

The Centers for Medicare & Medicaid Services' Office of Research, Development, and Information (ORDI) strives to make information available to all. Nevertheless, portions of our files including charts, tables, and graphics may be difficult to read using assistive technology. In some cases due to size or complexity, we were not able to make files fully accessible using assistive technology. Persons with disabilities experiencing problems accessing portions of any file should contact ORDI through e-mail at ORDI_508_Compliance@cms.hhs.gov.

Appendix B.4

Of the

Evaluation of Lifestyle Modification and Cardiac Rehabilitation in Medicare Beneficiaries*

Cost-Effectiveness of Cardiac Rehabilitation in Older Coronary Patients

Authors

Donald S. Shepard, Ph.D.* Jose A. Suaya, M.D., Ph.D.*; William B. Stason, M.D., MSci*; Philip A. Ades, M.D.§

* Schneider Institutes for Health Policy, Heller School, Brandeis University

§ College of Medicine, University of Vermont

*Supported by the Centers for Medicare & Medicaid Services under contract number 500-95-0060, Task Order 02 to Brandeis University and number 500-02-0012-MDBU to the Delmarva Foundation for Medical Care

TABLE OF CONTENTS

ABSTRACT.....	1
INTRODUCTION.....	2
METHODS.....	3
Framework.....	3
Initial Study Cohort for Medicare Data.....	3
Cohorts of Beneficiaries.....	4
Cost Analysis during the Observation Period.....	4
Effectiveness of CR during the Observation Period.....	5
Quality of Life Adjustment.....	5
Extrapolation of Cost beyond the Observation Period.....	6
Extrapolation of Mortality beyond the Observation Period.....	6
RESULTS.....	7
Overall Cohort Characteristics.....	7
Costs during the Observation Period.....	8
Outcome and Cost Projections.....	8
DISCUSSION.....	9
ACKNOWLEDGMENTS.....	11
REFERENCES.....	12

LIST OF TABLES AND FIGURES

Table 1. Impact of CR on mortality (matched pair analysis)	Error! Bookmark not defined.
Table 2. Effects of cardiac rehabilitation (CR) on costs and discounted life years	16
Table 3. QALYs gained per participant from cardiac rehabilitation.....	17
Table 4. Cost-effectiveness of cardiac rehabilitation.....	18
Figure 1. Total Medicare costs per year alive	19
Figure 2. Ambulatory Medicare costs per year alive.....	20
Figure 3. Institutional Medicare costs per year alive	21
Figure 4. Net costs of cardiac rehabilitation (CR)-users compared to non-users per year alive .	22
Figure 5. Projected total cost of non-users over their remaining life expectancy.....	23

Figure 6. Projected net costs per year alive of CR users compared to matched non-users by time period..... 24

ABSTRACT

Introduction: More than 13 million Americans had coronary heart disease (CHD), the major component of cardiovascular disease, over 860,000 of them had an acute myocardial infarction (AMI), and 480,000 Americans died of CHD in 2003.² Cardiac rehabilitation (CR), which optimally includes monitored aerobic exercise and varying protocols for lipid control, weight loss, or stress modification, is recommended for patients with CHD and related indications. In a previous analysis of 601,099 Medicare beneficiaries with CHD, we found 21% to 34% lower one-to five-year mortality rates in CR-users than non-users with three statistical techniques (each $p < 0.001$). This paper conducts a cost-effectiveness analysis of CR in older Americans based on the propensity-based matched pairs analysis from these data.

Methods. Using the framework recommended by the US Public Health Service, we estimated the cost-effectiveness ratio as net impact on lifetime health costs divided by the net impact on lifetime on quality adjusted life years (QALYs). Quality of life (QoL) for persons with CHD without CR were derived from the Medical Expenditure Panel Survey (MEPS), a national data set. Improvements in QoL from CR were based on a published randomized trial that used a utility scale, the EQ-5D. Impacts on cost and mortality during the 5-year observation period were based on Medicare data for the matched pairs. Cost results beyond that period were based on trends from years 3 through 5 of follow up, a period when patterns of care were no longer affected by the initial coronary event or procedure that made the patient eligible for CR. Likewise, mortality results beyond the 5 year period were also based on the mortality ratio of non-users compared to demographically matched cohorts in the general population.

Results: Only 12.2 % (73,049 beneficiaries) received one or more CR outpatient sessions. Older patients, those with co-morbid conditions, residents of low income neighborhoods, and women were particularly unlikely to use CR. Cumulative mortality was 16.3% in CR-users vs. 24.6% in matched non-users at five years, a 34% reduction ($p < 0.001$). Overall, each participant gained 0.32 QALYs over the observation period and 0.69 QALYs over his lifetime. About two thirds of the lifetime gain was the result of mortality reductions, and one third the result of improved QOL. Without quality adjustment, each participant gained 0.62 discounted life years.

The incremental lifetime cost in CR users compared to non-users was \$7414. This was almost entirely due to their greater survival, as the cost per year alive was virtually identical in CR users and non-users. The incremental cost-effectiveness of CR is \$11,883 per discounted life year gained and \$10,771 per QALY gained.

Discussion: To interpret this result, we can whether this result lies below accepted thresholds. A 1999 health policy analysis for another branch of the US Department of Health and Human Services suggested a threshold of \$100,000 per QALY.³⁶ The World Health Organization's guideline of three times the country's per capita would increase the threshold to \$145,000 or the United States in 2007. Thus, CR is more favorable by almost a factor of ten compared to either of these thresholds, and substantially more favorable than increasingly used technological approaches such as implantable defibrillators.

Several limitations must be acknowledged. The claims data on the Medicare beneficiaries do not show quality of life and do not show risk factors and behaviors, such as smoking history, diet, and adherence to CR or medication regimens. Nevertheless the size of the cohort, the length of follow up, and the availability of neighborhood characteristics (based on residence) and detailed payment information were unexpected benefits.

The combination of very favorable effectiveness and cost-effectiveness of CR coupled with low rates of use suggest that policy makers may wish to examine strategies to improve utilization. A range of options, including public reporting of use rates and incentives for attainment and improvement, deserve consideration.

INTRODUCTION

Cardiovascular disease is the leading cause of death worldwide, responsible for 30% of global deaths and almost 50% of deaths in high income countries in 2001.¹ In the U.S. alone, more than 13 million Americans had coronary heart disease (CHD), the major component of cardiovascular disease, over 860,000 of them had an acute myocardial infarction (AMI), and 480,000 Americans died of CHD in 2003.² Older Americans (65 years of age or older) account for over 55% of AMIs and 86% of CHD deaths.³ The estimated economic cost of cardiovascular disease in the U.S. was \$448.5 billion in 2008.⁴

Cardiac rehabilitation (CR), which optimally includes monitored aerobic exercise and varying protocols for lipid control, weight loss, or stress modification, is recommended for patients after myocardial infarction, with stable angina, or after revascularization with coronary artery bypass graft (CABG) surgery or percutaneous coronary intervention.⁵⁻¹⁰ Meta-analyses of randomized controlled trials of CR have demonstrated 15% to 28% reductions in all-cause mortality.¹¹⁻¹⁵

Previous research and reviews of the cost-effectiveness literature on CR found the program to be highly cost-effective.¹⁶⁻¹⁹ However, the randomized trials and associated cost-effectiveness studies included very few older persons, women, members of racial/ethnic minorities, or high-risk patients (e.g., patients with congestive heart failure). Hence, their results may not accurately reflect effects in older or more socio-demographically diverse populations. We recently analyzed one-year to five-year mortality in 601,099 Medicare beneficiaries who were hospitalized in 1997 for coronary disease or a revascularization procedure using three statistical techniques. All three techniques (propensity-based matching, regression modeling, and instrumental variables) showed significantly lower one- to five-year mortality rates in CR-users than non-user, ranging from 21% to 34% ($p < 0.001$ for each technique). Mortality reductions extended to all demographic and clinical subgroups including patients with acute myocardial infarctions, those receiving revascularization procedures, and patients with congestive heart failure.²⁰ The present study uses a portion of this Medicare data set with the matched-pair analysis to address the cost-effectiveness of cardiac rehabilitation in the elderly.

METHODS

Framework

We used the framework recommended by the US Public Health Service for cost-effectiveness analyses in health.²¹ To calculate the cost-effectiveness ratio, we estimated the net impact on lifetime health costs as the numerator and the net impact on lifetime on quality adjusted life years (QALYs)²² as the denominator. While the five years of Medicare claims provide the primary data source, we used the literature for parameters not available in these data and modeling to extend beyond the observational period. A sensitivity analysis examined the cost per discounted life year gained without quality adjustment. We performed the analysis from the perspective of the Medicare program where coverage has been an ongoing policy concern.⁹ We discounted costs and QALYs at the recommended rate of 3% per year and conducted all analyses using constant (2007) prices. We adjusted for price changes using the Medical Care component of the Consumer Price Index.²³ Since CR improves both survival and quality of life, the analysis required that we take a lifetime perspective, extrapolating costs and impacts beyond the 5-year period of observation.

Initial Study Cohort for Medicare Data

We included all Medicare beneficiaries age 65 or older who were hospitalized in calendar year 1997 in non-federal, acute care hospitals in the 50 U.S. states or the District of Columbia for coronary diagnoses or procedures paid by Medicare, the almost-universal health insurance for older and disabled Americans. The principal diagnosis codes used to identify beneficiaries were 410.xx for AMI, 411.xx for other acute coronary syndromes, 413.xx for stable coronary syndrome,

and 414.xx for other chronic ischemic heart disease conditions (414.xx). Procedure codes included 36.1 for coronary artery bypass graft surgery (CABG) and 36.01, 36.02, 36.05, or 36.06 for percutaneous coronary intervention (PCI)—angioplasty or stent. Other inclusion criteria were: a hospital stay of 30 days or less (to identify probable candidates for CR); being alive for at least 30 days after hospital discharge; and uninterrupted enrollment in fee-for-service (FFS) Medicare Part A and Part B during the index hospitalization and for at least 12 months after discharge (in order to obtain complete billing information). The study cohort consisted of the 601,099 Medicare beneficiaries who met the inclusion criteria.

Cohorts of Beneficiaries

Medicare's National Claims History File was the primary data source. Use of CR services was defined by Medicare reimbursement for at least one CR session (denoted by Current Procedure Terminology codes 93797 and 93798) within one year following discharge.

We created two primary cohorts of Medicare beneficiaries for the cost-effectiveness analysis: the matched pairs of CR-users and non-users. The non-users were identified through propensity-based matching, which paired CR-users with non-users using all observable risk factors.²⁴⁻²⁶ Using the entire study cohort, we fit a multiple logistic regression model of CR use as a function of explanatory variables assembled from multiple sources. Medicare's master enrollment database included information on date of birth, sex, race, date of death (where applicable), residence zip code, enrollment status over time, Medicare entitlements (Part A and Part B), and group health plan membership. Census 2000 data were linked to residence zip code statistics as proxies for the patient's socio-economic, educational, and disability statuses. American Hospital Association and Medicare data were used to determine hospital characteristics for index admissions.²⁰ To check the closeness of our matches, we calculated standardized differences, defined as the difference between means divided by the pooled standard deviation of the two groups, and checked to see whether they exceeded 10%.²⁷

In addition, to understand the effect of selection factors on cost, we created a "random" cohort consisting of a random sample of 70,056 beneficiaries from the original cohort 601,044 beneficiaries. The random cohort reflected the overall rate of CR use (12.3%), so most members were non-users, but it contained pro-rata share of CR users and overlapped, in part with the CR-user and non-user cohorts.

Cost Analysis during the Observation Period

We assessed fee-for-service payments by the Medicare program over the 5-year follow up period. Thus, costs were amounts paid by Medicare for services rendered beginning the day after the patient's index hospitalization and ending 5 years after discharge or when the patient

died, which ever came first. All patients were in fee-for-service Medicare on entry. We examined five types of Medicare claims: those for primarily ambulatory services (physicians' services and hospital outpatient services) and those primarily for institutional services (hospital services, skilled nursing services, and home health services). We treated the latter as institutional since eligibility for home health care is often linked to discharge from a hospital or skilled nursing facility. We excluded durable medical equipment as the costs were relatively minor and we did not anticipate any major impact from CR. We also classified claims by their principal diagnosis as cardiovascular or non-cardiovascular, where cardiovascular entailed falling within aggregated condition categories numbers 16 (heart), 17 (cerebro-vascular), or 18 (vascular) used in the DxCG program for risk adjustment.²⁸

Effectiveness of CR during the Observation Period

The health outcomes of each cohort during the observation period was the estimated average number of QALYs lived within 5 years from discharge from the index hospitalization. These were derived by combining data on survival data and quality of life. Survival data for each of the five years were obtained from Medicare records, which maintain this item for managing Medicare eligibility, and quality of life was based on the literature.

Quality of Life Adjustment

Since members of all cohorts had been hospitalized for CHD prior to the start of the follow up period, they could all be considered having that condition. In addition, many had other morbidities as well. We rated their quality of life using data from the questions on health status using the Eurqol EQ-5D quality of life scale (QOL) applied to a representative sample of the US population, the Medical Expenditure Panel Survey.²⁹ A recent report indicated the quality of life of respondents by age. Among the 1,234 respondents with CHD, those aged 65-74 reported a mean (with 95% confidence interval) QOL of 0.756 (0.734 to 0.779) with corresponding values for those aged 75+ of 0.708 (0.688 to 0.728).²⁹ We weighted these two values based on the proportions of our cohort in each age category, getting an overall average of 0.739.

A number of studies have compared the effects of CR or exercise programs on quality of life compared to usual care. While some studies found benefits from CR, interpretation of the findings has been complicated by small sample sizes in some studies, varied outcome measures, specialized populations, or the presence of other interventions alongside CR.^{14, 30} The HF-Action study also found large improvements in quality of life among CR participants with heart failure, and small but significant improvements over usual care participants.³¹ For cost effectiveness studies, literature that converts the changes in quality of life to net changes in QALYs is the most pertinent. Because it used time-tradeoff estimates, the randomized trial by Yu et al. (2004) best

meets this need. That study found that the mean annual improvement in quality of life over 2 years was 0.0458 and the improvements were statistically significant ($p < .01$).³² As the analysis of survival showed that annual mortality reductions attenuated, but did not disappear, after the first two years of follow up, we applied a similar pattern to QOL improvements. We assumed that the annual quality of life improvement in years 3-5 and after year 5 were half of the values in years 1-2 (the period of observation in the QOL study). Thus, over the 5-year observation period for the survival study, the resulting gain in QOL per year alive is 0.032, and after this period it is 0.023.

Extrapolation of Cost beyond the Observation Period

To extrapolate cost, we first examined the time pattern of costs in the non-users and then determined the cost in CR-users. We hypothesized that two competing factors could affect the costs of non-users. In the early years, costs would be expected to fall over successive years as treatment related to the initial hospitalization and its complications was finally completed. Furthermore, the patients at highest risk (e.g. the very old and those with severe comorbidities, such as congestive heart failure) would be most likely to die, so that the survivors in successive years would be healthier. On the other hand, the entire cohort is aging and all its members experience the higher utilization of medical services that accompanies other ages. To operationalize this process, we found the lowest year of overall costs fit a linear function to cost per year alive from this year through the end of the observation period.

With a similar process, we examined the difference between the cost per year alive of the CR-users and non-users. Initially, the CR-users should have higher costs due to the costs of CR services themselves and associated other services. In subsequent years, the CR group should have lower costs due to the averted costs of disease. As the mortality differences between CR and non-CR tended to diminish with time, the cost difference between CR-users and non-users should also attenuate over time. We modeled this pattern with an exponential decay function.

Extrapolation of Mortality beyond the Observation Period

For each year of our 5-year observation period, we calculated the average survival as the average of the proportion of the initial cohort alive at the beginning and end of that year. We calculated the lifetime costs and life years for each group as the sum of the present value of costs (and life years) in the initial 5-year period plus the product of survival rate at the end of the 5-year period times the costs (and life years) beyond 5 years conditional on survival to the start of that period.

To evaluate the impact of CR mortality beyond the five year period, we compared the actual death rate for each demographic group in the random cohort in the fifth year of the follow up

against the expected number using the US standard life table.³³ Demographic groups were based on gender, race (white or non-white) and age (in 5-year categories). We derived a standardized mortality ratio reflecting the fact that our cohorts had all been hospitalized for coronary heart disease, which was approximately 1.7 in each demographic group. Using the standard life table, we found that an average person 6 years older had the same age-specific mortality as the random cohort in our study with coronary heart disease. For each demographic category (gender, race, and decades of age) then constructed survival curves and calculated discounted life expectancy. The overall discounted life expectancy was a weighted average of the numbers for each demographic category, where the weights were the proportions of the cohort in each category.

RESULTS

Overall Cohort Characteristics

Of the 601,099 Medicare beneficiaries who met the study's eligibility criteria, 12.2 % (73,049 beneficiaries) received one or more CR outpatient sessions, and CR-users received a mean of 24 sessions (SD 12). CR-users were more likely to be male, white, younger, not on Medicaid (a health program for individuals and families with low incomes and resources), and to have been admitted for an AMI, CABG or PCI procedure than non-users. They also had fewer comorbid conditions, were less likely to have had prior admissions for AMI or CHD, co-existing CHF, peripheral vascular or cerebrovascular diseases, musculoskeletal conditions, chronic pulmonary disease, or diabetes.

While CR-users and non-users differed considerably on clinical and location-of-care measures, matched cohorts were well-balanced on all observable characteristics. Successful matches were obtained for 70,040 CR-users with a like number of non-users. The large size of this cohort did not require trying to match more than one non-user to each user. As almost all standardized differences were below the 10% threshold,²⁰ we considered the matching process a very good fit.

In the matched-pair analysis, CR-users were less likely to have died at each time point. Cumulative mortality rates were 2.2% in CR-users vs. 5.3% in non-users at one year and 16.3% vs. 24.6% at five years. These mortality reductions represented relative reductions of 58% at one year and 34% at five years and were statistically significant ($p < 0.001$). Table 1 translates the mortality reductions into person years alive at the midpoint of each year in the follow up period. The sums for years 1 through 5 show the gains in life expectancy during the observation period (0.265 years undiscounted and 0.242 years discounted).

Costs during the Observation Period

Figure 1 shows the total expenditure on Medicare services per person alive by year. This graph shows that expenditures during the index hospitalization (of about one week) were generally similar in both groups. While the matching did not explicitly match on this variable, the other factors resulted in cohorts with similar hospitalizations. In year 1, both groups had substantial costs due, in part, to the ongoing care related to their coronary hospitalization, including transfers to other hospitals and facilities. For example, in some cases the patient was transferred from a smaller to a larger hospital. In that case, the care in the larger hospital was part of the year 1 expense.

Figure 2 reports the portion of these expenditures for ambulatory care by year. It shows, as expected, that ambulatory expenditures during the index hospitalization were minimal; the amounts shown were likely tests and procedures billed by the hospital as hospital outpatient services. During year 1, the CR patients received more ambulatory services. These were likely the CR services themselves, associated testing (such as stress tests), and other ambulatory care. The average CR patient in this cohort received 24 sessions³⁴ and the Medicare reimbursement per session typically ranges from \$14 to \$35.³⁵ In the subsequent years, the differences in cost per beneficiary alive were small in relation to the absolute cost per year.

Figure 3 reports the portion of these expenditures for institutional care by year. The similarity in institutional costs during the index period the close agreement of the two cohorts prior to CR. During year 1, the CR cohort experienced greater costs, perhaps because that group was significantly more likely to have been transferred to another acute care hospital (odds ratio 1.71 with 95% confidence interval 1.64 to 1.79).³⁴ In the subsequent years, however, the CR-users had lower institutional costs.

To clarify the differences between the two primary cohorts, Figure 4 shows the differences by setting and year. It shows that during year 1, CR users had more ambulatory and institutional care. In year 2, CR users were slightly lower on ambulatory care, but higher on ambulatory care in all subsequent years. Institutional costs were lower in each of the subsequent years. These findings suggest that the investment in CR resulted in somewhat lower total costs per year alive from year 2 onwards.

Outcome and Cost Projections

Our comparison of mortality found that members of the random cohort had mortality rates of 1.7 times those of unselected members of the US population of the same age. This was equivalent to the mortality experience of unselected persons 6 years older. On average, members of our

matched cohort were about 73.7 years old at the start of follow up and, assuming mortality was uniform, would be 78.7 years old at the end. Without discounting, the life expectancy of our cohort at the end of our observation period would have been 9.00 years. With the 6 years of accelerated aging, however, the life expectancy is reduced to 6.22 years. Thus, we sought to make projections for 6 years. When discounted to the start of the projection period, however, this additional life expectancy is reduced to 5.41 years, and when discounted to the start of the observation period (the starting point for all economic analyses), the discounted life years per additional survivor at 5 years becomes 4.60 years.

To project future costs, we found that total costs of non-users (in constant prices per year alive) began to rise in year 4 and increased by \$136 from year 4 to year 5. As cost-effectiveness analyses seek to use the best estimate for each parameter, we assumed that due to aging, costs would continue to rise at this rate and projected future costs with a linear projection, as shown in Figure 5. In Figure 6, we project the future annual savings in costs between the CR-users and non-users. In the last year of the observational period, these were \$277, but the declining amounts indicate they will be only \$20 in year 11 (the sixth projection year).

Table 2 shows the impact of CR on lifetime costs and discounted life years. Even though the beneficiaries in this study were older, the lifetime perspective adds to projected costs and outcomes. The projected costs (\$4,009) and projected life years (0.38) represent 54% and 61% of the lifetime totals, respectively. Table 3 shows the weighting factors and associated gains in QALYs. Overall, each participant gained 0.32 QALYs over the observation period and 0.69 QALYs over his lifetime. About two thirds of the lifetime gain was the result of mortality reductions, and one third the result of improved QOL.

Table 4 shows the results of cost-effectiveness analysis. From the main (lifetime) perspective, the cost-effectiveness of cardiac rehabilitation is \$11,883 per life year gained and \$10,771 per QALY gained. The lower the cost-effectiveness ratio, the more cost-effective is the intervention. The lower panel in Table 3 shows the cost-effectiveness ratio derived from the observation period only. It is interesting that the cost-effectiveness ratio for this period was relatively similar -- \$14,064 per life year gained and \$10,721 per QALY gained.

DISCUSSION

This matched pair analysis found that the cost-effectiveness analysis of CR was \$10,721 per QALY gained. The results of a previous analysis, when adjusted for inflation, were also favorable (\$6,000 per life year).¹⁶ That study did not include quality adjustment nor count the costs of

general medical care in the additional years of life, resulting in a somewhat more favorable estimate than the present study.

In a 1999 health policy analysis for another branch of the US Department of Health and Human Services, a threshold of \$100,000 per QALY was suggested.³⁶ In a global context, the World Health Organization considers cost-effectiveness ratios that are less than three times the country's per capita GDP to be highly cost-effective. For the United States in 2007, this threshold would be \$145,000. Thus, CR is more favorable by almost a factor of ten. It is also more cost-effective than a recent high tech procedure, the implantable cardiac defibrillator, coming into routine care for certain heart conditions.

In analyzing the impact of CR on survival, an alternative statistical technique that seeks to correct for unmeasured variables (instrumental variables), found somewhat lower, though still statistically significant, benefits from CR. Compared to the 34% reduction in 5-year mortality using the matched pair analysis, the reduction was 21% using instrumental variables. Thus, this more conservative approach found benefits only 62% as large. If the lifetime costs were the same as those that we estimated but the benefits were only 62% as great, the cost-effectiveness would become about \$26,000 per QALY. This is still a highly favorable value.

Based on the effectiveness and cost-effectiveness of CR, policy makers and payers may wish to examine and seek to overcome the barriers against more widespread use. System level factors, including low reimbursement and attitudes of physicians, are among the barriers.³⁷ For patients without a documented contra-indication, subsequent use of CR among hospitalized patients with target conditions should be routine. We feel that utilization may be a better indicator about CR than referral in view of the large gap between these two indicators. For example, a Boston study reported a 55% referral rate but only 19% utilization among CR candidates.³⁸ Both public and private payers may wish to undertake public reporting of utilization rates with risk adjustment among the patients they insure, and possible incentives for high ratings, are among the options that deserve consideration.

Several limitations in this study need to be examined. There were no data from medical records on patient severity, no data on medication use or expenditures, and the matching was limited to factors available in the claims. Thus, levels of adherence, and levels of risk factors such as smoking and lipids, were not available and could have differed between the CR-users and non-users. The instrumental variable approach, which endeavors to correct for such unmeasured factors, however, also found highly significant benefits and cost-effectiveness from CR. Additionally, the patients had their qualifying event in 1997, so the data are over a decade old.

On the other hand, apart from broadening of eligibility criteria in 2006, practitioners report relatively little change in the delivery of CR since these data were collected.

Also, we did not have medication costs which could have varied between groups. Another limitation is that several of the measures are modeled, such as the extrapolation of mortality and cost beyond the observation period, or based on literature, such as quality of life.

Strengths of the study are the fact it is derived from the most comprehensive analysis published to date on CR in the elderly. It is based on an unselected cohort so that it reflects national practice. Furthermore, it uses actual Medicare payments, rather than hypothetical patterns, for the cost analysis. The study found generally consistent patterns across the various statistical techniques used in estimating benefits. Furthermore, the inclusion of quality adjustment and extrapolation beyond the observation period had offsetting effects, so the cost per life year gained and results for five years only were similar to the lifetime cost per QALY.

ACKNOWLEDGMENTS

Drs. Suaya, Stason, and Shepard had full access to the data analyzed and take complete responsibility for the integrity of the data and the accuracy of the data analysis. The authors thank Armen Thoumaian, PhD (CMS), Kathleen Connors deLaguna, RN (CMS), Roxanne Rodgers, RN (Delmarva Foundation for Medical Care), and Sidney Triegeer (CMS) for support as Project Officers and managers; Grant Ritter, PhD (Brandeis University) for statistical assistance; Celia Hsu Dahlman, MA (CHD Research Associates) for preparing the Medicare data files; and Clare L. Hurley, MM (Brandeis University) and Chrisann Newransky, MA (Boston College) for their contributions to the style and organization of the article.

REFERENCES

1. Gaziano TA, Reddy KS, Paccaud F, Horton S, Chaturvedi V. Cardiovascular disease. In: Jamison D, et al., eds. *Disease Control Priorities in Developing Countries* (2nd Edition). New York: Oxford University Press; 2006:645-62. Web: <http://www.dcp2.org/pubs/DCP/33>.
2. Thom T, Haase N, Rosamond W, et al. Heart disease and stroke statistics—2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation* 2006;113:85-151.
3. Arias E, Anderson R, Kung H, Murphy S, Kochanek M. Deaths: final data for 2001. *National Vital Statistics Reports*. National Center for Health Statistics, Centers for Disease Control and Prevention 1999;52(3).
4. Cardiovascular disease cost. American Heart Association, 2009. Accessed Feb. 1, 2009, at Web: <http://www.americanheart.org/presenter.jhtml?identifier=4475>.
5. Wenger N, Froelicher E, Smith L, et al. Cardiac rehabilitation as secondary prevention. *Clinical practice guideline, No. 17*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research and National Heart, Lung, and Blood Institute; 1995 October. Report No.: AHCPR Pub. No. 96-0673.
6. Thompson P, Buchner D, Pina I, et al. Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease: a statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity). *American Heart Association. Circulation* 2003;107(24):3109-16.
7. Leon A, Franklin B, Costa F, et al. Cardiac rehabilitation and secondary prevention of coronary heart disease: an American Heart Association scientific statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity), in collaboration with the American Association of Cardiovascular and Pulmonary Rehabilitation. *Circulation* 2005;111(3):369-76.
8. Smith S, Jr., Allen J, Blair S, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update: endorsed by the National Heart, Lung, and Blood Institute. *Circulation* 2006;113(19):2363-72.
9. Centers for Medicare and Medicaid Services (CMS). Cardiac rehabilitation programs. In: *Medicare National Coverage Determinations Manual, revision 98, chapter 1, part 1, section 20.10*. Accessed Feb. 1, 2009, at Web: http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf. 2008.
10. Ades P. Cardiac rehabilitation and secondary prevention of coronary heart disease. *N Engl J Med* 2001;345(12):892-902.

11. Oldridge N, Guyatt G, Fischer M. Cardiac rehabilitation after myocardial infarction. Combined experience of randomized clinical trials. *JAMA* 1988;260(7):945-50.
12. O'Connor G, Buring J, Yusuf S, Goldhaber S, Olmstead E, Paffenbarger R. An overview of randomized trials of rehabilitation with exercise after myocardial infarction. *Circulation* 1989;80(2):234-44.
13. Jolliffe J, Rees K, Taylor R, Thompson D, Oldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease (Cochrane Review). *Cochrane Database Syst Rev* 2001;1(CD001800).
14. Taylor R, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis of randomized controlled trials. *Am J Med* 2004;116(10):682-92.
15. Clark A, Hartling L, Vandermeer B, McAlister F. Meta-analysis: secondary prevention programs for patients with coronary artery disease. *Annals of Internal Medicine* 2005;143:659-72.
16. Lee A, Strickler G, Shepard D. The economics of cardiac rehabilitation: a review of literature. *J Cardiopulm Rehabil* 2007;27(3):135-42.
17. Levin L, Perk J, Hedback B. Cardiac rehabilitation--a cost analysis. *J Intern Med* 1991;230(5):427-34.
18. Bondestam E, Breikss A, Hartford M. Effects of early rehabilitation on consumption of medical care during the first year after acute myocardial infarction in patients greater than or equal to 65 years of age. *The American Journal of Cardiology* 1995;75:767-71.
19. Ades P, Pashkow F, Nestor J. Cost-effectiveness of cardiac rehabilitation after myocardial infarction. *J Cardiopulm Rehabil* 1997;17(4):222-31.
20. Suaya JA, Stason WB, Ades PA, Norman S-L, Shepard DS. Cardiac rehabilitation and survival in older coronary patients. *Journal of the American College of Cardiology* 2009;In press.
21. Gold MR, Siegel JE, Russess LB, Weinstein MC, eds. *Cost-effectiveness in health and medicine*. New York: Oxford University Press; 1996.
22. Zeckhauser RJ, Shepard DS. Where now for saving lives. *Law and Contemporary Problems* 1976;40(4):5-44.
23. Medical care services, U.S. city average, not seasonally adjusted (series CUUR0000SAM2). Bureau of Labor Statistics. Web: <http://data.bls.gov/PDQ/servlet/SurveyOutputServlet>, 2008. (Accessed Sept. 10, 2008, 2008, at
24. Newhouse J, McClellan M. Econometrics in outcomes research: The use of instrumental variables. *Annu Rev Public Health* 1998;19:17-34.
25. McConnell KJ, Newgard CD, Mullins RJ, Arthur M, Hedges JR. Mortality benefit of transfer to level I versus level II trauma centers for head-injured patients. *Health Services Research* 2005;40(2):435-58.

26. Stukel TA, Fisher ES, Wennberg DE, Alter DA, Gottlieb DJ, Vermeulen MJ. Analysis of observational studies in the presence of treatment selection bias: effects of invasive cardiac management on AMI survival using propensity score and instrumental variable methods. *JAMA* 2007;297(3):278-85.
27. Mamdani M, Sykora K L, Normand S, et al. Reader's guide to critical appraisal of cohort studies: 2. Assessing potential for confounding. *BMJ* 2005;330(7497):960-2.
28. DXCG. DxCG risk adjustment software. Analytic Guide Release 6.0. Boston: DxCG, Inc.; 2001.
29. Nyman JA, Barleen NA, Dowd BE, Russell DW, Coons SJ, Sullivan PW. Quality-of-life weights for the US population. *Medical Care* 2007;45(7):618-28.
30. Oldridge N, Guyatt G, Jones N, et al. Effects of quality of life with comprehensive rehabilitation after acute myocardial infarction. *The American Journal of Cardiology* 1991;67:1084-9.
31. O'Riordan M. AHA 2008: HF-ACTION: Early and Sustained Quality-of-Life Improvements With Structured Exercise Program. *Medscape* Accessed Feb 2, 2009 at: Web: <http://www.medscape.com/viewarticle/583464>. 2008 Nov. 12.
32. Yu CM, Lau CP, Chau J, et al. A short course of cardiac rehabilitation program is highly cost effective in improving long-term quality of life in patients with recent myocardial infarction or percutaneous coronary intervention. *Arch Phys Med Rehabil* 2004;85(12):1915-22.
33. Life table for the United States, 2000. U.S. Department of Health and Human Services,, 2003. (Accessed 2006, at Web: http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_14.pdf
34. Suaya JA, Shepard DS, Normand ST, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. *Circulation* 2007;116(15):1653-62.
35. Lee AJ, Shepard DS. Costs of cardiac rehabilitation and enhanced lifestyle modification programs. *Journal of Cardiopulmonary Rehabilitation and Prevention* 2009;In press.
36. Food and Drug Administration. Food labeling: Trans Fatty Acids in Nutrition labeling, Nutrient Content Claims and Health Claims; Proposed Rule. *Federal Register* Web: <http://vmcfsanfdagov/~lrd/fr991117html> 1999;64(221):62,772.
37. Gurewich D, Prottas J, Bhalotra SM, Suaya J, Shepard DS. System level factors and use of cardiac rehabilitation. *Journal of Cardiopulmonary Rehabilitation and Prevention* 2008;28.(6):280-5
38. Mazzini M, Stevens G, Whalen D, Ozonoff A, Balady G. Effect of an American Heart Association Get With the Guidelines program-based clinical pathway on referral and enrollment into cardiac rehabilitation after acute myocardial infarction. *American Journal of Cardiology* 2008;101(8):1084-7.

Table 1. Impact of CR on mortality (matched pair analysis)

Year	<u>Undiscounted PY</u>			Years ahead	Discount factor	<u>Discounted PY</u>		
	Non-user	CR-user	Gain			Non-user	CR-user	Gain
Index	1.000	1.000						
1	0.973	0.991	0.018	0.5	0.985	0.959	0.976	0.017
2	0.922	0.963	0.041	1.5	0.957	0.882	0.921	0.040
3	0.874	0.931	0.057	2.5	0.929	0.812	0.865	0.053
4	0.826	0.895	0.069	3.5	0.902	0.744	0.807	0.063
5	0.776	0.855	0.080	4.5	0.875	0.679	0.749	0.070
Sum	4.370	4.635	0.265			4.076	4.318	0.242

Notation: CR denotes cardiac rehabilitation; PY denotes person years per person in the original cohort

Table 2. Effects of cardiac rehabilitation (CR) on costs and discounted life years

Time Period	Group		Net change	
	CR users	Non users	Absolute	Relative
	Lifetime costs			
Observed (years 1-5)	\$64,130	\$60,725	\$3,405	6%
Projected (after year 5)	\$43,579	\$39,570	\$4,009	10%
Total	\$107,709	\$100,295	\$7,414	7%
	Lifetime discounted life years			
Observed (years 1-5)	4.32	4.08	0.24	6%
Projected (after year 5)	3.85	3.47	0.38	11%
Total	8.17	7.54	0.62	8%

Table 3. QALYs gained per participant from cardiac rehabilitation

	<u>Source of improvement</u>		
	<u>QOL</u>	<u>Mortality</u>	<u>Total</u>
<u>Weighting factors per year of life</u>			
Years 1-5	0.032	0.740	n.a.
Projected (after year 5)	0.023	0.740	n.a.
<u>QALYs gained per participant over interval</u>			
Years 1-5	0.14	0.18	0.32
Projected (after year 5)	0.09	0.28	0.37
Total (lifetime)	0.23	0.46	0.69
%	33%	67%	100%

Notation: QALY denotes quality-adjusted life years; QOL denotes quality of life

Table 4. Cost-effectiveness of cardiac rehabilitation

Indicator	Effectiveness measure	
	Life Years	QALYs
<u>Lifetime perspective</u>		
Incremental cost	\$7,414	\$7,414
Incremental effectiveness	0.62	0.69
Cost-effectiveness	\$11,883	\$10,771
<u>Perspective of observational period only</u>		
Incremental cost	\$3,405	\$3,405
Incremental effectiveness	0.24	0.32
Cost-effectiveness	\$14,064	\$10,721

Notation: QALY denotes quality-adjusted life years

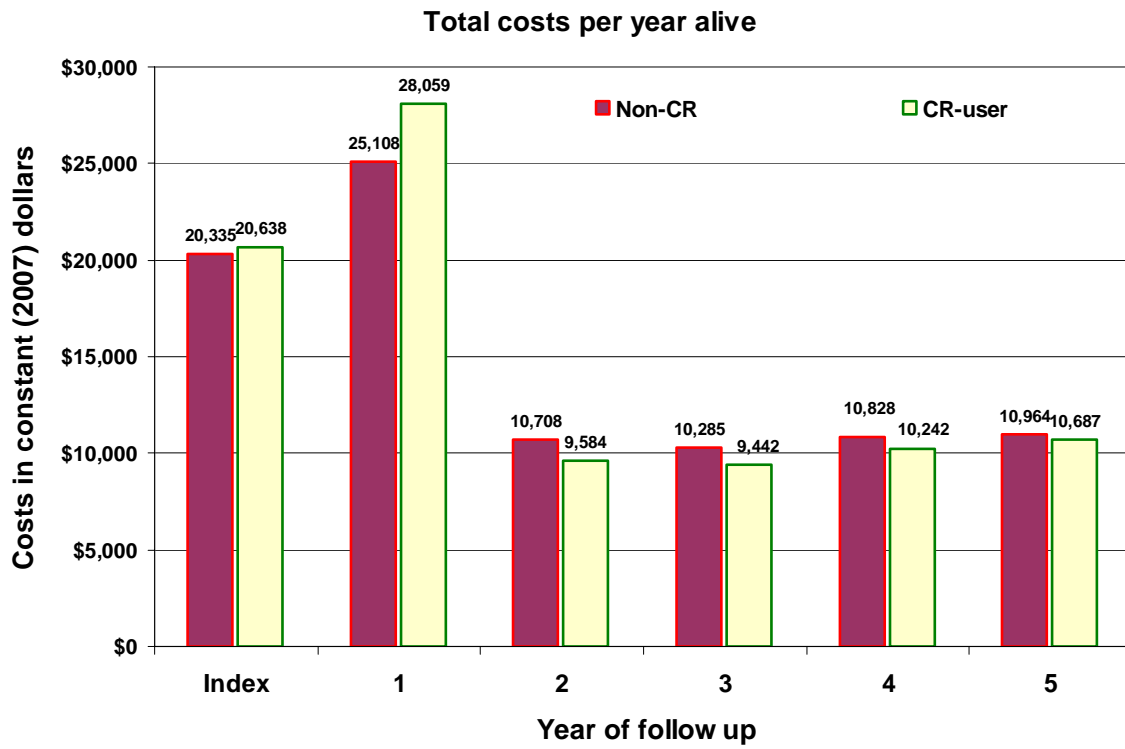


Figure 1. Total Medicare costs per year alive

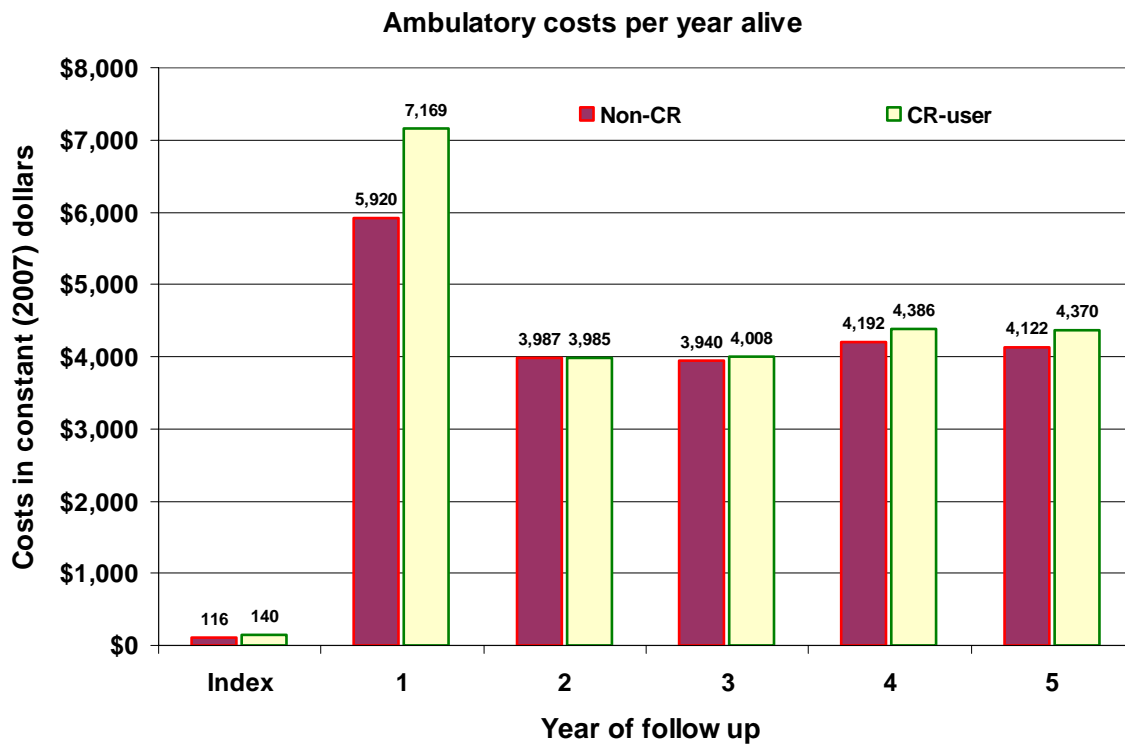


Figure 2. Ambulatory Medicare costs per year alive.

Note: The index period does not include physician claims as these data were not available.

Notation: CR denotes cardiac rehabilitation

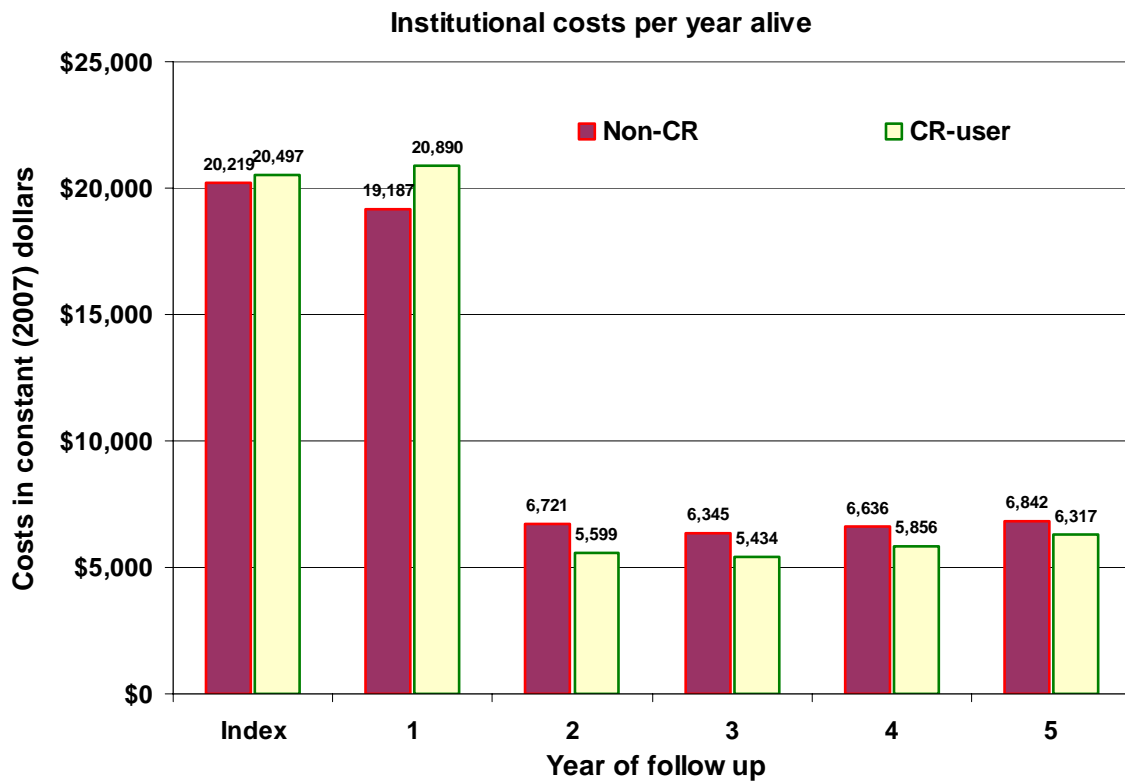


Figure 3. Institutional Medicare costs per year alive

Notation: CR denotes cardiac rehabilitation

Net costs by setting of CR-users per year alive compared to matched non-CR users

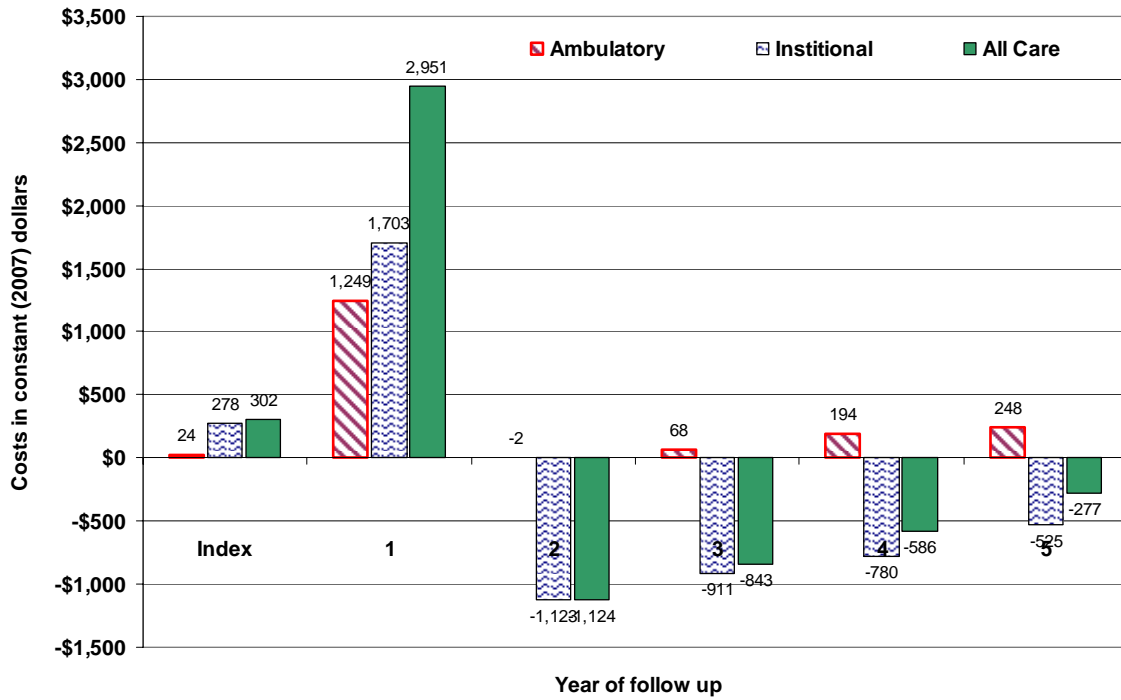


Figure 4. Net costs of cardiac rehabilitation (CR)-users compared to non-users per year alive

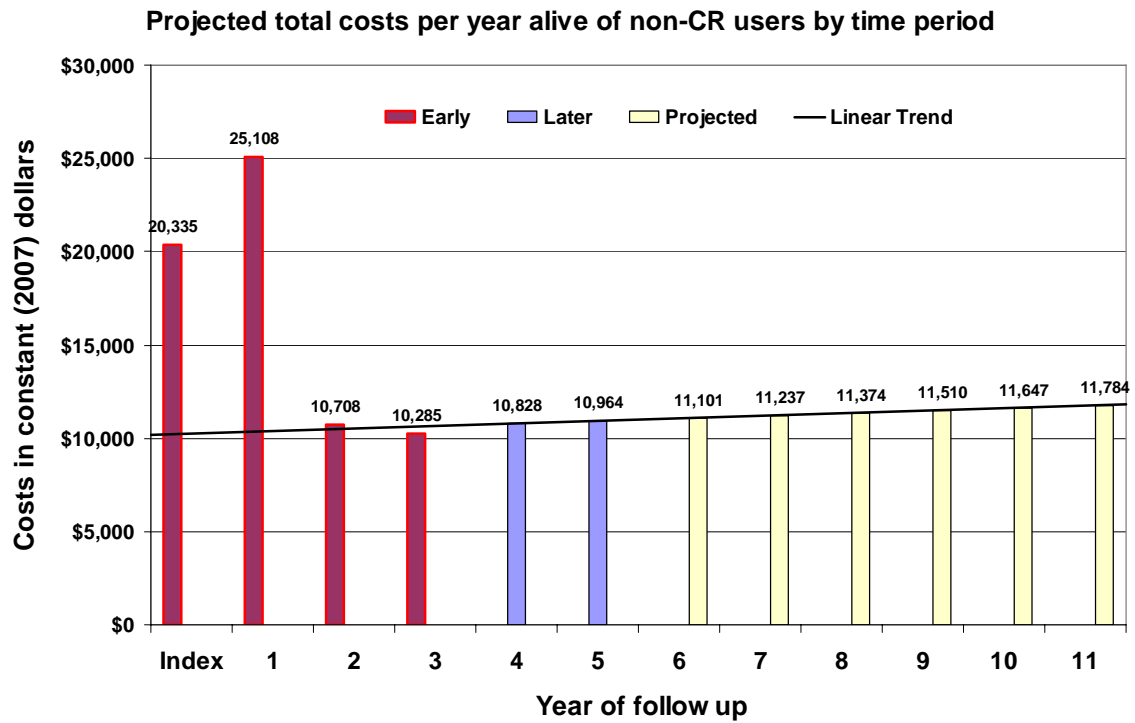


Figure 5. Projected total cost of non-users over their remaining life expectancy

Notation: CR denotes cardiac rehabilitation

Projected net costs per year alive of CR users compared to matched non-CR users by time period

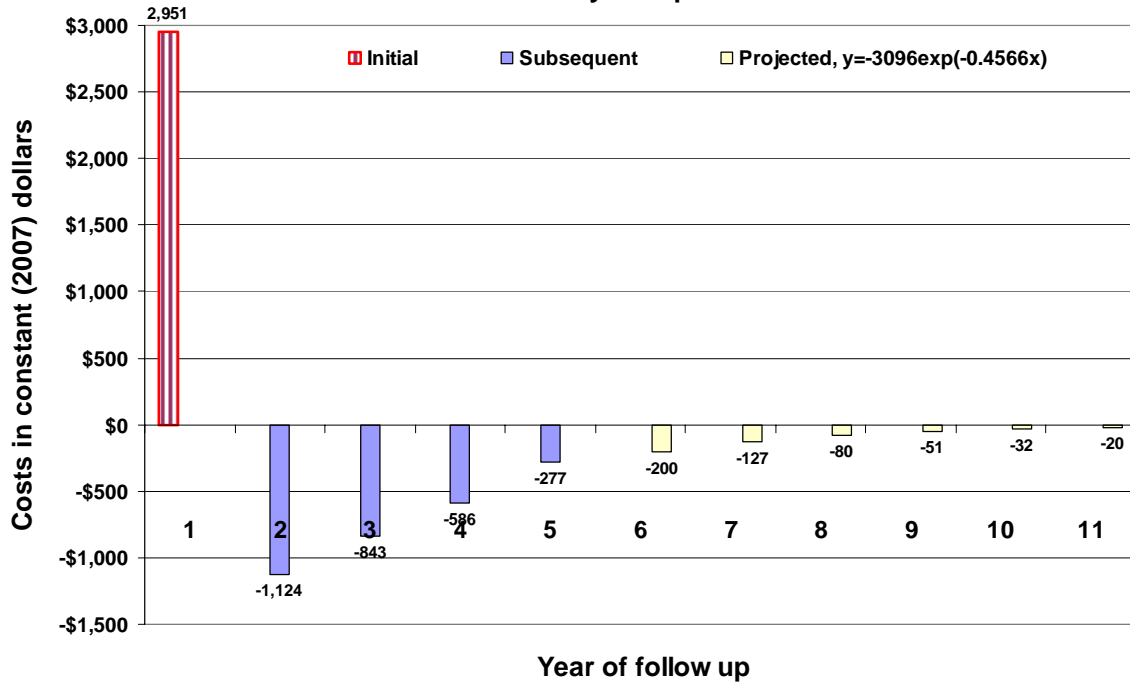


Figure 6. Projected net costs per year alive of CR users compared to matched non-users by time period.

Notation: CR denotes cardiac rehabilitation