omaha, and our health care system said we would deduct the cost of any procedures from the cost of the program. So if the patient required bypass surgery or angioplasty, we would decrease the cost of the angioplasty or bypass surgery by the amount of the cost of the reversal program. In essence, it was a guarantee; Mutual of Omaha would be out no money

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at all. They said if you will commit to that, we will commit to the program, and that was the beginning of the start of heart disease reversal. Our demonstration project included from 1993 to 1998, there were eight national sites, we participated in that program. 77 percent of the patients were eligible for bypass surgery or

angioplasty, and there was a cost savings of well over $30,000. The attrition rate was one percent per month, a 30 percent decrease in hospital stays, 53 percent decrease in angina, 12 percent increase in exercise capacity, a decrease in anti-anginal and blood pressure medicine, and a decrease in lipid meds. Of the 194 patients, 88 percent avoided a procedure within a year. We weren't really too smart then, but we do now know how the program works. As a cardiologist, we affect the lipid content of plaque, we know that the lipid tie that passes through the blood stream plays havoc on the coronaries. We know there's an increase in minimum diameter, a change in the fibrin cap, a decrease in vasoreactivity, certainly a decrease in inflammatory response, a drop in protein, and the process is called plaque stabilization with

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increased collateral flow. Of course decreased anger, anxiety, depression and hostility are the major components of stress management anger support. The core of the program, you know about that. I feel as a cardiologist, there is no question in my mind that the patient can intervene better in lifestyle control than I can with a catheter and a balloon on the end. The bottom line is alternative medicine should not be alternative therapy but a part of mainstream medicine, as it is the inner spirit and self-empowerment that creates healing. A physician can treat only in the physical sense. It is time to allow those individuals who desire to be medically self-empowered, allow them to participate in the program. This committee is going to make a major decision today that will have a major impact on chronic disease management and I firmly believe that it strikes at the very center of chronic disease control. Thank you very much.

DR. DAVIS: Thank you.

(Applause.)

DR. DAVIS: David Lambert.

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DR. LAMBERT: My name is David Lambert, I am vice president of health services of Mountain State Blue Cross Blue Shield. Mountain State is the largest health insurer in the state of West Virginia. We began covering intensive lifestyle modifications for our members in 2002 and just last year we began covering it for our members in the federal employee health benefits program. I would like to say a few words about why we made this coverage decision and about the results we have experienced to date.

West Virginia has the highest mortality rate from cardiovascular disease in the country. It has the second highest mortality rate for coronary artery disease. Our death rate from heart disease is 20 percent higher than the national rate. One-third of all West Virginians die of either heart disease or diabetes. The culprit is not hard to find. West Virginia is the most obese state in the country. We are highest in prevalence of known high blood pressure, second highest in diabetes, fourth highest in smoking, and tenth highest in lack of any leisure time physical activity. We are also the oldest state in the country.

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With these statistics and the human misery that is evident in our workplace, our hospitals and our physicians' offices every day, we believed that we needed to do something to directly address these unhealthy lifestyles, these modifiable risks, if you will, that were causing so much misery and premature death in our state. We looked at other insurers who had gone before us. We reviewed the very positive clinical outcomes that Highmark Blue Cross Blue Shield had achieved with a very similar demographic population in Pennsylvania, and we looked at the cost savings that had been achieved by Mutual of Omaha in patients with serious heart disease. There were no intensive lifestyle modification programs available in West Virginia, so Mountain State partnered with ten hospitals to deliver the program in eight cities across our state. The West Virginia Public Employees Insurance Agency, which is the state agency that provides the health coverages for state employees and retirees and for public school teachers, also made a decision to cover the program. We are extremely pleased with the clinical outcomes that we have experienced to

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date. Over 400 West Virginians have participated over the past three years. The average age is 56, about half are women, and we've had about a 90 percent completion rate for this program. Collectively, these individuals have reduced their risk of a cardiac event by 50 percent as measured by the ATB-3 or Framingham risk tool. Think of what that 50 percent risk reduction means both to these individuals and to their families. In terms of specific outcomes, the West Virginia program participants reduced their dietary intake of fat by 64 percent, lowered their total cholesterol by 28 points and their LDL by 21 percent, dropped their blood pressure levels by eight percent to near ideal levels, reduced their

body fat by 12 percent, increased their weekly exercise by 160 percent, decreased depression and stress by 37 percent, and increased functional capacity by 23 percent, results all consistent with the studies that you have heard discussed earlier today.

For these results to be achieved in West Virginia with our unhealthy life styles, our older population, our rural population, our socioeconomic challenges, we believe bodes well

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for a service that can be of real benefit to Medicare beneficiaries across the country.

Just a quick word about costs. Our average reimbursement for these programs is about $5,700. The average cost of surgery or angioplasty in West Virginia is between $57,000 and $67,000. If we are able to avoid one procedure, we pay for ten of our members to complete this program.

The reason that we believe the programs are successful is that it is a comprehensive approach delivered by a multidiscipline team and what happens is that the people make the changes and feel the results immediately, and that is what motivates them to stay with the program and to maintain the healthy lifestyles. Our biggest challenge with these programs in West Virginia is the lack of reimbursement from other payers. That makes it difficult for the hospitals that are delivering these programs to cover the costs of the clinical staff and the highly structured programs that they are offering. For those of us in the private health insurance world, Medicare is the leader, it is the leader and the standard in terms of coverage decisions, and I strongly

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believe that if Medicare makes the decision to cover these programs, then the private insurers and the local public payers eventually will follow.

I would like to close with just a couple of statistics from the 2005 statistical update from the American Heart Association. The average age for a first heart attack in this country is 66 for men and 70 for women, the Medicare population. This year 1.2 million people will suffer heart attack and over 40 percent of those will be recurrent attacks. 335,000 people die from heart disease in the emergency room or on the way to the hospital. Such was the case of my own father, who died of a second heart attack. The average years of life lost due to a heart attack is 11.5 years.

We have seen positive clinical results from the program in West Virginia, but far more

powerful is the fact that it has not just reduced risk factors for our members, is has enabled them to regain their lives, and you're going to hear stories from patients who will tell you directly. This is the clinical evidence here before you today. We have members who woke up every day

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afraid of dying and whose lives were severely restricted by shortness of breath, frequent chest pain, and essentially hopelessness. I have had the privilege of traveling the state and meeting with the participants that have completed this program. These are people who now play with their grandkids, they can go out shopping, they can walk, hike, or in some cases run marathons, and we've had all of those results, and I cannot tell you how personally and professionally gratifying it has been to be a part of making this treatment option available to our members. I wish that opportunity for this panel today and for the literally thousands of older Americans that your decision will serve and save. Thank you.

DR. DAVIS: Thank you very much.

(Applause.)

DR. DAVIS: Donald Shepard.

DR. SHEPARD: I want to thank the panel very much for the opportunity to speak this morning. In response to the disclosure statement, I want to indicate I have no financial conflicts. I do want to acknowledge that we received a phone call on January 12th from Dr. Dean Ornish requesting a meeting. As we were working under a

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contract with CMS, we consulted with our project officer, and on whose advice then participated in a conference call hosted by CMS on the 18th of January with CMS, in which Dr. Ornish and some others participated.

What I'd like to do is speak on behalf of, first, myself and my two colleagues who have also been given the opportunity to speak, Dr. Sarita Bhalotra and Dr. William Stason. I will be speaking as the principal investigator of the Medicare Lifestyle Modification Program Evaluation.

The evaluation is designed to address four questions. First, what is the feasibility of a lifestyle modification program for the Medicare population? Secondly, what is the effectiveness of such a program? Third, what does it cost to Medicare and to providers to run such a program? And then finally, what is the cost effectiveness? The demonstration is still ongoing, so the results today are interim analyses that focus some part of the results on effectiveness and some part of the results on feasibility. I will be skipping a few

slides in the interest of time.
I'm speaking on behalf of a team that
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includes physicians, health economists, statisticians, health services researchers and management specialists. Our project officer is Dr. Arman. The Medicare program is looking at two models of lifestyle modification; the first is the Dr. Dean Ornish program to reversing heart disease that Dr. Ornish described earlier today; and the second is the Mind-Body Medical Institute enhanced cardiac wellness program developed by Dr. Herb Benson, who is also in the audience today.
I would like to give a couple of words of context building on the presentation earlier this morning from Dr. Clark from Alberta. As part of this context, we have also been looking at cardiac rehabilitation studies as one of the types of enhanced physician-supervised interventions, and this slide summarizes two of the meta-analyses of cardiac rehabilitation which examined 21 randomized trials of cardiac rehab conducted around the world. Two points I think are relevant today.
First is that they showed reductions in cardiovascular mortality as we heard. The multifactorial programs had a reduction greater than the reduction for exercise programs alone.
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The past literature focuses primarily on middle aged men and the demonstration that's underway now importantly adds to the population of older Americans in the study.
One of the characteristics of cardiac rehab is it has different degrees of breadth under different conceptions. Under the U.S. Public Health Service, it is very much like the comprehensive cardiac rehab that Dr. Clark spoke about earlier today, it is comprehensive, it includes not only exercise, but also education and counseling.
Under the Medicare program, the regulations are more narrow, they date back to 1989, and in Medicare it is seen primarily as exercise programs for cardiac patients.
The slides are, I'm skipping around, but in the interest of time, I will focus on these. We have been looking at the utilization of cardiac rehab in the Medicare population as a whole, and focusing on approximately 200,000 Medicare patients who had heart disease in 1997, we found that 13.5 percent or about one in seven received some cardiac rehabilitation services.
Medicare authorizes payment for up to 36 sessions
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of the outpatient type, and only 20 percent

completed this full number, the average number completed was 24 sessions. The utilization of cardiac rehab shows some of the same variations that we've seen earlier. Although the use overall was one in seven, we see it's below that in females, below that in black, and below that rate in the higher aged population.

In terms of the questions that the panel is addressing, in terms of effectiveness, as other speakers have said, I think there is strong evidence of effectiveness. In terms of generalizability to the Medicare population, I think the evidence shows an ongoing challenge that health professionals are facing.

I would like to speak now on behalf of Dr. Sarita Bhalotra. Does this button here also move? I'm trying to get to the next presentation. Let me see if I can push buttons at the same time. The next part of the presentation relates to involvement in the lifestyle modification program and so I would like to speak next to the question about enrollment in the program on behalf of my colleague, Dr. Bhalotra, and let me skip to slide 11. This slide presents

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the cumulative enrollment in the lifestyle modification program as of November 2004. As we see, there are 401 patients who have enrolled in the demo as of that time period, approximately 28 percent in the program of Dr. Dean Ornish, previously called Lifestyle Advantage, and 72 percent in the Mind-Body Institute's program. As we see, enrollment began in the year 2000. It was relatively slow until late 2002 and has picked up substantially. Again, recognizing some of the challenges in enrollment, the Dr. Dean Ornish program instituted a program with a nurse recruiter at several hospitals in West Virginia who spoke directly to patients to make the program available to them, and if you look carefully at the slide, you can see some decrease in the rate of enrollment as that program began. These data will form the basis of some of the interim findings I will present and will continue to provide follow-up data, both on participants as well as control subjects, not only on effectiveness, but also on cost.

If we skip to slide 40, slide 40 speaks to the question of what some of the barriers are that patients have found in participating in this.

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As we find, approximately half of the patients who were contacted didn't meet one of the enrollment criteria. Of the other half who did, there are a number of factors here that limited the enrollment, physical limitations being the

largest, patients that had trouble exercising to levels the program required or those not interested. But nevertheless, despite these barriers, as we saw, a significant number of patients had enrolled in both of the program models.

Go to slide 43. Enrollment I think is important to the panel in that the panel addresses the question of generalizability to the Medicare population, that understanding both the strengths and the constraints around enrollment, I think could inform future policy around coverage. And so, the analyses so far have found a number of barriers to participants in the time that's required in the programs, the stringency of the program, and in some cases, a copayment that the patients face.

The last part of question five for the panel asks about barriers to physicians and so from our management work of interviewing program

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people and physicians, we found a number of factors that have constrained enrollment, the important ones affecting the efficacy of the programs or not, to the patients. And so in summary, the enrollment today I think is helping us to understand that this is an attractive option to many patients and the understanding the factors that favor and keep enrollment, I think can be valuable to Medicare coverage.

Can I skip now to Dr. Stason's slides, and I would like to go to slide 50 of Dr. Stason's presentation. This presentation speaks to the interim effects on cardiac risk factors and stress. Thanks very much. The data are available on 287 of the enrollees as of November of 2004. 72 percent are in the BMI program and 28 percent from the Dr. Ornish program.

There were some earlier questions about compliance. 228 patients have been enrolled in the program long enough to have 12-month data available and data were actually available on 67 percent of those patients. That's approximately the number of patients who were participating at the 12-month time period, because the data comes directly from the programs.

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Can we skip to slide 52? One of the things that's striking about the demonstration is that the statement was made earlier, the patients already come into the program have made changes on many of the risk factors, so the baseline LDL is 89.9, already below many of the treatment guidelines that have been recommended. Total cholesterol is 160, and the body mass index refers to mild obesity.

DR. DAVIS: Dr. Shepard, I'm sorry to interrupt, but are you wrapping up?
DR. SHEPARD: Yes. Let me skip to slide 52, which is the last one, thank you. One of the major changes in risk factors is that at 12 months, the lipids fell by 5.3 milligrams. Both programs have been associated with favorable changes in risk factors as well as in stress. And so in conclusion, the program appears to be having beneficial impacts for those who enrolled in it and the challenge remains to the question of enrollment. Thank you very much.
DR. DAVIS: Thank you very much.
(Applause.)
DR. DAVIS: Nicholas Jacobs.
MR. JACOBS: Good morning. My name is

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Nicholas Jacobs. I am the president of both the Windber Medical Center and the Windber Research Institute in Windber, Pennsylvania. Just to give you some bearing on that particular area, it was a town that was created about a hundred years ago by the Berwind White Coal Company. It's now the home of ski resorts such as Seven Springs, Hidden Valley, Nemacolin are all in that same area, and it's about 30 seconds from where Flight 93 went down and about ten miles from where the coal miners were saved a few years ago. So it's in south central Pennsylvania and an area where after the 1977 Johnstown flood, we had the highest out-migration of population of anywhere except East St. Louis, Missouri. So it is a stark and difficult area, and I'll tell you my story as someone who endorses this program from literally the bottom of my heart.
In 1996 I went for my annual physical and although symptomless, due to a family history, it was suggested I go through a thallium stress test, and that stress test was picture perfect, I did my 14-minute run and had, again, no symptoms whatsoever. Two days later there was a knock on my front door and it was my family physician, who

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had never been to my home before. So if that ever happens to you, run and hide, because he came to tell me that the results of my stress test were imperfect. And in fact, a few days later I went in and they found that I had a 60, 80 and 90 percent blockage, but was still symptomless. I had two stents put in place at a cost of $43,000, and about a year and a half later I had two more stents put in at a cost of $28,000 due to the damage caused from the first heart attack.
So it led me to believe as a hospital administrator that we needed to find chlorine to put into the water to literally stop treating

typhoid case by case and needed to find a way to reach out to people that would help them help themselves so we could stop being cardiac victims. And so I got on the Internet and found the Preventive Medicine Research Institute. And I went to the program there, and met people who had been taken off the heart transplant, met people who were given months to live years earlier, and it was then that I decided that we needed to bring this program back to our little town in south central Pennsylvania.

And so I began to lobby Dr. Ornish and

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his people to allow us to do that, and in fact I was met with resistance. And the resistance was much of the resistance that I have heard here this morning, that is from the standpoint of could you really set this program up in a rural area where people, we had a higher percentage of octogenarians anywhere except Dade County, Florida, and would they really conform to lifestyle changes.

And in fact, I can say aha, we proved that they could. I came back from that trip completely committed to the program and what could happen with the program, and was invited to dinner at a physician's home. And the physician's spouse did not know what to prepare for me that evening, because I was now a full-fledged patient of the program. And so she gave me a large white plate with two little egg whites on the plate for dinner. And seated beside me was our congressman, who turned to me and said what's wrong with you? And actually it gave me a grand opening to tell him what was wrong with me.

And he said we're spending about a billion dollars a year in the military on heart disease, and this was, remember, 1997, '98. If

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you could find somebody at Walter Reed or Bethesda who would work with you, we might be able to help you with the program. So, I got in my car and drove to Washington D.C. the following week and was very graciously dismissed from Bethesda and ended up over at Walter Reed where I, the first white coat that I ran into was a gentleman who understood congressional earmarks, he took me directly to the head cardiologist, Dr. Marina Vernal, and she had Dr. Ornish's book on her desk. I explained to her the opportunity that we had to do research on this program for the military, and she agreed to work with us. And hence, at that point insurance coverage was not an issue, because it was a research project set up in cooperation with Walter Reed and with Windber Medical Center. We literally shared staff, shared

all results, and we moved forward in a very successful program that has gone on for five years. The result of that program for all of us has been phenomenal in the sense that people were asking about the dropout rate. We've had 298 participants, we have about a 13 percent dropout rate. And we have not had any problem recruiting

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people of those 298. I knew we had a winner. Before our actual Ornish building was built, our center was built, we were using the churches in Windber and I can remember walking through church rec rooms and seeing these 80-year-olds doing yoga, literally not unlike the pictures that we saw earlier in Dr. Ornish's presentation. And this is an area where 23 countries of primarily Eastern Europe settled, and so the primary menus in our area were kielbasa, pirogis, and gravy was on everything, and to see these people convert and become vegetarians and to see them move into this program with such vigor and such enthusiasm, I should have brought for you the folders that I have of thank you letters from the participants and their family members who have extended their lives and their quality of life from the work that they've done in this program.

DR. DAVIS: Mr. Jacobs, could you wrap up, please?

MR. JACOBS: I'm done. So I will complete this by telling that I personally am committed in every way and I have had a wonderful nine years now because of the program myself, and I hope you find the chlorine for the water. Thank

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you.

(Applause.)

DR. DAVIS: Thank you. Jeffery Dusek.

DR. DUSEK: Thank you for the opportunity to speak to you today. I wonder if I came to the right meeting. We're in the vast minority here, the Mind-Body Medical Institute, but I think the data will speak for themselves. I only wish our colleagues from Brandeis had more time, because I think what they were describing earlier was there has been a benefit to both programs, and I think we're going to raise all the ships, and I would like you to take what I have to say to heart.

I'm Dr. Jeff Dusek, research director of the Mind-Body Medical Institute. Dr. Herb Benson, who started the program over 30 years ago, had some conflicts and we weren't sure he could attend; he has and he will address you for the one minute this afternoon.

I just want to speak to what we have

been doing or Dr. Benson has been doing for the past 30 years. It has been typified in the Harvard Medical School Press, a book published last year, 80 pages by the nurse director of the

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program who couldn't make it today, but Dr. Benson is here, and this book goes through 30 years of evidence and experiences of the program. And I'm going to speak to the balance or lack of balance in our current health care system, namely the three-legged stool, there's pharmaceutical, surgery and self-care, and self-care is frittering away, and we would like to boost that back up to more of the model in which we have balance. Current health conditions covered by the cardiac wellness program include hypertension, diabetes, arrhythmia, and cardiovascular disease. It's a 13-week program that has group sizes of 12 to 15 persons. I'd just like to say I have no conflicts of interest. I am paid by the Mind-Body Institute and am fully covered by federal grants, so I have no financial interest in this program. The program has four components, a supervised exercise program, independent life exercise prescription, and includes aerobic exercise and training. This is for individuals who are post-MI and/or post-bypass, they have never exercised before, so it's a very individualized exercise prescription, but it's a programmatic development that is applied to people of really able bodies or

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unable bodies. The stress management, which is what we do exceptionally well, is based upon relaxation of the mind with physiological underpinnings, which are decreased heart rate, respiration rate, and a whole host of biochemical changes in the blood. This is based on yoga and mindfulness, and relaxation response training through audiotapes. Comprehensive training is performed in this program. Nutritional counseling, as you have heard all morning, is a major component of all these comprehensive programs. This particular diet is less restrictive, it's about 25 to 30 percent calories of fat. It's a balanced plate. Namely, how in this world, in this America do you have volumes of plates? The plates are overflowing, that's why people keep filling them with food. How do you teach people to eat appropriate amounts, stop when they're done? This program works on that. And also the Mediterranean diet, how do you incorporate more olive oil, more of the things that we know -- I'll stop there. Group support is critical to these programs. Educational presentations are coupled

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with group discussions. You have really taken these people after MI, after CABG, we have a multidisciplinary component and the group support really provides huge benefits.
I want to briefly go over our last four years of data. This does not include the Brandeis data that was provided in the health care lifestyle program. We've had 427 participants, 80 of which complete all eight programs, or eight or more sessions. 60 years of age, education 16 years, mostly male, some are smokers. Obviously we need to work on broadening this to older adults and women, there is no doubt about that.
I'm going to skip to the numbers, and I apologize for some of the glitches here.
Essentially, the pre-to-post numbers suggest that blood pressure, both systolic and diastolic, improve. Total cholesterol, high density lipids, low density, triglycerides all improve with a 13-week program. Our symptom checklist consists of 90 questions in which you report you either have a symptom or don't. Global stress dramatically goes down pre-to-post. Depression is an epidemic and we have a really effective program for that. If you look at the stress subjects,
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it's really remarkable, 69.2 to 62 on global stress, and 69.4 to 62 on depression.
I will skip that.
Essentially what we're trying to show is individuals who have symptoms at the beginning of the program don't have symptoms afterwards, and it's mostly angina and other physical symptoms.
So across the board both psychologically, physically, lipid normalization and reduction of blood pressure are all benefits of this program.
So, I encourage you to look at the evidence presented today, add this to that pool, and recognize that this is a program that can be used and is used across the country. Thank you.
(Applause.)
DR. DAVIS: Thank you. Dr. Mark Wexman.
DR. WEXMAN: Good morning, ladies and gentlemen, Mark Wexman. I'm a practicing cardiologist so maybe a little bit of a rare breed here. I'm a senior member of a 12-person cardiology group in Marin County and San Francisco. I hold a clinical faculty appointment at UCMSSF. I do receive a stipend as the medical director of our lifestyle program and
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I am here today under the good graces of the Heart Health Institute, which is a 501(c)(3) corporation that has paid for my transportation.

The TAM program has been is existence since 1993. It is community based, it is in a cardiology office, it maintains changing standards. What do I mean by that? I tell the participants different information in 2005 than I told them in 1993 because the landscape has changed. We now have different end points for lipid targets, we try to maintain coherency with the scientific data as it comes out.

There are five primary components of this program. As in many others that you've heard, we believe in exercise, we believe in nutrition. Our nutrition program is slightly different than Dean's. Our percent calories from fat is generally between 10 and 15 percent. We tend to incorporate some of the Mediterranean diet approaches into the diet, and it therefore is perceived maybe as less restrictive by some of our patients. Stress management in our program has used also a slightly different model, showing that there are many paths of this ilk. We use Tai Chi in addition to sitting meditation as a way to

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elicit the relaxation response that the Mind-Body folks have discussed with Dr. Benson's excellent work.

We believe in group support. We have used the model of the Center for Attitudinal Healing, which is Dr. Jerry Jampolsky's group. In order to have facilitators, we have trained psychologists who act as advisors, but the groups themselves are led by the stress management consultant and by one of the nurses, all of whom have gone through the training program at the Center for Attitudinal Healing.

We strongly believe in medical education. I know that my patients are smarter and better able to cooperate with physician care from having gone through the program. They receive a total of about 96 hours of face time with myself or my staff over an eight-week program, that is considered a core program. They are then invited to participate in a graduate group should they want. In order to reinforce the stress reduction and the group support program, staff members are always available individually for questions that may come up.

We host an annual meeting each year

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which, this is an example from earlier years showing a lot of happy smiling faces, some of them Medicare age, some of them not. We have touched many different areas and places in our community. We believe that this is a benefit at any age. Our oldest participant started at 84, claiming that by this time in her life it was time to make

significant changes.
The TAM population consists of a total of 421 people who have done the program because they had the identified disease. We've also had spouses participating in the program, there are about 120 of those who have gone through the five-year follow-up but they are not included in it. We have had 48 TAM programs since 1994. The average age is 61. We suffer from too low female gender, 20 percent, with 80 percent male. 74 percent have had myocardial infarction, angioplasty and/or bypass prior to the program, 13 percent had coronary disease without an event, and 13 percent of our participants had risk factors only.
The data that I'm about to show you is five-year follow-up data on the first 103 patients who had known coronary disease coming into the

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program, these were not the primary prevention group. There are three lines here. This speaks to compliance. If you were a highly compliant patient in all the various areas, 88 percent of them remained event-free over the course of five years, the average for the program was 77, and if you were less compliant the average was 74.
I think this points out something I tell my patients; anything worth doing is worth doing imperfectly. None of them will do this program perfectly and yet, the results can move them in the right direction.
This is our five-year mortality.
Again, out of 103 patients completing five years, less than four percent have died. The demographics have been spoken to but just to say them in another way, about 12.5 to 13 millions Americans today have experienced heart attacks, angina or both. In 2001, heart care costs exceeded 15 billion, each hospitalization cost the health care system a lot of money. And something that needs to be said hasn't been said, that we baby boomers are on our way and as they enter the Medicare population beginning in 2010, we understand clearly the politics of this, there are

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over 80 million of them who will become seniors over the next 20 years.
DR. DAVIS: Dr. Wexman, are you able to wrap up soon? I apologize but we are falling seriously behind.
DR. WEXMAN: I will do my best.
DR. DAVIS: Thank you.
DR. WEXMAN: The cost of our program is about $5,000 per year per participant. As an interest to the group, we had insurance coverage in only about 10 to 20 percent, the vast majority

of our patients paid for this. Patients who were not able to pay for this received scholarships from my practice, thanks to grateful patients who had been through and who were able to donate money, or secondary to the Heart Health Institute, which helped provide scholarships. I personally believe that no patient should do a program like this as an entitlement, everybody should put a few dollars in to their level of payment. This is, again, an example of survival compared to other studies. This may be something that is important to the physicians in the audience as well as our patients; if you do not change, you can become extinct. I would argue against extinction and in

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favor of change.
Thank you for your time. There are some additional backup slides with lipid data, depression data, hostility data, that are included in your handout. Thank you.
(Applause.)
DR. DAVIS: Thank you. I think we have a representative from the American Physical Therapy Association.
DR. TEPPER: Hello. My name is Dr. Steven Tepper. I am the director of the division of physical therapy at Shenandoah University and am representing the American Physical Therapy Association. I have no financial conflicts and was not paid by the American Physical Therapy Association to be present today. The American Physical Therapy Association is a national organization representing 67,000 physical therapists, physical therapist assistants and students of physical therapy. Our members play a vital role in lifestyle modifications for healthy individuals and for persons with coronary heart disease, diabetes, and other serious health concerns. We work with these individuals to promote healthier

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lifestyles through exercise and education. As part of being a physical therapist, we have what is called the guide to physical therapy practice, which we attempt to use as much as we can, and one of the specific guide patterns is called primary intervention for cardiovascular risk reduction, risk factor reduction.
Specifically, on the next slide, there was a nice article that came out and since I'm here to not present the data, I figured I would just show some very informative articles. There was an article that came out on physical activity and public health recommendations from the Centers of Disease Control and Prevention in the American College of Sports Medicine, as well as endorsed by

the American Medical Association. Basically the article stated that if we walk briskly for three to four miles on all days of the week, we could prevent 284,000 or more deaths from cardiovascular disease or roughly about 30 percent. What we can see from this one slide right here is that cardiovascular disease, and this was presented earlier by Dr. Ornish, that recently when they took 5,700 asymptomatic women, put them up on a standard Reuss protocol treadmill

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test and then followed them for eight years, what they found with these individuals, there was a decreased mortality risk of 17 percent for every net increase in their endurance. This is a very nice prospective study that looked at the role of walking as compared to vigorous exercise in the prevention of coronary heart disease and it remains controversial because the data on women in this population is sparse. When they studied 32,418 female nurses who were between the ages of 40 and 65 years old, and followed them for eight years, what they found was the prospective data indicated that brisk walking for three hours a week caused a 35 percent reduction, where that vigorous exercise for six minutes or above caused about a 30 to 40 percent reduction, so there were similar reductions in the incidence of coronary events among women. But again, the statement is just trying to show that a higher level of activity or activity in general causes reduction in coronary artery disease. When we looked at the study here to assess the type, amount and intensity of physical activity in relationship to coronary heart disease for the enrolled 44,452 U.S. males and they

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followed them for two-year intervals from 1986 through 1998, the conclusion was that total physical activity, running, weight training and walking were associated with reduced coronary heart disease risk. Average intensity was associated with reduced risk, as was the number of net hours spent in the activity. In this study right here, what they did was looked at a prospective study of two clinical examinations that were separated by five years to assess change or lack of change in physical fitness as associated with risk of mortality during follow-up and subsequent examinations. When they studied this group of 9,777 men, what they found was men who improved from unfit to fit between the first and subsequent examination had an age-adjusted death rate of 67.7 for every 10,000 man years, which represented a reduction in mortality risk of 44 percent. The conclusion was

men who maintained or improved their adequate physical fitness were less likely to die from all causes of cardiovascular disease during the follow-up than persistently unfit men. Physicians should encourage unfit men to improve their fitness by starting a physical activity program.

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And finally, in one study that already has been cited looking at diabetes, when they studied 3,234 individuals that were going down the alley to becoming diabetic, they were overweight, had increased resting glucose levels to begin with, when they followed them for 2.8 years, and they stopped the study one year in advance because the results from that were dramatic, when they looked at the control group as compared to the drug group with Glucophage, they found a 31 percent decline in the control group. With the lifestyle of mild dietary restriction with a goal of a seven percent weight loss and 30 minutes of walking five days a week, led to a 58 percent decline. I think that something I just want to key back to that is probably more interesting to this group is that when they looked at the group that was 60 years of age or older, that there was not a 58 percent decline but a 71 percent decline in the lifestyle group in the elderly population for becoming diabetic.

Just a little cost differential. I just got on the web and just did a little bit just to come up with an analysis, and I looked at the drug group and looked at how much it would cost to

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take that drug for 2.8 years, and I came up with roughly $2,657 and again, I imagine it would be a lot cheaper if you bought the drugs in bulk, but when I compared those to a lifestyle modification type, it was significantly decreased in the lifestyle modification as well as the other things, and that was almost twice as effective.

And so absolutely, exercise also has been shown to reduce risk of stroke, shown to reduce the risk of breast cancer as well, and so the more physically active individuals are reducing the risk of breast cancer. And finally, even though we know that exercise is something that we should do, it's amazing how often we don't follow what we know. Thank you very much.

(Applause.)

DR. DAVIS: Thank you very much. Susan Laramee.

MS. LARAMEE: Good morning. My name is Susan Laramee. I am employed by Prudential Healthcare Services as director of professional relations. I am here today as president of the American Dietetic Association, on whose behalf I

will be speaking. For the record, I have no conflict of interest related to this presentation.

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The American Dietetic Association wants to commend the committee for its important leadership role in undertaking the analysis of the role of physician-supervised behavioral interventions for Medicare beneficiaries with symptomatic coronary artery disease. Modification of eating behavior, food choices and food preparation techniques through the process known as medical nutrition therapy provided by registered dietitians is one of the clinical and behavioral interventions demonstrated to significantly affect treatment and quality of life outcomes for individuals with symptomatic heart disease.

The American Dietetic Association and its members are leaders in nutrition research and the development of evidence-based practice guidelines for nutrition interventions that effectively contribute to the management of disease. Specifically, modification of food choices and behaviors designed to improve cardiovascular risks have been shown to improve the quality of life and clinical outcomes. Similarly, medical nutrition therapy for diabetes, currently a Medicare-covered

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service, improves patient outcomes. The diabetes prevention program clearly demonstrated the importance of dietary behavior intervention resulting in lifestyle modification that can prevent, treat and manage diabetes and subsequent cardiovascular complications.

Treating and managing coronary artery disease is the primary concern as the health and quality of life of those afflicted plummet and health care costs and the financial burden continue to soar in this population. Currently, 78 percent of the Medicare population has one or more chronic diseases that require ongoing medical treatment. Almost two-thirds of the population have two or more chronic conditions, and 20 percent of Medicare beneficiaries have five or more chronic conditions. Coronary artery disease is among those chronic medical conditions that consume a large portion of Medicare funds.

Medical nutrition therapy is defined by law as nutritional diagnostic therapy and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutritional professional pursuant to a referral by a physician. Medicare coverage,

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however, is limited to diabetes and chronic kidney

disease. The coverage does not include hypertension, hyperlipidemia, and other conditions associated with symptomatic coronary artery disease. In March of 2003, the Center for Medicare and Medicaid Services sent a report to Congress on how to expand the MNT benefits. This report has been mandated in the law that created the diabetes benefits and a key finding of the report was that there may be a benefit resulting from dietary modification using medical nutrition therapy for patients with hyperlipidemia and hypertension.

A variety of groups acknowledge the importance and benefits of nutrition services provided to individuals with a variety of diseases and for conditions such as coronary artery disease. The U.S. Preventive Services task force report in 2003 commented, intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease, extensive counseling can be delivered by primary care in clinicians or by referral to other specialists such as nutritionist or dietitians.

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National evidence-based guidelines recommend nutrition therapy as the first-line management of hyperlipidemia.

According to the IMI report, the role of nutrition in maintaining health in the nation's elderly, evaluating coverage of nutrition services for the Medicare population, basic nutrition is defined as education and advice and can generally be provided by most health care specialists. Nutrition therapy, on the other hand, is an intensive approach and requires significantly more training in food and nutrition science than is commonly provided in the curriculum of health professionals.

According to that same report, nutrition therapy is effective as part of a comprehensive approach to the management and treatment of many conditions affecting the Medicare population and the registered dietitians currently are the single identifiable group of health care professionals with standardized education, clinical training, continuing education and national credential requirements necessary to be directly reimbursed as providers of nutrition therapy.

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DR. DAVIS: Miss Laramee, are you wrapping up.

MS. LARAMEE: I'm ready to wrap up, thank you.

Although other medical nutritional

professionals can provide nutrition education, the registered dietitians do go a step further, and it's our association's recommendation that this esteemed committee recognize the role of the dietitians along with the medical community to impact behavioral intervention, and recommend that their RCD include in it the team of health care professionals to recognize and provide behavioral intervention for seniors with coronary artery disease, and we hope that coverage should require demonstrated adherence to evidence-based practice guidelines for patient quality and optimal outcomes. I want to thank you very much for this opportunity. Thank you.

(Applause.)

DR. DAVIS: Thank you.

We have now a list of seven patients who have requested an opportunity to address the question and since they don't have Power Point presentations, we've asked them to use the

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microphone in the center so they can see us and we can see them more easily. And I realize that many of these individuals have come a long way to be with us today, but I would ask if you could limit your remarks to two minutes or less, we would appreciate it. Linda Bowman.

MS. BOWMAN: Thank you. My name is Linda Bowman, and I haven't worked outside the home for over ten years because of health problems. I am here on behalf of CMI, they did pay my transportation and costs, but there is no other benefit or financial interest. I am just here as an American that knows that life-changing things can work.

I come from a family history, most of my family has gone from heart disease and until recently, I have one sister left, and she had quadruple bypass three years ago, and she didn't want to have more surgery, she had multiple surgeries and angioplasties and different things and still died of heart disease. And she wanted to go check out this program, and I went along for the ride. And I think God really had a reason for me going there because I started thinking about the program and at first I thought there was no

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way I could make those changes, but with God's help I was able to.

And I can be up here now, but two years ago, I couldn't have made that ride. Because with my health problems, I couldn't come out in the cold weather because I had to wear something over my mouth. I also have asthma, which is virtually under control with my drugs. I lost a lot of weight, I was like 232 pounds, and I just know the

program works. Yes, you have to put a lot into it, but if I continue, and I already graduated a year ago and have kept with the program, and I even mentor and I just want to give back now because I'm able to. And if I could just say how much -- I didn't think I could have control or the hope I have now, so I feel that if I could make these changes, anybody could. And my goal in life now is to be the only family member that wouldn't have heart surgery or heart attack and die from some other cause, and I don't know that that will happen, but I know that I'm going to do my part since I was taught with the tools that I needed. Because I did try some cardiac rehab at one time, and I must be bull headed or whatever. It took me the year program to incorporate all

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these changes, and I do think that the program worked for me because I needed all this, I needed the stress management and the dietary changes and the exercise. Thank you for your time.
DR. DAVIS: Thank you.
(Applause.)
DR. DAVIS: Geraldine Waiter.
MS. WAITER: Hi. My name is Geraldine Waiter, and PMR paid for me to be here today, and I am so happy to be here today, because for the past year I'm alive. And from 1993 to maybe April of 2003, I was bedridden because I had a stroke, I had a massive stroke, and I have a bad bad heart, and I have diabetes. And when I was in a hospital, I saw the pamphlet on the program and I called my doctor and he said go for it. And at first they weren't going to take me into the program because of my medical condition, but the next day they called me back and said you're in, and for the past year and a half, I'm so alive and have so much energy and feel great, and I have lost 34 pounds on the program, and I'm a diabetic but my sugar is normal. Thank you.
(Applause.)

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DR. DAVIS: Thank you. Larry Massey.
MR. MASSEY: Good morning. My name is Larry Massey. I am self-employed, a preventive maintenance consultant in the mining and industrial industry in Bridgeport, West Virginia, and I have no conflict of interest.
And I did have coronary artery disease. A little of my prior history. Back when I was 42 back in 1991 I had a heart attack and had double bypass surgery which went well for quite a few years but then about five years ago I started to have problems again, and those problems led to a stress test and some ischemia that was there, and

some recommendations which I did not like at the time. My family physician then recommended that the Dean Ornish program was coming to the area, and I was fortunate enough to be among one of the first cohorts in that program. And after the 12 weeks of the program, I did have a subsequent stress test and no problems, and things have went exceptionally well since. It will be three years into the program coming in April of this year. We started a self-help community and I'm doing exceptionally well and trying to help others to also maintain adherence to the program.

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One thing I do want to mention also, those questions were addressed earlier, my insurance did not pay for the program, so I paid for the program myself. But it is not -- a motivation from my standpoint to stay with the program is that I feel better, and that's the important thing. I have a better outlook on life every day, my family outlook is better, and also I'm seeing a trickle down effect to also the rest of my family. My daughter, she cooks better for her husband and her family, they're looking at the ideas of exercise and things they need to do, and the total lifestyle change is just unbelievable. Thank you.

(Applause.)

DR. DAVIS: Thank you. Werner Hebenstreit.

MR. HEBENSTREIT: Good afternoon. I am Werner Hebenstreit. I'm 90 years old, was born and raised in Germany, and which country I had to leave under duress, and I lived in the San Francisco Bay area since 1946. As an independent self-employed businessman, I was during the entire time of my career on the run to stay on top of all my obligations. There was never enough time for

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relaxation or planned vacations. From a health point of view, I am a nonsmoker, I always had normal blood pressure, and I never had an overweight problem. However, in '73, a medical routine check established the sobering fact that my cholesterol was 320 milligrams. In '76 I began having chest pains and in '81 had my first heart attack. Exactly five years later, in January of '86 I had my second heart attack. An angiogram showed that one of my arteries was completely closed up and that two further arteries had severe blockages; at that time I had to undergo an angioplasty procedure. In April of '86, I got into the Ornish program, which just started around that time. It was a condition of this study that also the spouse or the living partner of the participating patient

had to make similar lifestyle changes. My wife, who unfortunately passed away not too long ago, had no real difficulties with the low fat diet. We also got relatively soon accustomed to the stress management and relaxation techniques. Only the group support section, that presented the real problem for me. As a typical loner who always kept in tightly his emotions, I

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found it difficult to talk about my feelings, and each living soul to listen to those of others. In order to evaluate the effect the program has had on me personally, one should consider the following observations: Before the program, the slightest emotional upset or physical effort gave me intense chest pains. To cross the street with the traffic light, for example, was practically impossible for me as I simply couldn't walk fast enough. I couldn't even shave and shower without angina. In addition, as a psychological problem, to adjust to the mentality of this, I was mad at myself, I was mad at the whole world. I hated the entire medical profession and I saw myself as a permanent coronary cripple who was on his way out. The program started first with a week-long therapy in San Francisco, and in that first week I started to feel the positive change in my condition. The frequency and also the intensity of my chest pains began to went on, and I also felt all of a sudden that I had a home again. And just to give you an example, when I got into the program, my cholesterol as I mentioned was 320 milligrams, and it went down relatively soon to an average of 145 milligrams.

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Also, my participations in the group support sessions has become more and more positive. I know now that many psychological factors play an important part in the development of my heart disease. It has dawned on me that I had the unfortunate tendency to flare up and lose my temper in connection with subjects and happenings over which I had no control whatsoever. A headline in the morning paper, for example, could upset me to such an extent that I couldn't enjoy and finish my breakfast. How could this blasted politician make such a mistake? A road detour or a traffic jam on my way to San Francisco made me swear up and down. And in order to draw my own attention to this constant and senseless explosions, I began to jot down thoughts of mine in a little notebook whenever such an occurrence took place. On the very best day I counted in the evening 33 entries, 33 times that day my blood pressure shot up and 33 times my heart started to race, and they gave all

this in connection with things which I couldn't change in the slightest. I gave up a long time ago to carrying a notebook. Nowadays whenever I feel frustration coming up, I do some deep

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breathing and think of the little notebook and simply start to breathe.
In the beginning of the program all patients had to undergo this type A/type B determination at the Friedman Institute in San Francisco. This is kind of a lie detector test which shows how a patient reacts to certain questions and mental images. This in turn makes it possible to recognize a specific behavior pattern which is very much connected with the development of heart disease. Incidentally, it could be proven at the Friedman Institute that the training for changing one's behavior can also change the likelihood of a heart attack. In my own case, I was requested to do some visualization, which simply means to use one's imagination.
You in your mind set are going out to dinner to celebrate a special occasion. It is one of those rare evenings in which everything works out beautifully, you find a parking space, your dinner reservation is in good order, there are fresh flowers on the table, you have a nice waiter, and also the hors d'oeuvres and the wine is excellent. Just as the main dish was being

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served, the doctor continued, the neighbor at the next table starts lighting up a fat black cigar. Would that bother you? Of course it would bother us, I replied. Who wants to breathe in cigar smoke whilst eating one's dinner? What would you do about it, she asked. Well, let me see, what would I do about it? I would call for the maitre d' and ask him to either address the smoker to extinguish his cigar or to please give us another table. And once you are talking to the maitre d', the doctor remarked, the man with the cigar stares at you provokingly and says drop dead.
So although this was nothing else but pure imagination, I was in a rage all over, my heart was racing, and though I was connected with all kinds of electrical wires, I started to jump up. At that time I was a typical type A person that had had two previous heart attacks. But this perception really took over my heart and took control of my feelings. This program has improved my entire personal, my marriage, and also the way in which I can now manage by former type A behavior as well as pain and stress.
And what about my physical? I can only

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tell you that I feel very very good. In fact, I know that there are no limitations or restrictions as to what I can do and would like to do. All this positive transformation is borne out by scientific evidence. Angiograms, I had one at the beginning of the program, and after one year, and after four years. All showed a spectacular reversal of my blockage. The 54 percent blockage at the beginning of the program went down to 40 percent after one year and to 13.3 percent after four years. Even the one that was completely blocked opened up again and showed after four years a blockage of 71 percent. Over the first six years in the program, I have all together five annual coronary PET scans at the University Hospital in Houston, which all showed without exception a continuous improvement in the blood flow to my heart, so far, so good.
Do I have two minutes more?
DR. DAVIS: I'm enjoying the whole story, but if you could wrap up, I'd appreciate it.
MR. HEBENSTREIT: Thank you very much. I have no financial conflict either, and I enjoyed talking to you.
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(Applause.)
DR. DAVIS: You got over your anger apparently.
(Laughter.)
DR. DAVIS: James Latterner.
MR. LATTERNER: I'm Jim Latterner. I have a family history of heart disease. My mother died at the age of 60 of coronary artery disease and my father died of congestive heart failure. PMRI is paying my expenses to attend this meeting. I am a participant in the Medicare demonstration program currently.
Several years ago I had chest pains and I had stents put in my arteries on two different occasions. About two years ago I had a serious virus infection in my heart that caused my breathing to be very difficult and a very traumatic experience trying to stay alive until the ambulance got me to the hospital. When I awoke at the hospital, I found myself with a respirator down my throat and my arms strapped to the litter. In the process they determined I needed to have catheterization, so in this condition they took me to the lab, they injected the dye, it upset my stomach, and I was vomiting
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with a respirator down my throat. This happened a couple of times and it was a very dramatic experience that stuck in my mind for a long time.

They then installed a defibrillator pacemaker in my body and at that point they determined my ejection fraction to be ten. They said once my heart strengthened I would need open heart surgery to keep open the remaining blockages that I had. On returning from the hospital, I was made aware of the Ornish program and through participation in this program, they determined through a thallium stress test that I didn't need open heart surgery, that they could handle the blockage with further stents, so I now currently have seven stents in my arteries. This past December, they did an echo stress test on me and my ejection fraction is now 50.

I have made it in the past to the ER with anxiety, and anticipation of another occurrence with my heart problem, only to determine that it was just that, anxiety, and there was no real reason to be there. This is enough incentive for me to stick to the program, not to involve my family in such traumatic experiences as running to the emergency room. And

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through the education and training program I have gotten through the Ornish program, that has brought me back to a life of relaxation and stability. So, I thank you very much.

DR. DAVIS: Thank you.

(Applause.)

DR. DAVIS: Wes Miller.

MR. MILLER: I'm Wes Miller. And I was using a cane to walk with and had the humiliating experience of riding around Wal-Mart in a wheelchair. I could barely walk to my mailbox because of angina. By the way, PMRI has paid for my expenses and I have no other conflicts.

In November 2001 I had a wake-up call with unstable angina, ended up in the ICU and got some disturbing news from my cardiologist. He said your bypass grafts are totally occluded and your vessels are too small, and we have to do bypass again, or do angioplasty; any further surgical intervention was discouraged. Well, that didn't give me a whole lot of choices. I thought that I had been doing most everything right for my coronary artery disease since my bypass surgery in 1994, but now I was convinced that I was going to die.

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My family practice physician informed me that I had been diagnosed with diabetes mellitus, type two, and that he had also referred me to a new lifestyle program that was soon to be offered by United Hospital Center. When I heard the phrase "reversing heart disease", I was interested. We live in a partially hydrogenated

world. When I began changing my diet and lifestyle, I began to see some amazing physical transformations.
This program has done more for me than I imagined possible. Because of angina, walking was difficult and I often needed a cane or a wheelchair. My physical condition was already less than desired due to a chronic back pain caused by three ruptured disks. Now I didn't like that, I wasn't going to settle for that. I knew that there had to be a better way and thank God I found a better way.
By the seventh week of this program, my angina disappeared. I no longer had any chest pain at rest or during exercise. I thought that this was too good to be true, but it was true. I used to get chest pain after walking 75 feet and now I can walk two miles without any pain at all.

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I can ride a stationary bike from eight to ten miles a day without any angina or other pains. I feel like I have been reborn, or like the Energizer bunny. I no longer use a cane or wheelchair. After being in a life giving transformation program, my heart ejection fraction increased from 45 percent to 60 percent. I lost 55 pounds. If you know anybody who needs a cheap wardrobe, let me know. My triglycerides came down from 819 to 28. My cholesterol decreased from 243 to 92. My LDL is up from 27 to 40. And with an HbA1c of 5.7, I no longer have to take medication for diabetes. My doctor, armed with this evidence, has discontinued or reduced the sum total of my 16 prescriptions by 94 percent.
Now these statistics are fine, and I have certainly worked hard to get to this point. But the most wonderful part of this program is the quality of life that I'm able to enjoy now, now that I thought that I would never be able to again. Instead of the fear of dying, it has been replaced by a gratitude of living. I have made a permanent lifestyle change. This is an emotional thing and it's not something to take lightly, and I am so thankful that I'm part of this program

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that has certainly been a life-saver for me. Am I going to die? Some day, but not today. I have too much life to live. To me, this life giving transformation program has given a whole new meaning to heartfelt thanks.
(Applause.)
DR. DAVIS: Thank you. Duane Jones.
MR. JONES: I am Duane Jones. My finances are paid for my PMRI and I have no conflicts of interest.
I am a product of two heart attacks,

open heart surgery, double bypass. Failing bypass after five years I was left with congestive heart failure whereupon at one time on a routine cardiac visit to my cardiologist, he asked me if I was tired and I told him yes, I had been. I couldn't even work in the yard without getting short of breath in one or two minutes. And he said he wanted to advise me that he wanted to be, wanted me to be evaluated for a heart transplant. At this time I felt I could not accept this, there had to be a better way, whereupon my wife and I decided to investigate the Dean Ornish program. And we were accepted, and the lifestyle change just increased my ability and the strength

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and my life was restored to me, and without the program I doubt if I would be here today. And I wish to convey my thanks and appreciation to the dedicated staff of Windber Hospital, because they have given so much to me. And I have been thinking about what I want to pass on, and I just want to pass on to other people that if they would accept this program and go work through it, be diligent and never give it up, because if you give it up, you're back to where you started, and I just want to thank them so very much and just ask that this program will be considered for this financial support. Thank you.

(Applause.)

DR. DAVIS: Thank you very much. That concludes the comments that were scheduled. Now we have the item on the agenda for open public comments, four people have asked to address the committee and you think if the subcommittee is up to it, we will take their comments and then break for lunch. And the first is James Barnard.

DR. BARNARD: Thank you. I'm Dr. Barnard, a professor at UCLA and director of research for the Nathan Pritikin Research

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Foundation Center. I have no financial interests. The Pritikin Longevity Center did pay my finances to get here.

I've been doing research on the Pritikin program since 1979. This includes experimental and animal work in my laboratory at UCLA, 42 publications on participants that have gone through the Pritikin program, and two studies that we've done at the Clinical Research Center at UCLA. These data have been published in the New England Journal of Medicine, Circulation, Hypertension, Diabetes Care, Cancer Research. The largest lifestyle trial was published initially in the New England Journal and then in the Archives, which involved an analysis

of over 4,500 people who had been through the program showing an average reduction of 23 percent in total and LDL cholesterol, an average reduction in triglycerides of 33 percent, just due to using a very low-fat diet and exercise intervention. We've published several other papers looking at other risk factors including CMS-reactive proteins, cell adhesion model tools, platelet aggregation, and many other factors related to atherosclerosis. We published a large

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number of studies on people with hypertension showing that the vast majority of people are able to normalize their hypertension, more than half are able to get off of their medication. We published a paper on people taking statins who came to the Pritikin center, almost 100 people, and within three weeks they lowered their cholesterol by an additional 19 percent by adopting the low-fat diet and exercise program. Probably the most important study was the five-year follow-up study we did on 64 cardiac patients that had all been recommended for bypass surgery but tried the Pritikin approach. At the end of five years, 81 percent had still not had their bypass surgery. Two people had reinfarcted and only two people had died from myocardial infarction. Those mortality statistics are as good if not better than what Dean presented for his randomized trials. I think the conclusions are very clear, that the majority of people who are willing to make the lifestyle change can benefit dramatically and reduce medical costs, improve their overall health status, and I urge the committee to approve this request. Thank you.

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(Applause.)

DR. DAVIS: Thank you. And just to make sure all the committee members are aware, we do have some written materials from you that have been distributed. Dr. Mark Fuller.

DR. FULLER: How are you doing. My name is Mark Fuller. I'm an internist and psychiatrist, and I'm here on behalf of Highmark Blue Cross Blue Shield. I was serving as the senior medical director for a number of years and it's a three millon member nonprofit health center in western Pennsylvania, but also serves people throughout the country. In the 1990s we were challenged with finding ways to improve our patient health while reducing our health care costs, which sounds mutually exclusive. And we didn't have to look very far to see what some of our highest costs were, which were cardiovascular disease. Using

the mother may I approach, utilization was our primary goal at that time, and we did reduce some unnecessary costs, but we did very little to actually help our patients. One of the programs we looked at that we found a great deal of success with was the Dean Ornish program, and in fact

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myself and some of the other senior executives brought that program to Highmark to cover our members with it.

We have now had over 800 patients complete the program and have been very satisfied with both the clinical results as well as the financial results. And also, it's one of the few things that I did as an insurance executive for which I got thank you notes for.

And with regard to your question with regard to regression, that's the toughest thing when you have a large group of people. Our group did three analyses trying to assess that. First we used a control group that was sort of free-ranging and consuming care, and we had about a half again reduction in care costs compared to the control group. We also age, sex and utilization matched our Ornish patients against our controls in the health plan, because they should have similar responses and indeed, we still saw a significant reduction in health care costs with the Ornish patients. Then we used the XEG modeling software to predict what might happen to our Ornish patients and we still got the same reductions in health care costs.

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So thank you very much, we are a very satisfied insurer. Good luck.

(Applause.)

DR. DAVIS: Thank you. Dr. Herbert Benson.

DR. BENSON: My name is Herbert Benson. I am the Mind-Body Medical Institute associate professor at the Harvard Medical School and I'm the founding president of the Mind-Body Medical Institute.

Over my 35 years of work in this field, I have come to recognize that indeed, as Dr. Dusek presented, we should view health and well being in our opinion as being akin to a three-legged stool being held up by one leg of pharmaceuticals, a second of surgery and procedures. But with over 60 percent of visits to health care professionals in the mind-body stress-related realm, there has to be a third leg and that third leg is self-care. And that's what you're hearing about today in this marvelous testimony that researchers, clinicians and patients are giving you.

And soon I hope that the way medicine

is being practiced in the United States will change, and will stop being solely dependent upon

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pharmaceuticals and surgery and procedures. We need them, many of us would not be here today without them. We also need self-care, and the wondrous happenstance of you as the committee coming together to consider for the first time a major endorsement of that three-legged stool in one of the most prominent diseases in the United States today, cardiovascular disease, is indeed a marvelous event, and so many people will continue to be helped by being able to pay for these programs. I'm delighted that this is occurring and I wish you success and I hope a favorable outcome in terms of supporting programs where people can be trained to help themselves. Thank you.

(Applause.)

DR. DAVIS: Thank you. And the last speaker is Caldwell Esselstyn, if I pronounced that correctly.

DR. ESSELSTYN: My name is Caldwell Esselstyn, Junior. I am a retired surgeon from the Cleveland Clinic, but I continue on as a preventive cardiology consultant to follow up with my arrest and reversal study in coronary disease which is now approaching its 20th year, and you

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should have a handout with my statement, which is stapled to a peer reviewed article which summarizes that.

What I want to do with you this morning is just to share with you two points, namely evidence-based research and focus of control. For evidence-based research, Paul, thank you, as you can see, this is an angiogram that on the left, this happens to be the left anterior coronary artery of a 44-year-old colleague of mine who with a cholesterol of 156 following his surgical schedule, had severe pain with the elephant sitting on his chest, and he infarcted. And this is the area of his disease in the distal third of his left anterior descending, but it was too long a segment for an angioplasty or a stent, and it was too far down for a bypass.

And we had him out to the house, and at that point in 1996 I said look, Joe, we've got ten years of data on this, and he said okay, I'll go the flat base route, but I'm not going to take any of that cholesterol lowering medication.

Two-and-a-half years later, as you can see here, he has completely resolved, and he did this without any instrumentation, and without anything

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other than this deciduous appearance. His

cholesterol went from 156 to 89, he was like a rural Chinese, and his LDL went from 98 to 38. But what about this, after two-and-a-half years, why do we see these rather profound rapid resolutions of angina? Here's an interesting PET scan that I want to share with you of a 58-year-old stockbroker from Cleveland with a baseline cholesterol of 248. As you can see here in the scan, where it's yellow or where it's orange, he is well perfused, but in this patch of green is ischemia. I saw him one hour after this, and ten days later his cholesterol was down from 248 to 137. We then repeated the scan after three weeks, and as you can see now, he is reperfused, and most of the endothelium has been restored. I'm proud and delighted to be with you today. There is a philosopher that once said that wisdom is knowing what is right, and virtue is doing it. Thank you. By the way, I'm unaware of any conflicts, although I did get some transportation support from Dean.

(Applause.)

DR. DAVIS: Thank you very much, and thank you to all the presenters this morning. Let

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me just review what remains for the rest of the day. We're going to take a lunch break in a moment, we'll see if we can get everybody to reconvene at about 1:30, which is about 55 minutes or so. And I think if we take about a half an hour for questions to any of the presenters from this morning and then move into open committee deliberations followed by voting, we'll be in good shape to finish on time, if not early. Just a heads up to those who haven't been through this process before, you will see at the end, we have an agenda and it says formal remarks and vote, so we'll go through the voting process for the questions that you have received, and Michelle has these numbered cards so that we will act like Olympic judges. And we will also go across the table and give each member of the committee and the opportunity if they'd like to explain why they voted the way they did, and that will be, again, taken down as part of the official record of the meeting. So that's the schedule. I thank you for your endurance, both members of the committee and members of the audience, and we will break now and reconvene at 1:30.

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(Luncheon recess at 12:37 p.m.)

DR. DAVIS: I hope everyone got their own batteries recharged over lunch. Now that everybody has had a heart-smart lunch, we can get back to business, and why don't we just open it up

for questions from panel members for any of our presenters from this morning. Yes, Bill.
DR. OWEN: From any of the presenters either this morning or this afternoon, if I could get a sense of what the start-up cost of a program such as this would be. Unencumbered by any knowledge, I just have a visceral feel that there is pretty substantial fixed start-up costs.
And then the other part of that question is, are we hearing about programs that can only be offered in selected centers or arguably, if I've got a number of substantially committed practitioners, that they could incorporate this into our office practice?
DR. DAVIS: And please identify yourself at the microphone for the transcript.
DR. ESSELSTYN: Caldwell Esselstyn. I think you're going to find that there are going to be a spectrum of start-up costs and I think as needed, there will probably be different programs

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for different sources. My motivation in sort of getting this going, the research study that I mentioned was completing its 20th year now, the whole focus that I had was to be as observant as I could of the dignity of simplicity.
And by that I mean how can this, suppose there is a patient in Tortilla Flats, New Mexico who can't afford to go to some fat farm, and that patient's physician wants to try to give the kind of care to his panel of coronary artery disease patients that is consistent with the best there is. And I maintain that if we can train that nurse clinician that he has, and so that perhaps the cost for that particular situation would be the cost of training that nurse clinician, so that she can get the same type of counseling skills, to have those coronary patients learn to eat the plant-based diet, and with that physician's help achieve the cholesterol goal of getting the total under 150 and maintaining the LDL under 50, and then with that feedback that comes from getting a lipid panel on a regular basis, know that once they have achieved and maintained that level, they have made that particular patient coronary disease-proof.

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That's an isolated setting, but I think it can be done that inexpensively. It doesn't require in all settings to have the exercise physiologist or the clinical psychologist or the dietitian, although this is not to say that those people are not terribly essential for other prototypes of programs which are more suited to that.
DR. DAVIS: Any other answers? Yeah,

please proceed to the microphone.
DR. CLARK: Thank you. Alex Clark.
Just reiterating some of the things that came up in the systematic review that the individual counseling models showed little difference in performance compared to the comprehensive contact rehabilitation and the contact rehabilitation, and those individual models, I guess could more readily have application, I guess, to primary care centers.
Start-up costs, we don't have any hard data, but the thing to consider, I believe, is that those interventions often involving individual counseling interventions with individual patients, whereas comprehensive contact, you have some group-based professionals

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which may cut down on staff cost.
DR. BARNARD: Jim Barnard. When Nathan Pritikin started his program in Santa Barbara, he sent the people out to go for a half hour walk in the morning, a half hour walk in the afternoon, which didn't cost anything at all, and he had a nutritionist that worked with him to teach them how to change their diet so they could follow a healthy diet. So the start-up costs don't need to be tremendous.
DR. SHEPARD: I'm Donald Shepard. At Brandeis we've been looking at some of the costs of the program. In our analysis so far, the start-up costs haven't been as significant as the ongoing costs. There's a couple of slides in your packet, numbers 69 and 70, in which we estimated the cost per participant, they varied from about $3,500 to about $10,000 among the program sites that we have examined, the cost primarily for the ongoing labor of operating the program.
DR. OWEN: Is that volume-related? In other words, the more I put through the system, the more the cost comes down?
DR. SHEPARD: In part, but also the intensity of the program, the number of classes,

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so we tried to estimate what the cost would be and those numbers are essentially full volume costs.
DR. HERMAN: Are those costs per year or for the 12-week program?
DR. SHEPARD: Yes, they are for one year of activity with the program, the first 13 weeks plus the remainder of the first year.
DR. HERMAN: And out year costs?
DR. SHEPARD: Out years, the program is primarily self-directed in the outer years, so we focused on the first year of the program and the costs at that point.
MS. LARAMEE: Susan Laramee, American

Dietetic Association. Dr. Clark was good to point out that the individual counseling model can be effective, but for medical nutrition therapy, from the nutritionist's point, there is no reimbursement for a Medicare patient either way. Whether it's to be intervention under a physician-supervised group setting or whether it's individual counseling, it still is not a benefit for Medicare recipients.

DR. ORNISH: I just want to clarify that the cost for a program like the ones that we have been talking about is more expensive than

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traditional cardiac rehab because it's a lot more class time, a lot more supervision, a lot more staff. But despite the costs, we have shown that there is substantial cost savings and we in fact cut the costs in half over the first year. And after three years, even including the total cost of the program, it saves money. It's a year-long intervention, but after the year Medicare in this case, or whomever, doesn't continue to pay for the patient continuing in the self-directed community where they meet among themselves, it doesn't cost the insurance payer anything.

It is volume-related and one of the reasons the costs have been high is that the enrollment has not been as great as it could have been, in part because it's a bit of a Catch 22. In other words, when I had dinner with Michael Wolf a couple of weeks ago, he was bemoaning the fact that while -- he had just written an article, an editorial in the American Journal of Cardiology that while there is more evidence than ever that these kinds of behavioral interventions are beneficial, most cardiologists don't want to do preventional cardiology, they want to do stents because that's what's reimbursed. And so, it

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becomes self-fulfilling. If Medicare would cover interventions like this, more doctors would start learning about them, more programs would be offered, more patients would go through them, and the volume of patients would go up. There are certain fixed costs when you have a staff of people, a dietitian, an exercise physiologist, and so on, you have certain fixed costs and when a larger volume of patients go through, it's lower. And also, there are certain costs associated with the Medicare demonstration project that wouldn't be involved in a clinical project.

DR. DAVIS: Rita.

DR. REDBERG: Just about the Highmark Blue Cross Blue Shield, I'm trying to understand the relationship between the revascularization rates and the people in the program. And in

particular, I guess I'm not clear on this slide that says change in event rates, cumulative two-year follow-up, and then it has decreases from baseline in PTCMSA and CABG. What was the baseline rate that it decreased from?
DR. ORNISH: I think probably Mark is in a better position to explain that.
DR. FULLER: Yeah. Could I see which

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slide you're looking at?
DR. REDBERG: It was from the presentation that Dr. Ornish did, and it's this slide.
DR. FULLER: What we did is look at the year before --
DR. REDBERG: It's on page 28, and at the top it says Highmark Blue Cross Blue Shield Demonstration Project, and then it says change in event rates, cumulative two-year follow-up, and it looks like 104 in the Ornish group, 36 in the control.
DR. FULLER: What we did was we looked at the net rate in the year before people went in the program because these people were insured by us and we had all the costs already in our system, so after they entered the program we could look retrospectively and see what happened to them the year before and then follow them out for however many years they remained a member. And the same with the control group, we could see what was happening to them beforehand and then follow what happened afterwards. And then the event rate, the baseline is whatever happened to them the previous year.

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DR. REDBERG: Okay. So then, both the control group and the Ornish group had fewer angioplasties than the year before?
DR. FULLER: Correct.
DR. REDBERG: And the control group had more CABG and the Ornish group dropped.
DR. FULLER: Correct.
DR. DAVIS: Anne, is this on the same topic?
DR. CURTIS: It's slightly different, so I can wait.
DR. HERMAN: And the control group, again, was?
DR. FULLER: The control group was a group of people who came to a lecture on what the Ornish program is like and then received a book, one of Dr. Ornish's books that described the program in detail and how to follow it, but then did not actually enter a Ornish program.
DR. HERMAN: Was there a choice, or was it by randomization?

DR. FULLER: There was no program available in their area.
DR. DAVIS: Anne.
DR. CURTIS: I wanted to get back to
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the same issue of event rates, and it might be Dr. Collins who would be better to answer this one. There was talk about using the program and then having the intervention rates go way down, that patients have fewer angioplasties, fewer stents, fewer bypass surgeries. There was a program involved and there was a financial incentive, obviously, to not have these patients undergo these procedures. How do we know that it wasn't just delayed, that the patients, you know, maybe didn't have the intervention at two-and-a-half years but did at three-and-a-half years after the program was over? In other words, could there have been some encouragement to delay patients having procedures because that was, your know, that would affect the efficacy of the intervention?
DR. ORNISH: Mark, you may want to address this too, but in the study published in the American Journal of Cardiology in 1998, the patients were, they went through a one-year intervention but they were tracked for three years, and 77 percent of those patients were able to avoid revascularization during that period of time.
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If we had 100 percent failure at three years, because if we were just delaying the inevitable, you still would have broken even, because if you took the 30 or $40,000 that would have been spent at the beginning, invested it at, say, ten percent return, it would have generated over a period of three years more than the cost of the program. But we didn't have 100 percent failure rate at three years, we had 77 percent success. And so even if it were just delaying, it still would have been cost effective, but it was much more than that.
Now, Rick or Mark, you might want to address the issue of did you just, were you motivated not to do angioplasty just because you wanted them to stay in the program?
DR. COLLINS: That's a very good question. No. It really, in the long-term follow-up of these patients which you don't have the data for, I can tell you in our experience in the ten years, we actually saw stabilization during the whole process. There was initially in that three-year period patients where they became unstable, but the number was not excessive. Where we saw the need for angioplasty or bypass surgery

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were in those patients who were not adherent into the program.
Remember, I told you about how we started the program and we told Mutual of Omaha at that time that if they failed the program and were participating, we would deduct the cost of that program against bypass surgery or angioplasty. We only had to pay on that for one patient, and that patient was one who had two vessels closed and had somewhat of a left main equivalent, but she wanted to start the program anyway to see if it would be effective. We also had another individual that in that three-year period was on a heart transplant list and was taken off and improved and did very well. So the main savings was of course up front, but there was a big savings down the road for Mutual of Omaha as well.
DR. FULLER: The patients that were in the program that we were covering were managed by their personal physician, so even though there might be that influence from the nurse case manager, perhaps exercise physiologist or other people working with them, it was ultimately up to the physician to decide whether they needed the procedure or not. But I think probably the thing
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that was most valuable for us is that many patients were having procedures not because it would extend their life. In fact, patients that were critically ill were excluded from the program, we would not encourage or even allow patients that were unstable or had left main and diminished left ventricular function even to enter the program. They were encouraged to undergo more traditional and more appropriate therapies. So most of the people in our program that were having angioplasty or having bypass were doing it in order to extend their life, so when their symptoms went away, they either delayed it or didn't have it at all. So, thank you.
DR. DAVIS: Other questions? Yes, Bill.
DR. HERMAN: I had a general question about the uptake of the program when it was offered through managed care. I enjoyed David Lambert's presentation very much but was struck by the fact that the managed care organization covered 426,000 lives, but over four years only 424 people enrolled in the program, and there has been a number of comments about eligibility for the program. And I was just wondering about
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particularly the managed care demonstration project experience with these programs, why does the uptake seem so low when it is a covered

benefit, or are there major hurdles in terms of people being eligible to enroll even when it's offered as a benefit?
DR. LAMBERT: Our program has actually been offered for between two and three years now. And because we wanted to implement it and make it available to our members statewide, that's why we approached ten different hospitals. But their actual beginning dates were phased over probably a six-to-ten-month period.
And this is different. This is change. And we traveled extensively to the communities where the programs were offered, we met with the physicians in those communities, and in almost every community there was a knowledgeable physician champion for this type of program. In one case it was a high volume cardiac surgeon, other cardiologists, and in some cases primary care physicians. But building the knowledge of the program, building the physician support and referral base for the program, all of that takes time.

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We have had significant increases in people inquiring and going to open houses about the program when, over the last year we have started to do something that's part of the new Medicare advantage plans, which is to identify our members that have cardiac-related diagnoses or treatment, and then communicate directly with them about the program, and we're doing that on a quarterly basis. We're going into claims data and sending them out information, and we're seeing a significant rise. But I think that it's in part because you have seen a number of start-up situations here, and it takes the results, the successes that you see and the word of that to spread in order for the numbers to go up.
And as I mentioned before, it also takes reimbursement. And there are many potential participants who come to our program sites in West Virginia that don't have coverage and we set up scholarship programs, there are those that are set up through the hospitals, but still that is not enough to make it available to everybody who wants to participate. And we have taken the unusual step in our state to actually go and try to meet with the medical directors and in some case the

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CEOs of our competitors, because there needs to be a critical mass of reimbursement in order to help build that critical mass of participation in order to support the viability of the programs.
DR. HERMAN: And is it limited to secondary prevention, so people with known coronary disease at this point?

DR. LAMBERT: Our program is available to individuals with diagnosed heart disease, diabetes, and we also make it available to an at-risk population. Based on Framingham risk scores, we precertify people, so it's actually an objective quantifiable measure, so it's actually pretty clean and pretty easy to determine eligibility for the program.

DR. COLLINS: Dr. Richard Collins. That raises a very interesting question, because as a cardiologist I have seen a changing attitude in America, and that is that cardiologists with a catheter and a balloon and a stent can fix anything, and they do. And patients arrive then and don't even participate in cardiac rehab because it's just a small pimple in their life, and they know that they can get another balloon and angioplasty, so they move on. So in essence

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they get no lifestyle control, they pop out with a statin, and the cardiologist is ready to do it again. And that's the way medicine is set up in America, and it's going to continue that way unless we take control and start to work on chronic disease management.

MR. JACOBS: Nick Jacobs. I forgot to mention before, I have no conflicts. I even paid my own pay here today. I just wanted to say that we're in an area where there are 12 practicing cardiologists, we've had this program for five years and we've had zero support from any of the cardiologists. So where goes Medicare, hence goes the practices.

DR. CLARK: Alex Clark, University of Alberta. I'm just going to talk mainly from my experience in Europe and Scotland in particular about some of the issues that you're raising. We know that there are (inaudible) generally. Despite a large body of evidence from international randomized control trials, it's been slow to take impact, particularly among non-specialists, family doctors. So uptake of evidence, even when there's evidence of clinical benefit, can be slow, and this has clearly, I

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think, impacted on the slow uptake in referral for patients with CAD, particularly to cardiac rehabilitation programs. With physicians often being the gate keepers, we are very much relying on them recognizing the evidence academiologically such as RCTs in support of these kinds of programs and referring patients on. So in this area, again, guidelines have only come on stream relatively recently. The first time we had guidelines in the U.K. were only published in 1997, the paper in Circulation was only at the

turn of the millennium, so it's only relatively recently that the evidence for all these programs has been visible. Even then, once the patients are on programs, there is the issue of capacity. I did a national study in Scotland that identified the programs that are effective in treating younger patients, but for older patients with comorbidity, they need much more tailored programs, and sometimes it's an issue of program resources and whether those programs can respond or not.

DR. FULLER: Mark Fuller from Highmark. One of the struggles we had internally as a payer when looking at coverage may be something that

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you're thinking about right now, so I wanted to share it with you. Part of our senior staff thought this program was so arduous and so painful, eating sticks and twigs, and exercising regularly, that no one would do it. So part of our staff said let's not do it, no one will take advantage of it. The other half thought we would be overrun by roving vegetarians and they would bankrupt our company. So we had these two sort of arguing, and the results were sort of in between. This program is not for everybody, and we did not have every single person eligible for this program coming and volunteering to do this. But there is a subsection of patients that are interested in this. They don't want their chest cracked, or they don't want it cracked again, they don't want to die prematurely, they don't want to live with the disability of heart disease, so there is a subsection of the population that embraces this program.

DR. ORNISH: I also want to build on what Mark and the others just said, that this program isn't for everyone. But the point is not how many people will do it, but of the people who want to do it, how many are going to be

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successful, because you don't pay for the ones who don't want it. And so what we found is that given the process of support, most people who think they can do it do it really well, and you're not paying for the other ones, and so that's an important point.

Another point is, one of the reasons why the recruitment was so low in the Medicare demo, especially in the first couple of years, is that we were only initially taking people who were choosing diet and lifestyle as a direct alternative to angioplasty or bypass surgery, and the reason was that the cost savings were the most dramatic and the most immediate.

But practice patterns change. Before a

person would have an angiogram, they'd wait a few days to a week and they'd decide to do the angioplasty, and during that window people could be recruited. Then people were having an angiogram and angioplasty in the same setting, so the window of eligibility was literally a few minutes. The doctor would say, here's a blockage here, we can fix it or you can go home and die, which is often the message people got, so naturally, most of the time the people would have
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the angioplasty. Then they changed it and the criteria were broadened so that they could be post-bypass or post-angioplasty, and so the criteria became much easier.
But I want to emphasize again how important reimbursement is, and why this meeting today for me is historic, because what Medicare covers really determines medical practice, it's as simple as that. It's not so much dying, it's reimbursement. I mean, let's be real here. And when I was talking with Dr. Welch about the American College of Cardiology during the break, he'd just written an article, an editorial in the American Journal of Cardiology bemoaning the fact that most cardiologists don't want to go to preventive cardiology at a time when there's more evidence than ever that it's effective, they only do stents because that's where the reimbursement is. So when we change reimbursement, we change medical practice and medical education.
And so, you know, if you decide that there is enough evidence here to warrant making a favorable decision at the end of the day today, my guess is there's a good chance that there will be a national coverage decision sometime in the next
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six months, and that will really rapidly change what's considered mainstream in medicine. There will still be bypasses and angioplasties, as there should be, but for that subset, as Dr. Fuller said, who want to make these changes, who will then have the support to do it, will become a part of the mainstream.
We've had the nurse recruiter for the last year and a half to try to help us recruit patients. One of the things we learned is that most of the cardiologists weren't even aware of the program in the hospital, again, because we didn't have reimbursement. When we have reimbursement, we also have awareness, so it all really centers around that.
DR. DAVIS: Dr. Phurrough.
DR. PHURROUGH: So I can take it from your comment that if Medicare stops paying for stents, that that would work okay?

DR. ORNISH: What would work okay?
DR. PHURROUGH: We stop paying for stents and that would solve the problem of reimbursement?
DR. ORNISH: No, no, let me be clear. I appreciate the gesture. Medicare should pay for
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stents, Medicare should pay for bypass. Medicare should pay for stents, but Medicare should also pay for programs like what Dr. Benson and Dr. Esselstyn and others are doing, and Dr. Wexman, because they work, and that way people have real freedom of choice, which right now they don't have.
DR. PHURROUGH: Let me ask this. If we move beyond the evidence discussion here for a moment, and let me talk about just some practicalities of Medicare policy. If we were to determine that we are going to reimburse for some type of behavioral modification program, we've heard two or three different versions of that, from Dr. Barnard telling them to go out and walk half an hour twice a day and telling them what to eat, to the very formal program that you discuss, to our Cleveland Clinic, the doctor with a long name that I'm sorry I don't remember, that's sort of somewhere in between there. This engenders some difficulty in determining what we would and would not reimburse for, and the difficulty of sort of the "build it they will come" phenomenon of, if it's a service that we provide, how in the world are you or any of the other programs going
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to expand to take care of the not 700 million beneficiaries with cardiovascular disease, but of our close to 40 million beneficiaries, a large portion of those will have cardiovascular disease, and where are they going to go? Who is going to provide these services for them? We have some significant utilization questions.
DR. ORNISH: Those are important questions and let me try to take a stab at addressing that. You didn't say this, but also there's been the question of how do you control for payment, fraud abuse, those kinds of things. Clearly, I think that part of what has come out of the Medicare demonstration program is it has shown that it's possible to set up formal patient selection criteria, to set up payment mechanisms, have a defined program, and as far as I know, there has been none, or very little if any fraud or abuse as a result. Essentially it's too hard to do; it's not that patients are going to do this unless they really need to, so I'm less concerned about that.
But you know, I'm obviously pretty

biased, because I've spent 28 years doing this, and I hear stories such as these patients have
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told thousands of times, which is why I'm so passionate about doing this. But you know, if we were sitting here and having a discussion and saying, you know, we found that if you blow up a balloon in someone's arteries that it makes them feel better, we'd say how in the world are you going to teach everybody how to blow up balloons in people's arteries. You know, how are you able to do that, how are you going to pay for that, how are we going to train all those people to do it? Well, it became a covered benefit and lo and behold, people learned how to do it.
The same is true here. We've shown that we can train other teams of people to do it, that there are different iterations and variations of the program that have different benefits, and that some are going to appeal to some people more than others. That those people that we train can motivate their patients in general to maintain these changes in very diverse parts of the country, in both academic and community settings.
And so, I strongly believe that, A, there is enough scientific evidence to say that these programs are safe and effective, and B, that if Medicare were to reimburse it, then there would
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be a lot of people who would be interested in learning it. And finally, so much of this becomes self-fulfilling. If I'm a doctor and I have a patient and I say, or they say, you know, Mr. Johnson, your cholesterol level is too high, and I know you're not going to change your lifestyle, and why would you want to anyway when I can just prescribe a stent. And then the patient doesn't change, and the doctor says well, he just didn't do it, so a lot of it becomes self-fulfilling.
But if reimbursement is there and people learn how to do it, it sets a different expectation, and that can also be self-fulfilling in a positive way.
DR. DAVIS: Yes. Let's start from the left and go this way.
DR. SLAUGHTER: I think this might dovetail with Dr. Phurrough a little bit, but I think an issue that a lot of physicians are concerned with is that they really deserve some short-term data, there's not really five or ten-year information, and atherosclerosis is clearly a lifelong problem.
And along the way also, there are various things that seem to be working, and we all
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know that diet is clearly very important. But

there are many diets out there, not only the ones described today. I personally had a neighbor that went on a diet, maybe lost 50 pounds, and he felt better for a while, felt more active, but yet, they fall back and they fail. So adherence is very important for long-term success, you know, on preventing future events.

A lot of the slides we've seen today, whether for one or two years, we'll say there was 77 percent compliance or adherence. But even within that adherence, the issue is what are they adhering with. I mean, are they still just doing their 30-minute walk a day and yoga, but they've gone off their diet and are starting to put back on weight? So the issue is, you know, within that adherence being long term, what parts are they adhering to, and maybe which would be most important and most beneficial to long-term prevention of progression of atherosclerosis.

DR. ORNISH: You've raised some important questions and let me try to answer them the best I can. I think we need to separate adherence from whether or not there's enough evidence to say that these programs work, and I

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use the example of statin drugs. The decision to reimburse statin drugs is not based on whether or not people will take them, it's based on the data that show that when people take them that people get better. Two-thirds of the people are not taking them after just six months, but still, nobody would argue that people shouldn't be covered for statin drugs simply because some people don't take them.

Now, we do have data. Our Lifestyle Heart data is a five-year randomized control trial and we showed there was even greater regression after five years than after one year in 99 percent of the patients, and that was by blinded tests, and that was by objective cardiac state-of-the-art measures which showed that 99 percent of patients after five years were able to stop or reverse the progression of disease, and that's pretty good.

In our demonstration project we found that after three years people were adhering, not 100 percent, but well enough that 77 percent of the patients who were eligible for revascularization didn't need it. Now, does that mean that 77 percent of the people are 100 percent cured? Of course not. Does that mean that this

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is the only perfect diet and that all the other diets are wrong? Of course not. I mean, I think there is a convergence of what is considered an optimal diet.

But if you're trying to get heart

disease to be reversed, you're going to take an evidence-based approach and say what diet and lifestyle programs have been proven to reverse heart disease? Dr. Esselstyn has shown that, other people have shown that, and we have shown that. So if somebody has data showing that they can reverse heart disease through diet and lifestyle, and remember, we're not asking for this as a primary prevention benefit, we're looking at this in a sense as either an alternative or an adjunctive treatment for people who have diagnosed symptomatic coronary heart disease. And so if people have data showing that they can reverse heart disease with diet and lifestyle, they would be eligible for coverage, or if they're offering programs substantially similar to one of the ones that does have those data, they would also be eligible for coverage.

DR. DAVIS: Bill.

DR. BARNARD: Could I just emphasize,

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if you look at the back of the folder that I gave you, there's a model that's been driving my research now for the last 20-some years, and one thing is very clear. High fat, higher refined sugars in the diet are probably at the crux of most of the health problems that we have in this country today, so if you get the fat content of the diet as low as possible, you cut out the refined sugars, and you add that to a good daily exercise program, you're probably going to cure most of the health problems that we have or at least prevent them.

And along these same lines is that if you start this program now, and you provide the evidence, and people who have documented coronary disease, the word will start to get out. For example, when I first began to be associated with Pritikin, 95 percent of the people who came there were sick, they had severe coronary disease, severe hypertension and diabetes. Now, 40, 50 percent that come, come for prevention because the word's getting out that this type of program really works, and I don't want to get into the situation where I have these serious events down the line.

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DR. DAVIS: Bill. I'm sorry, go ahead.

DR. LAMBERT: David Lambert, from Mountain State. If I were sitting in your shoes, I would be concerned too about a decision opening up to a plethora of programs, and so I really appreciate the practical questions that are being asked. But, I think that there is a lot more commonality in the science, and I say that as a nonclinician. But having just read recently the

joint scientific statement of the American Heart Association, American Cancer Society, American Diabetes Association, I think in terms of coming up with national guidelines for each of the components, that that would not be difficult at all. And if I were going for the biggest bang for the buck, so to speak, I would approve coverage of something that addressed all of the risk factors. There is the biggest chance for improvement in people's health, therefore the biggest potential for cost savings or cost effectiveness of the program.

And in terms of it not being immediately widespread available to the entire population, you know, we have to make those decisions all the time. They come into great

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relief in our little state. We may have a specialist in only one community that can provide pediatric oncology services, and that's not available anywhere else in our state, but we make that service available to whoever can avail themselves of that. So I think that, yes, if you look at approving individual programs for each component, that could be a pretty scary thing, but in terms of a comprehensive approach based on national guidelines, I think that would be a pretty straightforward task to put together, and then whatever requirement for certification would be necessary to show that the program meets that standard, again, that sort of thing happens all the time.

DR. DAVIS: Go ahead.

DR. ESSELSTYN: I wanted to just address the gentleman who is the cardiothoracic surgeon. He had an excellent question about what was the natural history of coronary disease. And I just share briefly that when I started this study, I had a bare bones research budget and I had no training in psychology but I was basically very competitive, and I did recognize that the rock on which this program would most likely

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flounder was lack of compliance. And I saw every one of these patients every two weeks for the first five years to make sure that I saw their diet diary and that they were meeting their cholesterol goals. The next five years I saw them every month, and then the last two years as we got further into the program, I saw them quarterly. Now obviously I think that's a little excessive, but I just wanted to try to prove that the thesis was viable, that patients with severe disease who had been sent home to die by expert cardiologists could survive and could reverse their disease. But to answer your question, I think

that the key thing here, and I think this is in the Ornish program and perhaps others, the key here is to let -- I had a cancer surgeon who taught me the most about dealing with patients with cancer, and this is the same mantra that I apply to patients with coronary disease. That is that patients with cancer are not afraid to suffer and they're not afraid to die, but they are afraid of being abandoned by their family or physician. And if we can keep these people engaged, and let them know that we're always interested in them, and don't ever abandon them, then they are going

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to continue to meet these lipid goals, and that of course annihilates the disease.

DR. DAVIS: Yes, please.

DR. OWEN: I heard two folks here today basically talk about pay for performance, and just to remind you that although there is a congressional mandate to do that, it is being studied right now, alpha tested. However, I will pose this query. And that is, the board of trustees of Medicare, which is Congress, has told them we are increasingly dissatisfied paying for products offered by the health care delivery system and the quality, whatever that definition might be, is not what we feel, and most importantly the consumers feel it should be. That being the case, those of you who have these sorts of programs, if this is endorsed and there is reimbursement for it, how do you see making certain there is some minimum level of quality around the training that the providers have? Do you see that occurring from the professional societies, do you see it occurring in the medical schools? At what level do you make sure that physicians aren't, and let's be realistic, they can be as mercantile as anyone

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else, saying oh, here is a way to diversify my revenue stream, I'll just call a nutritionist in and say hey, let's set up one of these programs.

DR. ORNISH: Are you saying -- I'm a little confused. Are you saying is there some kind of guarantee for performance, or are you talking about simply maintaining quality?

DR. OWEN: I'm not going to ask you to guarantee performance because you cannot do so. How can you at some level reassure me as a payer of this, and I'm a payer as a taxpayer if this is ultimately embraced, that the individuals providing this service have some minimum level of competency? What they do after you say they're competent is between them and their patient.

DR. ORNISH: Sure. That's a very important question. We train them at the

Preventive Medicine Research Institute and at over 40 hospitals, and we have ongoing quality assurance and quality control. As I mentioned earlier, my goal is to work with professional societies, indeed from our point of view, to get a way that we can train a group of trainers at the American College of Cardiology and/or the American Heart Association, work with the American Dietetic

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Association, the AACEP for exercise physiologists, the American Psychological Association for psychologists, and work out training programs where they in turn would train other people and they would provide credentialing and quality assurance. We've already done that, we know how to do it, we've shown that we can do it, and we would be more than happy to work with whomever, whichever professional societies to make that available.

DR. DAVIS: Of course certification programs are being used by CMS in some areas, so I think that may speak to your question in part.

DR. LAMBERT: That's exactly what I was going to say, two suggestions. In the private payer world we do credentialing, certainly do it for health professionals, but we do it for institutions as well. And for certain types of services, bariatric surgery is probably the most recent, moving to a centers of excellence concept is something that's very much under consideration and being implemented. But the Medicare certification is also something that we rely heavily on and in our state that's essentially the state licensing folks who also license the

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hospitals and a large number of health professionals, going out and making sure that the level of training has been there.

DR. DAVIS: I have Mary, Pam and Anne on my list.

DR. LEE: My question is for Dr. Clark. Dr. Clark, when you did your analysis and looked at the improved outcomes associated with some of the secondary prevention programs, I'm presuming that most of the patients in most of the studies were taking medications for their underlying diseases like diabetes and hypertension and for hypercholesterolemia, and I'm assuming that with the secondary prevention programs that were introduced that there was increased coaching and telephoning of patients and all this kind of follow-up that encouraged the patient's drug compliance. So, how do you separate that effect, the impact of that variable on the outcomes that you were looking at, which, a lot of the outcomes overlap for whether patients take drugs for those

conditions and with the improved diet therapy and exercise therapy.
DR. CLARK: Yes. I would say the studies as a whole, they tended to do more case

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note reviews to identify that the patients had been prescribed the right medications, and the studies as a whole did not overtly tackle that much the issue of promoting compliance, though we do know that diet in particular in relation to chronic illness was around 50 percent. So even then, the issue of a patient on the right medications and do they comply with medications, it's difficult to pull up the relevant effect of those two and then also on the hard outcomes. I think the broader issue, though, is the programs should not be seen as an either/or, I think they have synergistic benefits. They have benefits as an adjunct to bypass, before bypass all patients are on a waiting list, or after bypass when they are recovering. And they also have benefits not just as to lifestyle, but making sure that patients are on the right medications because often they're not. If you look at Spine and you look at the Stanford studies, 40 percent in terms of physician recommendations of therapies. So these programs also fall into -- and also a mechanism to identify these patients, supposedly the 60 percent of patients who indeed will be on the right meds, and then also provide

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some support for them.
DR. BARNARD: I'd like to emphasize and to follow up on that, rather than the data presented this morning. If you get people on the right data and the right exercise program, their need for medications is going to go down dramatically. More than 50 percent of the people who come to the Pritikin program discontinue antihypertensive medications and about 70 percent discontinue oral hypoglycemic agents. So your comments were really not valid; if they have the right diet and exercise program, they don't need the medications.
DR. ORNISH: Two quick points. One is the fact that diet and lifestyle interventions can improve compliance with medications but I think there is a synergy there that's good. And in terms of trying to understand the relative contribution of diet and lifestyle versus, say, medication, the only medications that have been proven to reverse the direction of coronary heart disease are statin drugs. And in the earlier studies we did, the Lifestyle Heart trial, in the entire five years, none of these patients were taking statin drugs or any lipid-lowering drugs.

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And so, we couldn't even do that study now because everybody is taking those, but then we were able to, so we don't have that as a confounding influence, we can look at the influence of diet and lifestyle alone. Now we can't separate the relative contributions of each component of diet and lifestyle, but at least we can say that the medications weren't a factor in that study.
DR. DAVIS: Pam.
DR. SNIDER: Thank you. My question is actually starting with Dr. Clark and I welcome other. It's about adherence. Because these programs vary a lot, and obviously from my reading and the technology assessment and all of the presentations, adherence becomes a very central factor in sustaining the change in the effect, concerning that the rate of variations of effectiveness was pretty broad in the studies, what, could you make any observations about features of the programs that seem to be pointing in the direction of stronger adherence, things like a few of the areas that were mentioned today, the structure of case management, individualization of care, practitioner training, going back to Dr. Phurrough's comment on the
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practitioner level that will deliver the services, and also the type of stress management?
DR. CLARK: Those are some really good questions. In terms of our research we did notice, obviously, a statistically significant long-term mortality benefit between 24 and 60 months, irrespective of the diversity of programs. Data of trends, within guidelines, and the trends within the studies and also my knowledge of the way programs are given, there is a movement towards individualization of programs. Traditionally the programs that were looked at, if they were reflective of the guidelines of the day, they would have been standardized, so there wouldn't have been as much assessment of patient needs, and I would have incorporated a more wider program. That is no more the norm. I think it's fair to say we need to make sure that the patients get the right interventions in terms of the behavioral change, the right course if you like. We also have the unfortunate situation in some programs where some patients may have been receiving smoking cessation advice when they don't smoke already. So there is the issue of the right course for each individual
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patient based on their individual risk factors, and that comes probably from program sophistication, which comes probably with

resources. And freedom to access health services such as would be common in Europe, resources have been a problem in this area and programs haven't been as flexible and therefore, they haven't been particularly individualized.

As far as psychological assessments are concerned, I think these types of interventions are most likely to be more effective, rather than just general interventions. For instance, there is some evidence in the trials that we couldn't include that cognitive behavioral intervention can be effective, in relation to some that were reported in JAMA. I would say that the studies were extremely vague in terms of what underlying theories or quality performance mechanisms were in place to make sure that the right issues got the right set of interventions at the right time.

DR. SNIDER: Thank you.

DR. DAVIS: Was that a follow-up to that particular -- let me go to Anne first.

DR. SHEPARD: I had a comment.

DR. DAVIS: Go ahead, please.

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DR. SHEPARD: As part of the evaluation, there is a survey of participants and also controlled subjects. One group in control is getting cardiac rehab, another getting usual care without cardiac rehab. So as those survey data become available, we will have long-term data on many patients from those data. Those data are still being compiled at this point.

DR. SNIDER: Thank you.

DR. DAVIS: Anne.

DR. CURTIS: I want to ask a question about the cost of these programs versus the effectiveness of them. I saw in some of the materials that we have here that a traditional cardiac rehab program in a hospital was estimated to cost about one-eighth of the Ornish cost and then the Mind-Body program was about one-third of the cost. Well, how much is enough? Is the traditional cardiac rehab program cheap but ineffective? Is the Ornish program great but too expensive, and you get diminishing returns for the amount of money you spend? How much do you have to spend to get a significant meaningful benefit for Medicare beneficiaries?

DR. ORNISH: It's great but effective.

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No, there is a spectrum, and it's a very important question, as I was laying out in my tsunami of information, as someone said earlier today. You have traditional cardiac rehab and then you have other interventions that are not as intensive, but also the more intensive cardiac rehab like the Mind-Body program, and then you have a program

like ours.
It does cost more. It is harder both in terms of the degree of lifestyle change that we ask people to make as well as the time commitment, just the total number of classes. As the analysis that you referred to noted, the cost per class is no more, it's just a lot more classes, a lot more follow-up. And so it's harder to recruit patients and that's why we have fewer patients than other programs where the barriers to enter are lower, it doesn't cost as much, people are not asked to make such big changes, and there is not such a time commitment. The fact is that, again, if you want to take an evidence-based approach, the program that we have been working with has been proven to reduce heart disease. The other programs have not, in terms of traditional cardiac rehab and the less intensive interventions.

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Dr. Esselstyn's program has, the Pritikin program has, but they are very similar to what we're doing. And so, it's like you get what you pay for, so it depends on defining what the goal is. What I'm asking for is that programs that have been proven to reduce heart disease be covered as an intervention, not as prevention but as a treatment, either as an adjunct to or in some cases an alternative to revascularization and/or other therapies.
That's where the areas show the greatest cost savings, that's where you can control the fraudulent use by limiting the eligibility to people with diagnosed heart disease, and that's where the treatment effect is greater. We've shown much greater reductions in weight, in LDL, in hemoglobin A1c, in all the different parameters that we've already talked about, than a conventional cardiac rehab program does. And so yes, it costs more, yes, it is harder, yes, there are fewer people who are going to want to do it, but those who do it feel extremely well, and we have shown a reduction and reversal in heart disease that the other programs have not.

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DR. CURTIS: So then, it sounds like you're suggesting there should be strict criteria for the kinds of programs that would be covered and not just any old cardiac rehab program.
DR. ORNISH: Well, cardiac rehab programs are already covered, so that's not in issue, but what I'm asking for is something different, which is as a defined program oriented for people who have bad heart disease, that it has been shown that it can be reversible. And I think it's a good place to begin, because that's what

the Medicare demonstration project and the other demonstration projects were all about. Because then you can define the selection criteria very narrowly, and so you don't have to worry about fraud and abuse and you know, the entire world wanting to come through a program like this, because you have defined it in a very narrow way. And then later if it turns out that it's working, and you find it's saving money on a larger scale, you can always revise the coverage as well.
DR. DAVIS: Tracy.
DR. GORDY: My question, maybe Dr. Clark can answer, but I think we've heard that there is basically no difference in the outcomes

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with the way the program is delivered. So the question would be, in the cases where there are individual practitioners who have found a way in their office to do a cardiac rehab one on one, which incidentally is reimbursible under Medicare because there is counseling in the code that can be reimbursed. So if a nurse practitioner delivers the care, it can be reimbursed, so that's not really the issue here.
The issue is, are there studies that indicate that that kind of a program that would address maybe what the Pritikin concept is, does that really work in those individual programs that you illustrated in your data?
DR. CLARK: I just want to make sure I understand the question. In terms of the three types of programs that we compared, are you asking, does it make any difference?
DR. GORDY: Well, if I understood correctly, it didn't, and so what we're looking at here is more elaborate programs that could be costly, and there is a way that we reimburse it now under the current.
DR. CLARK: Again, making qualifications about the heterogeneity of the

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programs that we have heard about today, the programs we studied were smaller in scale, they were from publicly funded health care systems and would have had more limited resources. That said, they did show significant benefits in mortality at 24 months and 60 months. I think the question you have to consider is can you extend those trends to these types of other programs. I can only comment on the benefits generated that the program changes generated. As I said, I think there are differences between those programs and these programs that are being talked about. They seem to be more intensive and do seem to have more long-term follow-up. One could argue that long-term benefits from responding to changes is

higher, but without a systematic randomized control trial that we could include, we haven't examined it.
DR. DAVIS: Rita, did you want to follow up on that?
DR. REDBERG: Dr. Clark, are you saying that the programs that you looked at in the technology assessment are similar to the programs that are currently looking at cardiac rehab and coverage in the United States?

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DR. CLARK: Certainly the comprehensive cardiac rehab contact programs would appear to be. It's less clear in the individual counseling program, I think, but as I said, I think the programs we discussed today do seem to be more sophisticated and do seem to provide longer-term follow-up than the studies that we looked at.
DR. REDBERG: So the programs that we heard about today were not in this technology assessment because they didn't meet the inclusion criteria.
DR. CLARK: That is correct. And again, I come back to this point. It's easier trying to postulate what the likelihood is that with these more rudimentary anyway, in all likelihood, that is the less intensive resource program, may show that benefit, but we are more likely to get replication of that benefit and the value with these programs that supported and extended these principles over a longer period and with greater professional involvement.
DR. DAVIS: Do we have another comment?
DR. SHEPARD: I wanted to follow up on the question about the benefits of different components to the program, whether one is more

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effective than others. In the work that we've done so far, both of the two program models appear to be effective, there's some differences between them that we're in the process of analyzing. In answer to your further point in your question, Dr. Curtis, the question about what are the incremental benefits and relationships to incremental costs, I don't think we know that yet, quite frankly. Because different populations differ of patients, and what other treatments to follow. And your comment, Dr. Herman, about incremental benefit of lifestyle on top of therapies, unless one has comprehensive data on the same group of patients to control for these things, I think it's very hard to say what the incremental benefits are of one program to another, whether a more expensive program is delivering greater benefits or not, that's something that evaluation will help to uncover

over time.
DR. ORNISH: I just want to challenge that for a second, if I can, because for example, the two programs they are comparing, a 35 percent fat diet, the studies which I reviewed in Harrison's, the Eugene Brown model in Harrison's

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Advances in Cardiology textbook, and every one of them with repeat arteriography studies, even though they're on a 35 percent fat diet, which is the diet in the Mind-Body program, shows progression of disease, arteriographically, but we've been able to show regression of disease. So it's not really accurate to say that the programs are comparable in benefits, because they're not.
DR. ESSELSTYN: This is in answer to Miss Curtis. I guess as a surgeon, I also always try to get down to the bare bones of this a little bit, and right now I think Medicare is providing an enormous remuneration for systems out there that are treating the symptoms of the disease. And I hope that what we're trying to convey today is we think it's rather exciting to think that there could be reimbursement for actual treatment of the disease, not the symptoms, but the disease process itself, where we can show that we can absolutely arrest it, and selectively in the majority of patients also reverse it.
DR. DAVIS: We've had a lot of good questions and informative answers. I wonder if members of the panel are getting ready to have some open -- not open, but I guess we call it

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closed committee deliberations, and then voting? Does anybody have any more questions that they want to pose to presenters? If not --
DR. GOODMAN: I'm sorry.
DR. DAVIS: Go ahead, Cliff.
DR. GOODMAN: A question for Dr. Fuller. One could be persuaded that these interventions can work in a highly selected, self-selected highly motivated population that undergoes some comprehensive strict program. In your experience, and if I were a payer, I would want to pay for perhaps that highly selected population that stuck with the program, and I wouldn't want to pay for the people who stopped the program. How would I know as a payer, or how do you know as a medical director when someone is no longer on the program, and how might that trigger a decision to say, I guess we don't have to keep paying for this anymore?
DR. FULLER: Well, that was a concern of ours as well. What we did was, we didn't treat it like a DRG, we treated it more like units of service, so we blocked it off into specific units

like a quarter or a month, and what we do then is track participation of the individual in the
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program, and if they stopped participating, reimbursement stopped.
DR. GOODMAN: So you track it by service and/or a period of time?
DR. FULLER: Correct.
DR. GOODMAN: Which, both?
DR. FULLER: Both. They would be the same thing. A month would be so many units of service, or a quarter, and we pay for that, and then they would have to submit both a bill as well as certification that the person continued to participate in the program in order to receive additional reimbursement.
DR. GOODMAN: So this is like fee for service in a way?
DR. FULLER: Correct.
DR. GOODMAN: Thank you.
DR. LAMBERT: We did, we also pay based on attendance. We pay in quarter increments, the first quarter is the most intense. But we run this program through our medical management and our utilization management program, and we will pay for that quarter of service but we will also make that the individual has attended that quarter of service. There is an incentive there for the
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provider of the service to make sure that people are in fact taking advantage of it.
Then there is a risk stratification process by which there is a determination of whether the person qualifies based on their health risk and their adherence to the program, whether there is a need for them to have another quarter of the program. And we will pay for people to be in the program for up to one year. So we use sort of a version of precertification to pay for the service.
DR. DAVIS: Is that a more stringent sort of approach than used for conventional medical treatment like diabetes? If you don't get a hemoglobin done as often as you're supposed to, you will not pay for insulin?
DR. FULLER: Not so much like that, but if you did not show up for your monthly appointment with the endocrinologist, we wouldn't pay for it.
DR. OWEN: Like payment for an ESRD services. We pay for a period of time and we kind of head count the number of times you have been there and if you don't hit a certain benchmark, ding, I'm going to go look to see if you're
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actually participating.

DR. FULLER: Right. Thank you.
DR. DAVIS: Other questions? If not, why don't we move to the closed committee deliberations and see if folks on the committee would like to raise any issues for discussion or debate. I mean, it's public, yes, but we are no longer going back and forth from one end of the room to another normally in this part of the meeting, but again, you know, we're not going to be super rigid about things, or am I opening a Pandora's box? Go ahead, Cliff.
DR. GOODMAN: Okay. Our panel questions address the same phrase over and over, which is physician-supervised behavioral change and that is a pretty broad rubric which as suggested before, would be subject to what some people call broader interpretation or would certainly open things up. And I don't know that physician-supervised behavioral change, is that an accurate enough depiction of the programs about which we have heard today? Is it an accurate enough description of what's included in the technology assessment?
And so, I might be persuaded, as I said

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before, that this stuff really does work in a highly self-selected population that stick to a strict program, but that doesn't sound at all like some physician-supervised behavioral change. So, I'm sorry about the long introduction, but can we discuss or clarify what the scope of physician-supervised behavioral change is for the purpose of our discussion?
DR. DAVIS: Dr. Phurrough?
DR. PHURROUGH: Sure. Next question.
(Laughter.)
DR. PHURROUGH: We only pay for cardiac rehab that is under direct supervision of a physician, that is the only way cardiac rehab is currently paid for. Now granted, there may not be direct supervision by physicians occurring in some cardiac rehab programs and I understand that, but our requirement is that they be under physician supervision.
These particular programs that we have been presented, both here at CMS before this meeting and at this meeting today, are also physician-directed programs, the Ornish program, the Benson program, those are all physician-directed programs. And so the purpose

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of the question was to look at the entire gamut of programs directed at behavioral changes, lifestyle changes supervised by physicians with the purpose of treatment of cardiovascular disease.
DR. GOODMAN: Of the type we heard

today, or I can open up my own shop as Dr. Cliff and I can supervise people in lifestyle change by saying stop smoking, lose weight, don't eat so much, go exercise, and I would be done?

DR. PHURROUGH: Of the types that were discussed today, which include the programs that were part of the technology assessment, some of that being individual counseling, which if done by a physician is a physician-directed behavioral change program. So as the panel deliberates, it may want to clarify what you are voting on and specify, we are only taking comprehensive cardiac rehab and the predicted Ornish, Mind-Body programs, or however you want to do that. But the purpose of this was the broad range of programs that physicians supervise.

DR. GOODMAN: Broad, but not permissive? You don't have to answer that.

DR. DAVIS: Rita, Mark, and then Bill.

DR. REDBERG: Could you clarify what is

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currently covered under the cardiac rehab and what is the additional components that we're looking at today? Because I'm right now a little confused about what's currently covered and what's not.

DR. SLAUGHTER: Let me add on to that question a similar concern. What I don't understand, and Dr. Gordy alluded to it, but if a patient goes to a family practice physician and they're coded for an office visit with counseling, and then they send him to rehab and they will pay for it and code for it, why doesn't it occur more often? I mean, is funding inadequate, people don't know the codes, or they're just not aware of the science out there? It seems like a lot of what we've heard today could currently occur in a primary care physician's office who often does have an assistant to help their patients to access to established cardiac rehab programs. And the other, as far as reimbursement goes, when you say inpatient cardiac rehab, we have a program that's very busy, but in the Chicago area there are innumerable cardiac rehab programs closing for supposedly financial reasons. So there's some confusion about what is paid for exactly, because I guess I don't know.

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DR. PHURROUGH: An explanation of what Medicare pays for would require several days worth of meetings. Patients can go to see a physician with disease processes and physicians can pretty much talk to them in whatever manner they wish. If someone with coronary artery disease shows up in their physician's office, undergoes an E&M visit, and evaluation and management visit that has codes in the code book for which we provide

reimbursement, and during the course of that visit they can say go out and exercise, and here's a diet you ought to follow. So they're providing an office visit for the treatment of coronary artery disease.
What we don't pay for is for sending that particular patient to someone other than a physician who is not authorized under the Medicare program to provide services. So they could not go to a dietitian and get counseling for medical nutritional therapy for coronary artery disease. They could not go to a physical therapist and get exercise counseling for coronary artery disease. Those are not covered services outside the context of a physician office visit.
Cardiac rehab is a service that we have

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provided for a number of years that is covered only within physician services and under direct physician supervision. It can also be incident to a hospital setting, which has different rules than physician services, again, a two or three-day conversation to understand all that, someone would have to tell me first. But cardiac rehab has to have an exercise component to it, and we don't define it much more than that except that it's a comprehensive program that includes an exercise component incident to it.
And in the context of an office visit where a physician is billing for the diagnosis of coronary artery disease, nothing prohibits that physician from taking a half hour walk around the block with the patient, it's direct supervision, it's part of the service he's providing, and the Medicare program in its coding for outpatient visits is such that we don't provide tremendous restrictions on what physicians do with patients in their office.
Now, what's being -- physicians could also run a comprehensive cardiac rehab program in their office and some do. In general, it's not something that we see. There's a whole host of

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hospitals that are telling us, that have cardiac rehab clinics, that are telling us they can't make it on the amount we reimburse for that amount of time, and that may or may not be the case, I don't know the particulars about that.
And I think a legitimate question to answer here, are the programs that are being proposed today by these four or five groups, do they provide significantly more, provide evidence that they result in significantly better outcomes, that the program ought to be -- well, you're not concerned about coverage for the program, but is there evidence that demonstrates that they provide

positive outcomes and are those positive outcomes better than the alternatives. And we didn't define all the alternatives either, but there's nothing that prevents you from answering the question of, is the Den Ornish, Pritikin and Mind-Body program better than comprehensive cardiac rehab, whatever you think that might be.
DR. DAVIS: Bill. Rita, did you want to follow up on this? Bill, why don't you go first?
DR. HERMAN: I think that that really is a tremendously important question, but I see a

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bit of a disconnect. Dr. Clark's technology assessments looking at comprehensive cardiac rehab was very methodologically rigorous and had fairly clear-cut outcomes. One of the issues, though, is that the Ornish, Pritikin and Mind-Body programs were for the most part not even included in that technical assessment, and I think by comparison, probably have a somewhat less rigorous design, I would say the randomized consent design, and though I understand why that was done, it is probably not as rigorous as a straight randomized controlled clinical trial.
At the same time, I think the outcomes of these programs are extremely impressive, more impressive than the cardiac rehab programs, but the question is really, is there generalizability to the larger population, and that's where I am really wrestling. Clearly they're effective in a select populations, but how they would apply to a more general population and how the weight of evidence would support them is still somewhat unclear.
DR. DAVIS: Rita.
DR. REDBERG: I think it does have a similar -- the technology assessment which Dr.

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Clark did provide data from randomized control trials and provided data on survival, and I now am beginning to understand as to cardiac rehab, but as to the diet and lifestyle programs that Dr. Ornish and others presented on, we don't have any survival data as far as I know, and we have a lot less of the other data that we are being asked to evaluate. Is that correct?
DR. ORNISH: Is it possible to participate or not?
DR. DAVIS: Yeah, go ahead, that's fine. Again, I don't think we need to be super rigid here, although this is more for committee members.
DR. ORNISH: I will try to be brief.
First, I appreciate that. Strictly speaking, we don't have survival data from our randomized

trials or demonstration projects but that's because of number of patients was too small. The point I was trying to make throughout my presentation is that there are many other randomized trials of large numbers of people showing that if lower blood pressure, if you lower LDL, if you lower HbA1c, if you reduce the lesions and improve perfusion, that translates into

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markedly improved morbidity and mortality. And it also shows that it doesn't matter how you do it, if you lower blood pressure through diet and lifestyle, that you still get the same benefits, or if you lower HbA1c. Most people have said that if you lower LDL through diet and lifestyle as the first step, for most people it's not going to be sufficient because the diet alone doesn't go far enough.

So I'm only making the point that it seems appropriate to be able to take the kinds of changes, like the 40 percent reduction in LDL that we found or that the Pritikin people found, or that other people have found by making intensive changes, and interpolate that into the larger studies and say even though we didn't look at mortality, based on the much greater change in risk factors than you see in traditional cardiac rehab or office visits, that there is a lot of evidence about mortality and morbidity, and it's reasonable to do that.

DR. BARNARD: I just briefly wanted to point out that in our five-year data in the study on 64 patients with cardiac disease, only two people had actually died from their coronary

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disease.

DR. REDBERG: I'm understanding the question that we're looking at on physician-supervised behavioral change as opposed to what we currently have in play, which is usually dietary counseling and exercise, these programs offer a longer-term program and then the group sessions with stress management; is that sort of what we're looking at?

DR. ORNISH: And a much more intensive diet.

DR. DAVIS: Yes, Christina.

MS. BIESEMEIER: I would echo what Dr. Ornish just said. At Vanderbilt, I know the very limited dietary counseling that's provided. It's a class, one class.

DR. REDBERG: But the technology assessment showed they were getting benefits with that program, so it's just hard to compare what the additional benefits are of the additional components. I mean, the testimony is certainly

impressive, but looking at the technology assessment, even though they were minimal programs, they might have been underutilized.
MS. BIESEMEIER: And Dr. Clark's
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comments that we have little understanding of the black box of interventions, that's where I have such, the questions I have are about. What is the comprehensive cardiac rehab program? This is opinion, but it would appear, and I have looked at several of them as a cardiac rehab dietitian, there is such variability, whereas at least the interventions that were discussed today, I do hear consistency in interventions within a range, and I can sort of put my arms around what I'm hearing from Dr. Ornish and some of the others, the Pritikin program, and when you want to look at approval of a program for reimbursement, consistency is a major factor.
DR. DAVIS: Let's go with Alex and then Paul.
DR. CLARK: Thank you. I would just reiterate what people are saying. Having went through 236 papers in some great detail about intervention types, the reality of eligibility criteria meant that if a program does exercise and some health education is done on site, you have to treat that not as a single modality intervention but as something approaching a more comprehensive intervention, just as you would with a program
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that says well, we offer a comprehensive program for diet, exercise, smoking, psychological behavioral factors. You don't get a sense of the intensity, and I think the involvement of specialist for physical activity and for psychological well being indicates that it does help to have specialists involved.
DR. DAVIS: Paul.
DR. BARRETT: In considering what we have read and heard, I try to keep fairly well focused on what information is highly likely to be valid from the randomized clinical trials and what information may or may not be, which includes all of the stories, and for better or worse, it includes most of what we've heard about the more intensive programs. The demonstration projects as some people who presented emphasized, they weren't really about effectiveness, they were about feasibility, about generalizability, and so it's just a little bit hard to be sifting through the information and trying to remember which is highly likely to be valid about the efficacy and the information we're getting from the other types.
DR. DAVIS: Yes, Tammy.
DR. BORN: One of the things I have

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been thinking about listening to the testimony is what are we really comparing. And I remember information from HHS about data coming from drug reactions and medical mistakes, when the properly prescribed, properly taken medications could be somewhere between the fourth and sixth leading cause of death. And when we're talking about comparing interventions like diet and exercise, what are the risks, there really aren't any, and the net benefit is huge, I think, compared to traditional therapy, which may be giving us much more, you know, as far as underlying disease and costs.

DR. ORNISH: I just want to make a quick point in response to your point because it's such an important point of the evaluative questions and I just feel compelled to make a few brief comments. We have been doing randomized control trials using what most cardiologists would say are the state-of-the-art measures, quantitative coronary arteriography, SPECT thallium, and cardiac PET scans, published in all the leading journals, JAMA, Lancet, the American Journal of Cardiology, in Circulation, and what have we shown? We show most patients become

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essentially angina-free within the first month, they not only feel better, but they are better. Their blood flow has increased by thallium scan, their blood increased by PET scan. Their lesions show some regression after one year, they show even more regression after five years. 99 percent of our patients are able to stop or reverse their disease by PET scan. And there are two-and-a-half fewer cardiac events compared to the randomized control. That's just the clinical trials, that's not even including the 2,000 patients we have data on from demonstration projects.

Compared to this, no randomized control trials have shown that angioplasty extends life or prevents cardiac events, and the randomized control trials have shown that the vast majority of people that undergo bypass surgery don't prolong life or prevent cardiac events. So it just, forgive me for being a little pedantic, but yes, the patients' stories are just stories, they are anecdotes, they are not randomized trials, but you see what kind a difference this can make in people's quality of life. $30 billion was spent last year on bypass and angioplasty despite the lack of randomized control trial data. Yet we

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have randomized control trial data on diet and lifestyle, and there is this big question about whether there is enough there. And so I would

just say hold it to the same standard, that's all I'm asking.
DR. BORN: And in the future, I think we will have tests that will show which diets are going to be more beneficial and which patients will have better results. I don't think that's so far in the future that we may be able to be much more clear as to which groups are going to work, which may be partly why some patients don't follow through, they really don't feel better and so adherence to the diet wasn't right for them, but I do think we will see more data that is more specific to the patients.
DR. ESSELSTYN: I want to take a second just to reinforce what Dean just said. I've been involved in the activity now going to 20 years, and 20 years, it's not really experimental anymore. We see these results from angiography, from PET scans, it's absolute physiology and the results are there, they're solid, and we've proven it four times now in peer reviewed journals where we've followed all the rules of science, and now

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we implore you to help us keep it going.
DR. DAVIS: I want to try to get us back to the question so that we can move toward voting. And this whole discussion got kicked off with a query about the expression "physician-supervised" so maybe I can ask Dr. Clark, how many of the studies that were in your technology assessment were what you might call physician-supervised?
DR. CLARK: It depends what you mean by physician-supervised. No one single paper used that term, but based on my knowledge of norms of the programs, historically at least, rather than even what the programs had described, the physician's level of involvement is ambiguous. My knowledge would indicate that few programs would involve physicians directly providing the majority of some of the intervention. The physician is likely to have been involved in a supervisory or directing capacity in terms of increasing, or often coordinating the protocol, for setting up which patients get the intervention, which patients are referred to whom, and then also what protocols, and in some cases referral back to the physician.

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So if we're talking about supervising or directing, we're often talking about a non-day-to-day involvement, but with some capacity whereby patients in greater need, perhaps you have contacts to see these patients, come back to get more specialized help from the physician. And the argument as these programs have developed is that

physicians are, to be honest, sometimes not the best people to promote health. We have health professionals such as dietitians, such as nurses, such as physiotherapists, who as part of their training have health promotion, who are able to then take up the time commitments to work with the patients with the overall assumption that the program has physician supervision and direction as a whole.

DR. DAVIS: Because the question does not say direct physician supervision and so we can all define that in different ways. And it's almost like a standing order from a physician that directs regular care on a hospital ward being carried out by nurses or others. And I'm just wondering if maybe we ought to try and get back to the body of evidence that was used for the technology assessment if the panel feels

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comfortable with that, with the idea that this doesn't say direct physician supervision, then people are going to interpret that phrase in different ways and CMS when it gets to a coverage decision is going to have to do what it can within its current processes under Medicare law. Anne.

DR. CURTIS: That's what I wanted to talk about was, the major thing we're supposed to be looking at today is the effectiveness of these programs and is it effective. And I think what we don't want to do is confuse effectiveness with compliance. I think the data is very good that if patients go through these programs and, you know, the way they are supposed to, it is effective and good things happen. That doesn't mean that every patient who starts these programs is going to comply with it or stick with it. But on the other hand, when I prescribe a statin drug to a patient, I don't tell them that they have to guarantee they're going to stay on it permanently or I won't give them the prescription in the first place. I give it to them with the hope that they will stick with it and get benefit long-term. If they don't keep taking the drug, don't keep refilling the prescription, they lose that benefit but there's

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no ongoing cost. The fact that there are benefits with these programs, if you, you know, block out units of time to pay for it, that accounts for the patients who started and can't go through with it. I do think, though, just in terms of the kinds of -- I like these kinds of intensive programs, because that's what we're showing has an effect, it's certainly better than telling them to go into the room and watch the video and it will give you some tips about diet, and thinking that might help

the patient. It won't. I mean, I think it really does take an intensive approach but if patients do go through it, I think there's been very good evidence presented today that outcomes are affected.
DR. DAVIS: Charlie.
MR. QUEENAN: I just wanted to come back to the question, because I think there was a suggestion earlier that the technology assessment was looking at a standard of care which actually would be currently covered and then by inference, not useful as a baseline or not useful as a comparison that's responsive to the question we're trying to address. And something that I just

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heard Dr. Clark say made me interpret that as saying actually, though, that is something that probably wouldn't be covered in the U.S. The U.S. does use specialists as part of the intervention the way these are, and therefore, it is responsive to the question we're being asked to address, and that seems to be an important distinction, so did I misinterpret that?
DR. CLARK: The comprehensive contact rehabilitation in Europe almost as a rule now involves multidisciplinary health care teams, it will not be a physician in isolation, it will often not be just a physician and a nurse, it will be specialists, rehabilitation specialists. I think we have been involved in between 60 and 70 programs coordinated by nurses and physiotherapists. 40 to 50 percent have a dietitian often as just a partner to the program, but she sees patients on a routine basis. Coverage by specialists such as psychologists is lower, one percent of programs in the U.K. have a dedicated psychologist and maybe five percent have some involvement by a psychologist. So the comprehensive cardiac rehabilitation programs that we included would have contained specialist care

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and whether Medicare covered that, I don't know.
MR. QUEENAN: So again, having heard that, unless I'm corrected, the way I would hear that is although that isn't as intensive as the other programs we have heard about today, perhaps on average it still is responsive to the question we're being asked to addressed.
DR. DAVIS: Steve may not appreciate me saying this, but while in most cases we have stuck with the questions that we have been given before the meeting, on occasion at these MCAC meetings we have --
DR. PHURROUGH: You change them all the time.
DR. DAVIS: -- either tweaked them or

had a whole new motion trying to structure an opinion of this committee to give advice to CMS. So one option would be to vote on these questions pretty much as is, with the idea that they relate to the evidence base and the technology assessment, and then add a motion that might address the likely impact of more intensive programs along the lines of the ones we have been discussing today, if you feel that you wish to extrapolate or to extend in whatever way you might

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want. Yes?
DR. GARVEY: But doesn't the body of evidence that we're asked to evaluate include everything, not just the technology assessment? Everything should be taken into account in terms of addressing these questions.
DR. DAVIS: It does, with the inclusion and exclusion criteria that were part of the technology assessment.
DR. ORNISH: Why -- I mean, I'm probably out of line for saying this and I apologize in advance, but my understanding and the reason that I requested this MCAC hearing was not just to do a technology assessment on cardiac rehab programs, it was to talk about intensive rehab programs. And so, it would be very concerning to me if you're saying we're really only going to look at the technology assessment when the technology assessment cut off programs that were 50 or less, and in a sense say we're not even going to look at intensive lifestyle interventions because they weren't part of the technology assessment. That's not my understanding of why we're here today.
DR. DAVIS: And what I pointed out is

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that I think the committee if it chose would have an option of adding to the questions that are before it.
DR. ORNISH: But I thought the questions that were before it were applicable to the kinds of programs we have been talking about, not just standard cardiac rehab. Standard cardiac rehab is already covered, so it would be a moot point for the committee to vote on whether cardiac rehab should be covered, which is really the whole focus of the technology assessment, because it's already covered. The whole point of this was to look at more intensive interventions, from my perspective, and maybe I'm just missing something here.
DR. DAVIS: Well, one question in my mind, and I think we have been kicking this around a little bit, is whether the comprehensive programs in the technology assessment are

comparable to --
DR. ORNISH: They're not. That's my whole point. Correct me if I'm wrong, Dr. Clark, but they're not much different than regular cardiac rehab. If they have one diet class and exercise, that's comprehensive. That's not

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anywhere near what we're doing, what Pritikin's program is doing, what Benson is doing, what Esselstyn is doing, what all these programs are doing.
The whole point of what we're saying is when you make really big changes in diet and lifestyle, way beyond cardiac rehab, it has a very different intention and a very different outcome. The intention is not just to do exercise to get the people back to work after their angioplasty or their bypass or their heart attack. It's to reverse disease. It's to get lipids down not five points, but 40 percent. It's not just to get a little bit of improvement, but a lot of improvement in angina. It can be a direct alternative in selected patients to revascularization, which cardiac rehab never intended to do, and that's where the cost savings come from. It may look like cardiac rehab included an exercise component, but it's much more than that. So it would be extremely upsetting for me if the committee were voting on only what's in the technology assessment, which is simply cardiac rehab or variations of that, and has nothing to do with what the whole purpose of the MCAC meeting

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is, which is to evaluate much more intensive programs.
DR. DAVIS: We have ambiguous terminology in the question which I think is the problem, and so I see two options. One is, interpret the language as referring to the technology assessment and then add another question to it, or for the committee to state that the language in the question refers to the more extensive programs, ala Pritikin and Dean's programs, and so on.
DR. PHURROUGH: Let me try and resolve this and I think move on. Our expectation is that you're going to give us your recommendations on what the evidence in the TA plus the additional evidence that was presented by the other presenters today demonstrates, is it good, does it show benefit. Answer those questions. Now you can choose to lump those together and answer the questions as a whole, both from the TA, all the evidence demonstrated to you. You could decide that there is a significant difference in the quality, validity,

generalizability of the two different evidences presented, one in the TA and one the rest of it,

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and recommend to us, and we would be agreeable to you answering these exact questions for each of those bodies of evidence separately. But then, either you do them together or do them separately, you don't exclude either one. And indeed, the questions that are here are the questions that you apply to either the body of evidence as a whole or the two separate bodies of evidence.

DR. DAVIS: Mark, and then Charlie.

DR. SLAUGHTER: Just quickly, so I understand the process. And with all due respect, I do consider myself remaining neutral, but my understanding is that Dr. Clark was asked to do a comprehensive review of cardiac rehabilitation and in his outline he made it very clear as to what did not meet rigorous scientific standards. And because of his established criteria, the current studies that we heard about today did not fall in. He did not specifically not review them, they did not meet the strict scientific rigorous criteria to fit into his review. So the idea is that although very important and compelling, and they will have an impact, they shouldn't be viewed in isolation. I

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thought part of the point was that they didn't show up because of low patient enrollment, not complete, some just looked at LDL, so forth, the idea is you can't say that doesn't apply or doesn't involve current information. This was an independent review of all data available and these small studies don't fit into rigorous scientific review.

DR. DAVIS: Well, let me first go to Charlie, then Pam.

MR. QUEENAN: I guess by my question at least, I wasn't just sort of pointing to separation of one versus the other, because it seems to me impossible and in my view incorrect to artificially separate the two pieces of information as if they are completely independent of one another. I think one informs the other and therefore, you know, if I were to address the question of a very intensive program, I would be informed by other studies that may include less intensive programs but still programs that I understand are beyond what is currently covered in Medicare. So you know, I don't like the idea of separating them, because I think it's artificial in taking the information apart because one body

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would be in isolation and you couldn't look at the

rest, they are an entire body of evidence that needs to be looked at together.
DR. DAVIS: Pam.
DR. SNIDER: I'm wondering if it's possible, rather than separating the questions to modify the definition by adding a few words to it. And as I was listening, there are three criteria that seem to make it clear that we're not just addressing the old programs, we're addressing something new, and it's multidisciplinary intensive programs that address, as Mr. Lambert said, the nine modifiable risk factors. That seems to make it, it covers the extra data that we heard and talked about. I don't know if you do that here.
DR. DAVIS: Well, it's possible, but we could hear other commence from the committee. Go ahead, Dr. Clark.
DR. CLARK: I did this quite deliberately when formulating the exclusion criteria. I think it's fair to acknowledge that there are useful studies that fall out by way of these criteria. These criteria are conventional ones used for systematic review and they reflect

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also the ones used in the 1998 review. If you like, they are the strictest criteria that we could apply. So I would say our conclusions do have a certain amount of rigor because if they weren't strict, they wouldn't meet the criteria for inclusion.
But I think accepting clinical realities, we need to take a broad approach to the evidence as well, and the systematic review should be considered amongst the body of evidence, and we would support and the team would support any data rigorously applied that could demonstrate the relative benefit or absence of benefit of these programs.
DR. DAVIS: Yes, Christina.
MS. BIESEMEIER: With Dr. Clark's information, I want to go back to what I thought he said, which was that many of the studies that describe the comprehensive cardiac rehab are from Europe, which are much more interdisciplinary issues; is that correct?
DR. CLARK: Especially the more recent ones. If you go back to pre-'93, you know, you would have a nurse providing psychological support, but the evidence published in Europe from

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1997 to 2000, though, focused on specialist care.
MS. BIESEMEIER: So in the TA what you're describing, the results you're describing are from cardiac rehab programs that have other disciplines intensively involved to a great

extent?
DR. CLARK: Some of them do and some of the older ones don't, but they all support the multidisciplinary area.
DR. ORNISH: Just a quick clarification. I requested this MCAC hearing to look at intensive lifestyle intervention programs like ours and others. I think it's perfectly appropriate as part of, in fact as part of what I was trying to present, is what Pritikin has done, what others have done in the context of other randomized lifestyle clinical trials, and variations on cardiac rehab makes perfect sense. I don't think they need to be carved out as cardiac rehab, let's vote on this, and more intensive programs, let's vote on that. I think the totality of the evidence is what needs to be considered, but it also needs to be this, this part of it needs to be considered as well, not just traditional cardiac rehab or variations on

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that.
And then if you can say well, taken as a whole, there is a lot of evidence showing that cardiac lifestyle interventions are safe and effective and that different people are going to want different intensities for diet and lifestyle intervention, recognizing that there is more of a personal cost, an economic cost, and there are more corresponding benefits, and different people are going to want different intensity of intervention, whether it's traditional cardiac rehab, something like the Mind-Body program, or something more along the lines of what we and Pritikin and Esselstyn are doing. That is the case, and I think that if you take that approach, from my obviously biased point of view, there is a lot of evidence there and you can say that. But I think it would be a mistake to either carve out, or certainly to exclude all the work that we and others have done simply because we had 48 patients instead of 50. That's kind of arbitrary.
DR. DAVIS: Cliff.
DR. GOODMAN: Okay. I think we ought to keep the bodies of evidence together. Great technology assessment, but it was all about RCTs

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and all about 50 people or more. I am the biggest fan in the room of evidence hierarchy and RCTs but recognize it's not the only source of evidence and we need to include other types of evidence, point one.
Point two, indirect evidence. If we know from other rigorous studies in the literature that knocking down blood pressure has good effect and knocking down weight has good effect on

outcomes, knocking down lipid levels, and we have an intervention that is shown to knock down those same things, it's feasible to infer that indirectly, we're not certain, but indirectly there is cause to think that this intervention might have an impact on the desired outcomes. So I say we keep it together and think broadly about this. That said, the body of evidence for Ornish and these other things is a less rigorous body of evidence, but we should still look at it.

DR. DAVIS: I want to throw an option here, because I sense that we're not quite aimed at a place where we are all on the same page. I mean, I'm sensing a consensus that people want to stick with the body of evidence that's in the

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technology assessment, but I also feel like the committee wants to make a statement about the intensive diet and lifestyle programs that may not have been captured in the technology assessment because of the criteria that we have been discussing. So we could answer these questions as they are written with the idea that they refer to the body of evidence that's in the technology of assessment, and then add a statement like, how confident are you that intensive diet and lifestyle programs will improve net health outcomes at least as much as traditional cardiac rehab, or something like that.

DR. ORNISH: I'm not at all comfortable with that, just for my two cents worth, and then I'll sit down. I think it's completely arbitrary and completely unscientific to say that a study that has 50 patients is scientific and a study that has 48 is not. There are so many more important factors, and I think it would be entirely appropriate that the entire body of evidence be included, not just the technology assessment. The technology assessment, even from Dr. Clark's own analysis, is only one part of the overall evidence that has been presented here

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today. So why should the evaluation relate only to one piece of a very large body of evidence? I mean, my suggestion to you in my humble opinion is that, and I feel very strongly about this, is that you know, if we have 48 patients that have shown after one year and after five years regression of coronary heart disease, and particularly was published in JAMA, that is not unscientific, and it shouldn't be considered that way. It shouldn't be an afterthought or a postscript, or an addendum. It should be part of the overall body of evidence that you consider.

DR. DAVIS: Dr. Ornish, I don't think

anybody would disagree that there is a significant difference between 48 patients and 50 patients. The problem is that the technology assessment was done as it was done, we have questions here that are worded as they are, and we have some wording here that is a bit ambiguous, and we have to do something with it.

DR. ORNISH: But as I understand it, and maybe I'm missing something, but the questions were not based on the technology assessment alone. And so all I'm saying is, of course consider the technology assessments, but when -- and I think

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Dr. Clark, maybe you can back me up on this. I don't think you're saying that studies that have less than 50 patients are unscientific, are you? But that's the interpretation that you're giving.

DR. DAVIS: Well, I'm not meaning to give --

DR. SLAUGHTER: But you're saying that we are here to evaluate your program and your presentations and not his.

DR. ORNISH: No, that is not what I'm saying. I apologize if I gave that impression. That is not at all what I'm saying. I'm saying just the opposite, that I would be the last person to dismiss the technology assessment, but I would also be the last person to say that that's the entire body of evidence that you should vote on. All I'm saying is that the fact that we had 48 patients instead of 50, and therefore didn't make it into the technology assessment, doesn't mean that A, it's unscientific, and B, that it should be voted on separately. We are saying that all of the evidence should be included, including the technology assessment, but also including what we've done and what others have done, not as an afterthought or addendum, but as part of the body

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of evidence, and I thought that's what we're voting on.

DR. DAVIS: Well, I think we need to be clear what we are voting on. Otherwise, our advice to CMS is not worth a whole lot. If we vote on a question and it's clear that we are unclear about what the question means, then I don't think we've helped CMS that much. So my own feeling is we need to clarify what we mean before we vote and then vote and then CMS can use our vote.

DR. CURTIS: Can I make a suggestion? I came in here today with the intention at this public meeting to look at the totality of the evidence I have been given, which as Dr. Clark said a little while ago, which is look at everything. So you know, I didn't sit here for

hours listening to all this evidence to figure that oh yeah, I'll listen to what Dr. Clark said, and everything else that everyone else said was kind of nice but is irrelevant, we're putting the whole thing together. And I don't think we have to have two complete sets of votes here. What we're looking at is comprehensive cardiac rehab programs that are multidisciplinary

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in nature. They go from the very extensive strict kind of Ornish program to things that aren't quite that extensive or strict. But I don't think anybody here has talked about cardiac rehab light. You know, I mean, it's a multidisciplinary program with a lot of components to it. We're not going to figure out that we're voting on this one and not that one or something like that, but rather the comprehensive program and what did it show. If we look at the totality of the evidence that we've had, I think we can vote on that today.

DR. DAVIS: So, are you recommending that we stick with the language that we have, but that we make it clear that the language refers to comprehensive multidisciplinary intensive programs?

DR. CURTIS: That's my recommendation.

DR. HERMAN: And the complete body of evidence that has been given to us --

DR. DAVIS: He said complete body of evidence that has been given to us. Both in terms of technology assessments, individual articles, testimony throughout the day.

DR. HERMAN: In the written materials and the testimony we've heard today.

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DR. DAVIS: Yes.

DR. BARRETT: So we have had a very intensive review of a body of literature that Dr. Clark looked at, and then we've had a lot of other information which really hasn't been rated as to validity or the likelihood of validity and this includes the more intensive programs, I think in two ways. One is that I'm not sure exactly how many of these studies that were reviewed are of this type, but I know when I reviewed the packet, I was not asking myself to think hard about programs that didn't have very much about them in the packet. And then secondly, we have heard a lot of reasonable information about intermediary end points, but we don't actually have that data in front of us. So I feel like I'm being asked to answer questions which I didn't prepare for.

DR. CLARK: Just one point, just to clarify for Dr. Barrett, any studies that were excluded, we passed no judgment on their validity, we only say that we couldn't include them based on

this criteria. And we do think that it's relevant, as a neutral party, that publications have been included in high impact peer reviewed journals, and I think that does provide you the

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committee with some reassurance that these papers have been peer reviewed, and though we excluded them from our analysis, they do represent good designs and you can trust them just as you would any article that appears in JAMA or the Lancet or the New England Journal, so don't make any judgments based on things we excluded.

DR. DAVIS: Let me just put this to a vote, to make sure that we are clear, and then we can proceed accordingly.

I heard a suggestion that was made with a lot of heads that were nodding, that recommended that we vote on the questions as worded, but with the idea that this refers to physician-supervised behavioral interventions that are comprehensive and intensive and multidisciplinary. Okay? So I'm going to ask for a show of hands of people who are supportive of voting on these questions with that interpretation in mind. So all those that are in favor of that approach, raise your hands.

(All members except Dr. Owen raised their hands.)

DR. DAVIS: All those opposed, raise your hand.

(Dr. Owen raised his hand.)

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DR. DAVIS: Okay. So we will proceed in that fashion. That being the case, I think we are about ready to vote.

There is one other, although if there is a dissenting view I would be happy to entertain it, there is one other definitional issue that I think we should raise before we vote, which was discussed by a few of us briefly before the meeting began, and that is the meaning of long-term survival and short-term survival.

Dr. Phurrough had indicated that usually CMS considers short-term survival to be one to three months and long-term survival to be a year or more. But we also have heard from, through the technology assessment that there may be differences in the data depending on whether you look at 12-month survival or 24-month survival, so we may choose to interpret long-term survival in a different way, or to define long-term survival in a different way, or leave it undefined. So, I look for guidance from the committee on that.

DR. REDBERG: We didn't get data on short term of one to three months, right?

DR. DAVIS: Well, we can either call

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short term and long term 12 months and 24 months, or we can call it one to three months and two years. I mean, we can do it different ways, and if it's one to three months then we don't have much data.
DR. CURTIS: Long term is greater than one year, because short-term is under a year.
DR. DAVIS: What do people think about that, short term under a year, long term over a year.
DR. GOODMAN: Sorry to be technical about this, but where exactly is one year? I thought the data broke at two years or more and less than two years survival.
DR. CLARK: Quickly, we most often saw follow-up at 12 months, 24 months and 60 months, and there were significant differences at 24 to 60 months.
DR. GOODMAN: So the break was at two years, and I think this is what you might expect with this population. You're not going to knock down mortality in weeks or a couple months. So I would say long-term survival is two years or greater.
DR. DAVIS: And so short-term survival
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is less than two years.
Again, this is for the purpose of voting today and giving advice to CMS. It doesn't mean that these are to be considered standardized definitions. Are people comfortable with that?
DR. REDBERG: How about long term greater than a year?
DR. GOODMAN: That would still exclude the 12-month cutoff.
DR. DAVIS: So long term is greater than a year and short term is a year or less. Are panel members comfortable with that? I see some nodding heads and no dissent, so we will go with that. Any other comments before we proceed to voting?
(No response.)
DR. DAVIS: Michelle is going to tell us who are the voting members, but as Dr. Phurrough mentioned at the beginning, we want everybody to vote.
MS. ATKINSON: For the record, the voting members present at today's meeting are Rita Redberg, Cliff Goodman, Anne Curtis, Tracy Gordy, Paul Barrett, Tammy Born, Mary Lee, William Owen and Mark Slaughter. A quorum is present and no
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one has been recused because of conflict of interest.
The entire panel, including the

nonvoting members, will participate in the voting. Two averages will be calculated, one with the voting members only and one including the entire panel. The voting scores will be displayed on the screen after the meeting. We will be using the numbered cards in front of you to record the scores for today's voting. These are the numbers that you will present for your vote.

DR. DAVIS: We're going to start with question number one, and you can get your voting cards ready. That question is: How well does the evidence address the effectiveness of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease as compared to usual medical/surgical management, with the response choices ranging from one for poorly up to five for very well.

And based on a vote that we took a few moments ago, we are interpreting behavioral interventions for this question and then succeeding questions to refer to those interventions that are comprehensive, intensive

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and multidisciplinary. Everybody clear on that? So, please at this point hold up the card that would represent your vote.

(Panelists voted, with average score for voting members of 3.67, average score for entire panel of 3.71.)

DR. DAVIS: Thank you. And by the way, when are these votes going to be made available?

MS. ATKINSON: As soon as we're finished.

DR. DAVIS: So when the meeting is over we will have these available.

Question number two: How confident are you in the validity of scientific data on the following outcomes with respect to physician-supervised behavioral interventions for patients with symptomatic coronary artery disease, with the responses ranging from one, no confidence up to five, high confidence. And we'll do this separately for outcomes, beginning with cardiac event, including angina, so please hold up your cards for that outcome.

(Panelists voted, with average score for voting members of 3.78, average score for

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entire panel of 3.64.)

DR. DAVIS: Thank you. The next outcome is long-term survival, which we just defined a few moments ago as greater than one year. Please raise your cards.

(Panelists voted, with average score for voting members of 3.78, average score for

entire panel of 3.93.)
DR. DAVIS: Thank you. The next outcome is short-term survival, which we just defined as one year or less. Please raise your cards.
(Panelists voted, with average score for voting members of 3.33, average score for entire panel of 3.43.)
DR. DAVIS: The last outcome for question number two is quality of life. Please raise your cards.
(Panelists voted, with average score for voting members of 3.78, average score for entire panel of 3.64.)
DR. DAVIS: Question three: How likely is it that physician-supervised behavioral interventions for patients with symptomatic coronary artery disease will positively affect the

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following outcomes when compared to usual medical/surgical management, with the response choices ranging from one, not likely, up to five, very likely. Beginning with cardiac event, including angina. Please raise your cards.
(Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.57.)
DR. DAVIS: Thank you. Next outcome is long-term survival, as defined previously. Please raise your cards.
(Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.71.)
DR. DAVIS: Thank you. The next outcome is short-term survival, as defined previously. Please raise your cards.
(Panelists voted, with average score for voting members of 2.67, average score for entire panel of 2.79.)
DR. DAVIS: Thank you. The last outcome for question number three is quality of life. Please raise your cards.
(Panelists voted, with average score for voting members of 3.56, average score for

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entire panel of 3.65.)
DR. DAVIS: Thank you. Question number four: How confident are you that physician-supervised behavioral interventions will produce a clinically important net health benefit in the treatment of patients with symptomatic coronary artery disease? Net health benefit is defined in the footnotes at the bottom of the page, incidentally, and the response choices range from one, no confidence, up to five, high confidence. Please raise your cards.

(Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.71.)
DR. DAVIS: Thank you. And the last question, number five: Based on the scientific evidence presented, how likely is it that the results of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease can be generalized to, A, the Medicare population, age 65 and older? And we will vote first on that before we go to question 5.b. So please raise your cards for question 5.a.
(Panelists voted, with average score for voting members of 3.22, average score for
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entire panel of 3.50.)
DR. DAVIS: Thank you. Question 5.b, generalized to providers, that is, facilities or physicians in community practice.
(Panelists voted, with average score for voting members of 2.78, average score for entire panel of 2.86.)
DR. DAVIS: Thank you. And as I mentioned before, we will now go down the table and give members of the committee a chance to explain why they voted the way they did, if they would like to do so. So, should I start on the left or on the right or in the middle? Rita.
DR. REDBERG: Thank you. I guess I voted, I tried to vote just based on the data that we were presented and I think we have a substantial amount of data from the technology assessment, and then the additional data including the TEC assessment on some of the more intensive programs. And to me the remaining question is, the intensive programs were clearly beneficial, but what was the value added? I would like to have had similar outcome data from those programs. And again, I have to say that it's always disappointing to me that we have a Medicare
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population that's 60 percent women and we're often basing these decisions on study data that is about five percent women, and I just hope at the next MCAC, I don't have to say that. And the same thing with age, the average age is about 50, and it's not always clear how things are going to extrapolate to a population over 65, particularly with increased comorbidities.
I did think we got a lot of data from community practice physicians and that was really helpful on today's MCAC.
DR. GOODMAN: I started at the top of the evidence hierarchy with RCTs as per the technology assessment, but did not confine my voting to that. I was strongly persuaded that

it's important to look at the whole body of evidence in something like this, especially because the interventions that we're talking about are basically a package of smaller interventions about which we know much. The other point I'd make is that while Pritikin, Ornish or the others have some bits of strong evidence, the body is not as rigorous as they really need to be in the long run for Medicare. An RCT, it had some useful findings,

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but in itself would not be sufficient in the long-term. So if Medicare ever were to cover these procedures in the absence of enough long-term data and rigorous data, I would be very interested in seeing some kind of a registry or follow-up data requirement attached to this so we might know prospectively what outcome for what period of time for what interventions, and I think Medicare would use that information perhaps for modifying coverage.

DR. DAVIS: Rita wanted to add one more point.

DR. REDBERG: I just would point out that I do think it would be more helpful for Medicare and our beneficiaries to have more consistent outcomes definitions, because when we are comparing these to usual intervention, we actually have a lot of usual interventions that don't have the kind of data that we're now asking for in this intervention, so I do think it would strengthen our position to have consistent outcomes data that we require for coverage decisions.

DR. CURTIS: I think that these intensive programs work, they do have a great

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effect on patients' quality of life, they do change outcomes, but I think they have to be done right. And so my concern in terms of Medicare covering this and it becoming more generalizable is the fact that it's a very labor intensive process, there's very much of a time commitment and a commitment on the patient's part to get the outcomes that you want from it. So if coverage becomes broadened, it's very important that these programs be done in the way that the good outcomes came from, and that you can't take a bit or a piece of this and think you're going to get the same results, so that's going to be the challenge in broadening that into the community.

DR. GORDY: Well, I would echo the comments of my colleagues to the left. I think that it definitely is labor intensive and while I tend to champion the concept of the individual patient, I would hope that Medicare would clearly

define if they should decide to enact a coverage policy, what the program should do and then have performance involved in the payment policy. I do have a problem, and my voting reflected that I think, I have a problem generalizing because in the material that I heard

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today, it seemed to be limited to a group of people and really was not generalized to the comorbid situations that we find in the Medicare population. So I do have trouble with that particular portion and it may even have to do with some of the ways that if payment policy was changed to include this, that that would also have to be addressed. I think it's a little easier to do this with providers and get providers on board than it would be for the general population.

DR. BARRETT: A process question which I made once already, which is, if we're going to end up considering indirect evidence as a significant part of our process, it would be very important to actually see that evidence summarized. In other words, the linkage between the intensive programs and the regression on coronary lesions and then to the ultimate outcomes, because we have all seen situations where intermediate outcomes did get better and unfortunately, the patient's ultimate outcomes didn't. In spite of that, I was convinced by Dr. Clark's papers as well as my own reading that there is very good evidence that there is long-term benefit, survival benefit, which in some

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ways is the ultimate outcome.

DR. BORN: I think maybe you've noticed in my voting that's my feeling too, because none of these questions were addressed to the confidence level with the interventions that were addressed. I've been in my clinic for 17 years and I've seen incredible outcomes and changes in patients and I'm very confident that interventions like this, like intense diet changes and intense exercise programs will make a difference for patients, and so these questions were very strong for me. I've seen it happen over and over and over again. It does take a committed patient, but I think that there are many many committed patients and I think in the long run there will be huge benefits and huge changes in the Medicare population, because patients who feel better cost the system less, and I want to make sure that we save Medicare for our children, and I think that that's just a huge benefit.

I agree with Dr. Wexman's comment this morning that there was some benefit to having patients participate financially and that Medicare

maybe should not cover 100 percent but there should be some kind of co-pay and that you make a,

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or consider having the patients take a financial interest in their participation so they feel like they own it also, there is some benefit to that. So, that's it, thank you.

DR. LEE: I can't concur with Dr. Curtis more, and I think the literature shows that some of the most intensive regimens seem to do best in patients, but I'm not sure that, especially when answering question 5.b where I gave the lowest score, if the current education of providers prepares them to be able to provide these services or if they have the resources in the community setting to do so.

DR. OWEN: I think this is a spectacular example of personalized health care, but this is also what bothers me about voting on this day. We've got a very diverse population. 75 percent of the population lives in cities and that's why we talk about urban health care, so there's been that sort of segmentation. So I absolutely believe this works in a patient segment, a patient segment that is cared for by very knowledgeable and very passionate providers. But I'm also impressed by numbers of 300 patients for four years, 400 patients for two and three

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years, so what we have done is a great study of a very small segment of the population, and I am hence uncomfortable in extrapolating from this to the larger body of the population.

DR. SLAUGHTER: I believe that the total body of evidence certainly supports the concept that you can have regression of atherosclerosis and stabilization of plaque, and we have emerging U.S. data from well-run clinical trials to support this. I think that I agree with Dr. Owen too that a lot of this has occurred in various parts of the country, but to have a significant motivation to make it work, and whether or not that is translatable to the entire population, I'm not sure.

I think also that it is fairly clear that diet and exercise have significant impacts. When we talk about more intensive regimens, I would love to know whether yoga, counseling, things like that make a difference. So it's hard to separate out which parts of the intense components truly all contribute.

The other is as far as a generalized population, is that we do more neurocognitive tests on patients who have atherosclerotic

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disease, particularly as they get older. I mean,

we've seen some great examples of people today that do very well, but we have a large number that do have neurocognitive deficits, and their ability to comply with such a rigorous program, I think is also unproven yet.

DR. GARVEY: At the risk of being repetitive, I will just state that I agree most with the comments made by Doctors Lee and Curtis. I really think that these programs work for patients, I think that they have to be intensive. I also struggled over whether or not this was generalizable to the standard community, the medical community, one that translates well. But I also believe that the physicians who really direct these therapies for patients really also have to be very intensive and really have to emphasize the need for the patients to comply. Patients really do listen to their physicians.

MR. QUEENAN: I was also very persuaded by the evidence and I guess I want to add as was mentioned before, it's very significant with my personal experience a different setting. But I guess I want to add a further comment from the perspective of being the consumer

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representative on the panel and that really is the perspective or philosophy with which one evaluates data and decides whether or not you're confident. And throughout the day we heard a lot about the studies, we never really heard anything that suggested this kind of, this particular kind of intervention would result in a bad outcome for the patient, and in fact where that was a concern, we heard that some of the programs that were ongoing and being reimbursed specifically had components to eliminate people where that might the case. I think in that context, I have to say I find it a little troubling that when you start with the perspective of prove to me that it works at a 95 percent or better confidence interval, as opposed to prove to me that it doesn't. Now I'm certainly cognizant that there are a lot of cost issues and other policy issues to be addressed, but I think when one is dealing with a kind of intervention that is clearly good for the patient that there ought to be some attempt made or some bias in favor of let's go out and do it, provide the reimbursement, and see how it works, as opposed to the other way around.

MS. BIESEMEIER: Well, I voted based on

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the technology assessment and the entire body of evidence. A few comments. I was so impressed with the ongoing work that you all have done, and I commend you for it. I think this is a very patient-centered option and it illustrates very

nicely the synergies among the team members to produce something, outcomes that are very impressive.

When I think about the generalizability, I don't foresee, and maybe I'm lacking in vision, but I see that my African American friends in Nashville should at least have the option to participate, and that lack of coverage should not be the reason that they don't follow a program such as Ornish, that they have every, they have the access that others have who have resources. Same way in the rural communities of Tennessee where no, I don't see lots and lots of those people right now, but I see some, and they benefit from the intensive individualized support which these types of programs provide, and they show that individualization does work, so I thank you.

DR. HERMAN: I think the emerging evidence shows the benefit of this in clinical

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practice, I still have some concerns about their generalizability and how they will be implemented into clinical practice, but I think like any other safe and effective medical or surgical treatment, they need to be considered for coverage.

DR. SNIDER: I also looked at the whole range of evidence, the technology assessment and all of the articles, and it was pretty clear that the whole intense comprehensive practices were the most successful over the long term, along with strong case management. And also, the question that I remain having is the applicability to a broader range of communities. It seems that there's some intriguing information in some of the studies about individualization of care, and I support what Mr. Queenan just said about the need to get the practice, there's enough evidence to get the practice out there, and I will be interested in seeing whole systems of care with actual underlying theories analyzed, a broadening of the multidisciplinary teams so that broader communities can be reached where care can be individualized. I also commend all the work that has been done.

DR. DAVIS: Thank you very much. I

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would like to thank all the members of the committee and all the presenters for all the work that you have done today and before today, and it was a bit of a challenge to bring into concordance the technology assessment, the testimony that we heard and the questions that we ultimately answered, but I appreciate the patience that you all showed in going through a little bit of the stumbling that we did to get there, and I think we

achieved success in doing that. Dr. Phurrough?
DR. PHURROUGH: I want to add my thanks. I think this is a superb example of how this public process works very well for us and we appreciate your willingness to join us in this process, it's extremely helpful to us. We are encouraged by how in the last several months of MCACs that we have received some very sound reasoned recommendations, and we thank you. That's important.
DR. DAVIS: I'm going to handle Michelle's duties here, and it's five after four, so we're finishing 25 minutes before we were supposed to or scheduled to. We need a motion and a second to adjourn.
DR. REDBERG: Motion to adjourn.

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DR. BORN: Second.
DR. DAVIS: Is there any objection to adjourning?
(No response.)
DR. DAVIS: We're adjourned. Thank you.
(Whereupon, the meeting adjourned at 4:05 p.m.)