

## **Summary**

### **Evaluation of the Medicare Lifestyle Modification Program Demonstration and the Medicare Cardiac Rehabilitation Benefit**

#### **Background**

The Medicare Lifestyle Modification Program Demonstration (LMPD) was conducted by the Centers for Medicare & Medicaid Services (CMS) from October 1999 through February 2007 to test the efficacy and cost-effectiveness of two cardiovascular lifestyle modification programs: the Dr. Dean Ornish Program for Reversing Heart Disease® (Ornish) of the Preventive Medicine Research Institute and the Cardiac Wellness Program of the Benson-Henry Mind/Body Medical Institute (M/BMI).

The goals of this demonstration were to determine the ability of these programs to enroll Medicare enrollees, assess their clinical outcomes, operating costs and impact on total Medicare costs, and to compare them with traditional cardiac rehabilitation.

The demonstration was implemented at participating sites licensed by the Dr. Dean Ornish Program for Reversing Heart Disease®, of the Preventive Medicine Research Institute and also at facilities licensed to provide the Cardiac Wellness Extended Program of Dr. Herbert Benson and the Mind Body Medical Institute (M/BMI) now called the Benson-Henry Mind/Body Medical Institute. Any facility licensed to provide either program was eligible to participate in the demonstration throughout the enrollment period.

Participating sites under each model were provided Medicare payment to enroll and provide treatment for Medicare Part B eligible beneficiaries who met the clinical enrollment criteria and voluntarily elected to participate in the demonstration.

#### **Cardiovascular Lifestyle Interventions Tested in Demonstration**

Each lifestyle program consisted of a one-year treatment program that included supervised exercise, nutrition counseling, stress management, and group support beginning with a three-month period of intensive supervised interventions followed by nine months of less frequent sessions with a greater emphasis on home maintenance of healthy behaviors. The two programs differed to some degree in the content and intensity of the intervention.

The Ornish program offered a 12-week intensive phase that included three 4-hour sessions in week 1, two 4-hour sessions in weeks 2 through 11, and three 4-hour sessions in week 12. Nutrition counseling focused on a vegetarian diet with 10% of total calories from fat. During the balance of the first year, participants received either 12 or 24 weeks of 2-hour weekly sessions or 40 weeks of 4-hour weekly sessions based on medical risk stratification and adherence to lifestyle change guidelines. In the second year, participants were offered assistance in obtaining self-directed community follow-up and were periodically reevaluated.

The M/BMI program was similar but less intense. Participants received one 3-hour session per week during the first 13 weeks. Particular emphasis was placed on adhering to the American Heart Association diet (about 30% of calories from fat), group support and behavior change, and one-on-one health contracting and assessment sessions. During the balance of the first year, they attended 3-hour sessions twice a month. At the end of the year they were given a program completion certificate, revised health contract, and information about “graduate” groups and community resources. Outcomes were followed during the second year.

Following the 1-year treatment program each site conducted a 1-year monitoring phase for beneficiaries that had completed the program.

### **Payment**

A negotiated fee of \$5,650 was established for beneficiaries who completed the Ornish program and \$4,800 for those who completed the M/BMI program. Medicare paid up to 80% of this allowed charge or \$4,520 per participant in the Ornish program and \$3,840 per participant in M/BMI. Sites could collect the remaining 20% coinsurance from participants although they were allowed to waive the coinsurance for their participants, and most chose to do this to encourage enrollment.

CMS made payments to the sites on a quarterly basis at 35%, 15%, 15%, and 35% of the total rate, respectively, for enrollees as long as they remained active. However, if a beneficiary disenrolled from the program prior to completion, the demonstration site received only a pro-rated portion of the total payment.

### **Quality Monitoring and Review**

Continuous quality monitoring and review was provided through a contract with the Delmarva Foundation for Medical Care, the Medicare Quality Improvement Organization (QIO) for Maryland, to ensure adherence to the enrollment criteria and to monitor the quality of care and the safety of Medicare patients. Before each enrollment was allowed, the Delmarva Foundation reviewed the clinical enrollment information for each potential enrollee to verify that the Medicare beneficiary’s medical history and status met the eligibility requirements for enrollment in the demonstration and either the Ornish or M/BMI lifestyle program.

### **Demonstration Enrollment Criteria**

Medicare beneficiaries eligible to enroll in the demonstration had to have: 1) an acute myocardial infarction, 2) cardiac surgery or a percutaneous cardiac intervention (PCI) within the previous 12 months, or 3) stable angina pectoris.

### **Evaluation**

Brandeis University was awarded the evaluation contract to assess the feasibility, outcomes, cost, and cost-effectiveness of providing payment for these comprehensive cardiovascular lifestyle

modification program services to Medicare beneficiaries. The evaluation consisted, in part, of a pre/post quasi-experimental, matched-pairs design with two control subjects: one with cardiac rehabilitation (CR) and one without cardiac rehabilitation treatment (non-CR). A 2-year follow-up was included for up to a maximum of 3,600 program enrollees and 7,200 comparison subjects. Demonstration enrollees were followed for 2 years ending in February 2008 for the most-recently enrolled participants.

The evaluation effort was subsequently expanded to include a meta-analysis of all lifestyle modification program published research and an evaluation of the Medicare cardiac rehabilitation program. This section discusses the findings from each component of this comprehensive evaluation.

## **1) Findings from the Demonstration Evaluation**

### **• Enrollment**

The demonstration sites were encouraged to advertise their programs and solicit physicians to make referrals and Medicare beneficiaries to enroll in the programs. The ability of the sites to enroll beneficiaries into the lifestyle modification program and the number of beneficiaries who stayed to complete the program was an important measure of the success of the programs tested under the demonstration.

A total of 24 Ornish sites and 9 M/BMI sites located throughout the U.S. began participation in the demonstration. The demonstration ended with 17 demonstration sites in seven states: 12 Ornish sites in two states (seven in PA, five in WV) and five M/BMI sites in five states (MA, RI, TN, VA, WA). Enrollment at Ornish sites began in October 1999 and at the M/BMI sites in September 2001. Enrollment under the demonstration ended February 28, 2006, with treatment ending February 28, 2007.

During the entire enrollment period of 7 years, 5 months for the Ornish program sites and 5 years, 6 months for the M/BMI program sites, sites submitted for approval enrollment information for 701 beneficiaries, 205 from Ornish sites, 496 from M/BMI sites. The Delmarva Foundation found that 611 of these met all of the criteria for enrollment (156 Ornish, 455 M/BMI). Of these, a total of 589 beneficiaries actually enrolled in the two programs: 442 into the M/BMI program and 147 into the Ornish program. Of these, 216 beneficiaries (58 Ornish, 158 M/BMI) dropped out of the lifestyle programs during the first year. A total of 373 beneficiaries (89 Ornish, 284 M/BMI) completed the 1-year program of treatment.

The evaluation included all 589 beneficiaries who enrolled and began participation in either program, including the 216 that later dropped out before completing the 1-year treatment.

### **• Clinical Outcomes**

The Ornish and M/BMI cardiovascular lifestyle modification programs both achieved favorable changes in cardiac risk factors compared to baseline values over the 2 years of follow-up, with

reductions in body weight, blood pressure levels, serum cholesterol and LDL levels, and improvements in psychological health. Improvements were also found in cardiac function.

Comparisons between the two programs showed that the Ornish program was more effective in achieving weight loss than M/BMI at 3 and 12 months, although the difference was not significant at 24 months. Changes in serum cholesterol and LDL were greater in the Ornish program after 3 months, but were comparable in the two programs thereafter. Levels of HDL (the “good” cholesterol) decreased during the first 3 months in the Ornish program, but significantly increased in M/BMI participants at each time point (3, 12 and 24 months). Changes in systolic blood pressure were somewhat more favorable in M/BMI participants and continued to decrease over the full period of follow-up.

When compared to their baseline levels, participants in both the Ornish and M/BMI programs experienced statistically significant improvements in all measures of physical and psychological health that were maintained through the first year of follow-up. Improved levels were maintained through two years of follow-up in the Ornish program but became statistically insignificant in the M/BMI program.

- **Re-hospitalization Rates**

By the end of the third year of follow-up, a significantly greater number of M/BMI participants were able to avoid hospitalization for cardiovascular reasons when compared to CR and non-CR matched controls. Similarly, in each year of follow-up, the average number of hospitalizations, for any reason, was significantly lower in M/BMI participants. No significant differences were found for either of these hospitalization rates, however, for participants in the Ornish program when compared to their matched CR and non-CR groups. That is, the results show no evidence that the Ornish program was better than regular medical care or traditional CR on either of these measures.

- **Mortality**

The mortality rate among M/BMI participants was significantly less than matched CR and non-CR controls over 36 months post-enrollment. The Ornish participants, however, did not show consistent or significant differences compared to the CR and non-CR matched controls. After controlling for gender, qualifying event, and age at enrollment, the M/BMI was found to reduce the mortality risk among participants compared to the non-CR group. The Ornish program was not associated with a significant change in mortality risk.

- **Cost Savings**

The analysis of Medicare costs was based on differences in fee-for-service Medicare expenditures during the demonstration and follow-up period for demonstration participants compared to their matched CR and non-CR controls. Multivariate analysis was conducted to control for differences in the participants’ and control populations’ pre-enrollment costs, demographic characteristics, and qualifying events. Such analysis found no significant

differences in Medicare expenditures for either the Ornish or M/BMI program participants compared to their matched CR and non-CR controls.

- **Effectiveness Analysis**

The main effectiveness outcome was increased time to the first cardiovascular hospitalization. This analysis showed favorable effects for the M/BMI program, but no differences from controls for the Ornish program. The Ornish program did not show any reduction in risk of cardiovascular hospitalization.

- **Payment Comparison**

Under the demonstration, the negotiated rates were \$5,650 for the Ornish program and \$4,800 for the M/BMI program, with Medicare paying 80% or \$4,520 and \$3,840 respectively, for a 1-year treatment program. At the same time, the regular Medicare program paid on average approximately \$683 for traditional cardiac rehabilitation for an 18-week program.

## **2) Literature Review**

As part of the evaluation effort, an extensive review of the literature was conducted to identify and rate all available evidence on the costs and effectiveness of cardiovascular lifestyle modification and related modalities.

The preponderance of evidence from these studies would support a finding that traditional, exercise-based cardiac rehabilitation programs are economically advantageous. For instance, it was found that cardiac rehabilitation interventions saved on re-hospitalization expense with lower costs per quality-adjusted-life-year when compared to no intervention.

However, it was also found that although there was a ten-fold variation in the intensity (in terms of hours spent) between the lifestyle modification interventions and traditional CR, the results did not support the contention that higher intensity programs produce better outcomes.

Finally, it was found that racial, ethnic and gender differences appeared at every step of the continuum with racial/ethnic minorities and women having a higher incidence of risk factors and a less likelihood of receiving needed cardiac procedures than white men.

## **3) Evaluation of the Medicare Cardiac Rehabilitation Benefit**

An evaluation of the Medicare cardiac rehabilitation benefit was conducted based on patients who became eligible in 1997 following a cardiac event and were followed up through Medicare and vital statistics data. The population studied was 601,099 Medicare beneficiaries who were hospitalized for a coronary condition or cardiac revascularization procedure.

- **Enrollees**

It was found that older individuals, women, non-whites, and patients with co-morbidities (e.g., congestive heart failure, previous stroke, diabetes, and cancer) were significantly less likely to

receive CR. Having heart bypass surgery during the index admission, residing in a neighborhood with higher median household income or a higher level of education, and a shorter distance to the nearest facility offering CR were important predictors of higher CR use.

- **Mortality**

Mortality rates were found to be 21% to 34% lower in CR-users than non-users. Among Medicare beneficiaries who enrolled in CR, those who completed 25 or more CR sessions were 19% less likely to die over 5 years than matched CR-users with 24 or fewer sessions.

- **Cost Effectiveness Analysis**

Although those beneficiaries who completed cardiac rehabilitation (CR) had somewhat higher institutional costs at baseline and the year following index hospitalizations, there appears to have been a modest reduction in institutional costs (for any reason) in the subsequent 4 years for the CR group compared with the non-CR group. The cumulative savings in institutional costs for a beneficiary who lived through years 2 to 5 was \$3,339 (here “institutional” refers to hospital inpatient services, skilled nursing services and home health services as opposed to ambulatory costs which includes physicians' services and hospital outpatient services.)

If one includes both institutional and ambulatory costs, as with institutional costs, the CR group experienced greater total costs than the non-CR group for the index admission and the year following discharge. However, if only the differences from year 2 through year 5 are included, after the hospitalization and the post acute care directly related to the hospitalization, the CR group total cost to Medicare is less than the non-CR group by an average of \$2,830.

- **Utilization**

The utilization of CR across the nation was found to be extremely low. Overall, only 12% of eligible Medicare beneficiaries enrolled in CR despite convincing evidence of its benefits and recommendations for its use by professional organizations. CR was used by 31% of patients who had undergone heart bypass surgery and only 14% of Medicare beneficiaries who had been hospitalized for acute myocardial infarction. Moreover, CR use among beneficiaries with myocardial infarction or who received a revascularization procedure varied 9-fold among states ranging from 6.6% in Idaho to 53.5% in Nebraska, with the highest CR rates clustered in north central states of the U.S and the lowest rates generally in southern states.

It was found that CR facilities in high utilization states were more likely to be located at or near the hospital and to take an active role in facilitating referrals, usually by encouraging physicians to make referrals before patients were discharged from the hospital. These facilities often instituted standing orders or other processes to routinely identify and recruit CR eligible patients. By contrast, CR facilities in low utilization states tended to be located separate from the hospital, had little or no role in facilitating patient referrals and engaged in few overt efforts to identify, refer and recruit new CR-eligible patients.

Finally, CR facilities in high utilization states tended to operate at or near capacity and had the ability to increase capacity when necessary in order to avoid waiting lists that tend to discourage patient enrollment.

## **Conclusions**

When results from the Ornish and M/BMI programs are pooled, they appear to have achieved better outcomes in terms of lower risk of cardiovascular hospitalization and other measures compared to traditional cardiac rehabilitation. For the M/BMI program, participation may have reduced mortality, and the times to first hospitalization and first cardiac hospitalization were extended. When results are separated by program, only the M/BMI program showed lower cardiovascular hospitalization risk or mortality benefits compared to the program's controls.

Neither program was found to have a statistically significant impact on costs. There were no significant differences found in Medicare expenditures for either the Ornish or M/BMI program participants compared to their matched CR and non-CR controls.

Limitations of the demonstration included low enrollment and the limited ability to adjust for differences in patient characteristics among lifestyle participants, CR participants, and patients who did not receive CR. Based on survey data, participants in the lifestyle modification programs were better educated and more motivated than their matched controls, but these factors could not be fully adjusted for because of incompleteness of the survey data, especially for the matched controls.

Even though enrollment began 2 years later in M/BMI than in Ornish, the cumulative enrollment at M/BMI sites was three times higher than at the Ornish sites. However, final enrollment in both programs was far below the 1,800-person target originally established for each program.

While the findings suggest that more intensive lifestyle modification programs are clinically effective, their additional costs and difficulties in enrollment reduce their advantage for the Medicare program compared to traditional cardiac rehabilitation. It should be noted, however, that in March 2006, Medicare included intensive CR programs, such as the Ornish and M/BMI programs, as acceptable CR programs for beneficiaries eligible for the CR benefit. In addition, the proposed rule on "Payment and Coverage Improvements" published July 13, 2009 (*Federal Register*, Vol. 74, No. 132, pp. 33606-10) describes an expansion of the Medicare cardiac rehabilitation benefit to include specific payment provisions for intensive cardiac rehabilitation, like the Ornish and M/BMI programs, which may be provided for up to six 1-hour sessions per day for up to 72 sessions over 18 weeks

Traditional, exercise-based cardiac rehabilitation programs were found to be cost-effective, extending life and reducing re-hospitalization. However, given low utilization rates of traditional CR across the U.S., it would appear beneficial to find ways to increase its usage.

Finally, racial and ethnic minorities, women, and beneficiaries with comorbidities were found less likely to enroll in the lifestyle modification programs or cardiac rehabilitation, and from the literature review, less likely to receive cardiovascular interventions in general. This would

suggest that these disparities should receive particular attention as part of any effort to increase utilization in cardiac rehabilitation.