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The Avera Medicare Coordinated Care Demonstration Program After One Year

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EXECUTIVE SUMMARY

The Medicare Coordinated Care Demonstration, mandated by the Balanced Budget Act of 1997, is testing a range of models aimed at improving the care of chronically ill beneficiaries with Medicare fee-for-service coverage. Fifteen programs are participating in the demonstration sponsored by the Centers for Medicare & Medicaid Services (CMS). Mathematica Policy Research, Inc. (MPR) is evaluating the demonstration using both implementation analysis and impact analysis based on a randomized design. This report is one of a series that will describe each program during its first year and will provide estimates of its impact on Medicare service use and costs during the first six months of program operation.

Research over the past decade suggests that successful care coordination usually has several features. These include effective patient identification, highly qualified staff, physician buy-in, and financial incentives aligned with program goals. Successful programs also offer a well-designed, structured intervention that includes:

- A multifaceted assessment whose end product is a ***written care plan*** that can be used to monitor patient progress and that is updated as the patient's condition changes
- A process for providing ***feedback to care coordinators, program leaders, and physicians*** about patient outcomes
- ***Patient education*** that combines the provision of factual information with techniques to help patients change self-care behavior
- Procedures for integrating ***fragmented care***, facilitating ***communication*** among providers, and, when necessary, arranging for ***community services***

The ultimate purpose of this report series is to assess the extent to which demonstration programs have these features, as well as describe early enrollees in the program and their Medicare service use and costs during the first few months after enrollment. Information for the report comes from telephone and in-person contacts with program staff, and analysis of Medicare and program-generated data. The next report series will focus on Medicare service use and costs over a longer time and will include all first-year enrollees.

This report describes Avera Research Institute's Medicare Coordinated Care Demonstration program, called "Helping Hearts." After presenting an overview of Helping Hearts, the following four questions are addressed: Who enrolls in the program? To what extent does the program engage physicians? How well is the program implementing its approaches to improving patient health and reducing health care costs? What were enrollees' Medicare service use and costs during its first months of operation? Thereafter follows a discussion of the program's strengths and unique features, as well as potential barriers to program success.

Program Organization and Approaches. Avera Research Institute is a department within the Avera McKennan Hospital and University Health Center (AMH/UHC), a 429-bed regional medical facility located in Sioux Falls, South Dakota. Unlike many other demonstration programs, Avera Research Institute did not have a prototype program for Helping Hearts, although AMH/UHC operates a certified cardiac rehabilitation program and a short-term health management program for a working-age managed care population with cardiovascular disease and diabetes. The medical director is located on the AMH/UHC main medical campus in Sioux Falls. The program director, care coordinator care, coordination supervisor, and research associates are based in a separate office nearby. The care coordination supervisor is responsible for day-to-day operations, and the research associates are responsible for enrolling patients, data management, and home monitor setup and maintenance

Helping Hearts has adopted two main approaches to improving patient health and reducing health care costs: (1) improving patient adherence to treatment recommendations, and (2) improving communication and coordination among patients and physicians. The program aims to improve patients' ability to adhere to treatment recommendations and recognize and respond to seminal symptoms early on by providing each patient with a home monitoring device, the output of which is reviewed daily by a care coordinator. The program seeks to improve communication and coordination by teaching patients to manage their own care and to effectively communicate with their physicians.

Patient Identification. Helping Hearts began enrolling patients in June 2002. The program targets patients with CHF (or related diagnosis). Patients must have had a hospitalization either (1) with a primary diagnosis for a target condition in the year prior to May 1, 2002, or (2) with a primary or secondary diagnosis for a target condition after May 1, 2002. The patient must have mild to severe difficulty in performing daily living. Participants must also live in the Helping Hearts' service area, which includes 71 counties in Iowa, Minnesota, Nebraska, and South Dakota covering 48,000 square miles. The program identifies patients primarily through lists generated by hospitals and clinics based on DRG codes for heart failure. Physicians approve patient participation by filling out a referral form that contains a checklist of the program's eligibility criteria. A research associate telephones eligible patients, describes the program, and tells them that their physician recommended them for the program. The research associate sends those interested in participating a brochure describing Helping Hearts, an informed consent form, and a medical records release form. After the patient mails the forms to the program, the program reviews the patient's hospital medical record to verify the hospitalization diagnosis.

Assessment, Care Planning, and Monitoring. Each treatment group patient receives a comprehensive, in-home assessment that covers physical health, medical history, psychosocial status, availability of social support, financial resources, home safety, functional status, and medications. From the assessment, the care coordinator develops an individualized care plan for each patient in consultation with the patient's physician and his or her nursing staff, family or caregivers, and other Helping Hearts care coordinators.

Helping Hearts uses a home monitoring device in addition to having care coordinators regularly telephone patients. Patients transmit their vital signs (for example, weight and blood pressure) to the program each day. These values are electronically compared to parameters set by their physicians. If monitor readings are outside the parameters, the monitoring system flags

the result, and the care coordinator follows up to determine if the patient needs to seek medical care. The monitoring system produces trend reports that are fed back to the patient's physician at a frequency requested by the physician. Care coordinators also assess patient progress toward care plan goals and provide education by contacting patients by telephone on a weekly basis for the first six weeks, and twice a month thereafter.

Staffing and Management of Program Quality. Maintaining and improving care quality and ensuring that programs attain their goals both require that staff have adequate qualifications, training, and supervision and that management has the tools and support to monitor program progress toward its goals. Helping Hearts prefers their care coordinators to be baccalaureate-prepared registered nurses. After a year of operation, the program had four care coordinators, each with more than 10 years of nursing experience. Upon hire, each care coordinator completed an orientation that began with a skill self-assessment examination. The care coordination supervisor conducts the orientation and educates care coordinators on program-specific topics such as research standards, problem identification, assessment, home monitoring, interventions, patient education, outcome measurement, and documentation. After orientation, the care coordination supervisor provides individual and group training sessions on an as-needed basis, including updates on CHF-related medication and dietary information. She also periodically sends care coordinators to seminars on disease management and arranges for staff from Avera McKennan Hospital to provide training when needed. The care coordination supervisor directly observes care coordinator performance, randomly reviews case files on a weekly basis, and meets weekly with the care coordinators and research associates.

The program evaluates its approach to patient care during its weekly staff meetings, which include the program director, care coordination supervisor, care coordinators, and research associates. At these meetings, staff discuss their approach and sometimes suggest changes to improve the care of individual patients. The program director and medical director also meet on a weekly basis to discuss the program's processes and enrollment.

After a year of operation, the program was not generating formal reports to monitor the effectiveness of its intervention, although it was in the process of developing an Access database to collect and store information on its activities. Helping Hearts previously used commercial case management software to document care coordination activities and help care coordinators determine when to contact patients, but program staff found it inefficient. When completed, the program will be using the Access database to generate enrollment statistics and reports of patient contacts and selected patient outcomes (such as quality of life and CHF knowledge) for the purpose of monitoring the effectiveness of their intervention.

WHO ENROLLS IN THE PROGRAM?

As with many care coordination programs, enrollment has been lower than anticipated. After one year of operation, Helping Hearts had enrolled 157 patients in the demonstration treatment group and 161 in the control group, less than half of the program's original first-year target of 788 in total. The program attributes its enrollment shortfall to initial difficulties in identifying eligible patients and to a high patient refusal rate. Some patients were reluctant to join the program because they felt uncomfortable sharing personal information.

To gain another perspective on the proportion of eligible beneficiaries enrolling in the program and describe their characteristics, the evaluation simulated Avera's eligibility criteria using Medicare enrollment and claims data. (September 15, 2002, was used as a pseudo-enrollment date for nonparticipants; it is roughly the midpoint of the six-month enrollment period considered here.) The simulation showed that, during the program's first six months of operation, less than 2 percent of an estimated 6,022 eligible beneficiaries enrolled. The simulation could not, however, be restricted to those facilities that were the primary sources of referrals to Helping Hearts. Thus, the number of eligible nonparticipants who might truly have had access to the program is probably smaller.

Program participants differed from nonparticipants in terms of age and Medicaid eligibility (Table 1). Program participants were less likely than eligible nonparticipants to be age 85 or older (23 percent were versus 37 percent of nonparticipants). Participants were considerably less likely to be dually eligible for Medicaid and Medicare than nonparticipants: 7 percent were dual eligibles, compared with 20 percent of nonparticipants. Slightly fewer than half of both participants and nonparticipants were male, and fewer than 2 percent were not white.

Participants also appeared to have been in poorer health than eligible nonparticipants. Participants were more likely than nonparticipants to have been treated for CHF—the program's primary target diagnosis, as well as for coronary artery disease, chronic obstructive pulmonary disease, and diabetes in the two years before intake. About 94 percent of participants had a hospitalization in the year prior to enrolling; over this period, they had monthly Medicare expenditures of $1,499. By contrast, only 85 percent of nonparticipants had a hospitalization, and their monthly Medicare spending was lower ($1,376) than that of participants. The difference in spending was not statistically significant at the 10 percent level. In addition, one-third of participants were hospitalized in the month before intake, compared with 13 percent of nonparticipants.

When developing the cost estimate for the program's waiver application, MPR estimated that Medicare costs would average $1,479 per month for control group members during the demonstration period. It thus appears that the program has enrolled patients who have costs that are very similar to what was planned.

Anecdotal information collected by the care coordinators suggests that patients and their caregivers are satisfied with the Helping Hearts program. There was no voluntary disenrollment during the first six months of the program.

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

Helping Hearts aims to make physician practice more efficient by providing physicians with timely medical information from the patient's home monitoring device. The program expects that care coordinators will "assist, rather than interfere" with physicians' medical management of their patients. Program expectations for physicians, therefore, are limited to: (1) approving patient participation, (2) specifying home monitoring parameters and the frequency of trend reporting, (3) responding to care coordinators' telephone calls when abnormal home monitoring readings or adverse events occur, and (4) reviewing trend reports for home monitors that care coordinators send.

TABLE 1

CHARACTERISTICS OF HELPING HEARTS PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING FIRST SIX MONTHS OF PROGRAM INTAKE
(Percent, Except As Noted)

	Participants[a]	Eligible Nonparticipants[b]
Age		
Younger than 65[c]	0.0	0.0
65 to 84	77.5	63.0
85 or older	22.5	37.0
Male	45.1	41.2
Non-White	1.8	1.4
Medicaid Buy-In for Medicare A or B	7.2	19.6
Medical conditions treated in last two years		
Congestive heart failure	97.3	91.7
Coronary artery disease	78.2	66.4
Chronic obstructive pulmonary disease	66.4	52.1
Diabetes	46.4	33.3
Hospital admission in last year	93.7	85.1
Hospital admission in last month	32.7	12.7
Total Medicare reimbursement per month (dollars)	1,499	1,376
Number of beneficiaries	**111**	**5,505**

Source: Medicare Enrollment Database and National Claims History.

[a] Participants who do not meet CMS's Medicare requirements for the demonstration or who had invalid Health Insurance Claim (HIC) numbers on MPR's enrollment file are excluded from this table because Medicare service use data were not available for them. Participants who are members of the same household as a research sample member are included above, but are not part of the research sample.

[b] Only nonparticipants who met the eligibility criteria between May 2001 and September 2002 were included here.

[c] The Avera MCCD excludes beneficiaries younger than 65.

Most physicians with patients who are participating in Helping Hearts are not affiliated with AMH/UHC, but some are familiar with Avera Research Institute's staff. During the first year of operation, the majority of the 210 participating physicians were independent practitioners serving rural areas, among whom only about a third were employed by AMH/UHC. Helping Hearts has adopted two primary strategies to promote cooperation between physicians and care coordinators in addition to having its advisory council available to make presentations to physicians across the program's service area: (1) having care coordinators conduct introductory conferences with physicians, and (2) providing physicians with home monitoring trend reports and a stipend for reviewing them. Care coordinators meet with physicians in person when the program enrolls their first patient in order to explain the program's model of care coordination and describe the

program's expectations of them. After the introductory conference, Helping Hearts provides physicians with trend reports of home-monitoring results at a frequency requested by the physician, as well as before patient appointments. To encourage the physician to review the reports, the program pays physicians a monthly stipend of $30 per treatment group patient. Efforts to engage physicians appear to have succeeded within the program's limited expectations. Physicians have approved patients for participation in the program, and most physicians specify home monitoring parameters within a week of receiving the plan of care form. Program staff also report that physicians are generally responsive to care coordinators' phone calls.

Although changing clinical practice is not the primary focus of Helping Hearts, the program does seek to improve physicians' prescribing of heart failure medications by having a pharmacist from its multidisciplinary team review the medications of each treatment group patient when the patient enrolls. The program provides the review to support physician decision-making and acknowledges that physicians may have access to patient information that the care coordinator does not, which might contraindicate its recommendations. Although the program does not track whether physicians are making the recommended changes, anecdotally, staff report that a few physicians have changed their patients' treatment regimens in response to medication reviews. After a year of operation, staff reported that physicians were highly satisfied with the program and its ability to deliver timely data for patients who are difficult to manage. One physician endorsed the program in a Helping Hearts brochure distributed to physicians with potential study patients, saying that the program "has been very helpful in managing some of my sickest patients," and that it has made patients, "more inclined to follow their medicinal program."

HOW WELL IS THE PROGRAM IMPLEMENTING KEY INTERVENTION APPROACHES?

Improving Patient Adherence. Improving patient adherence to treatment recommendations is the primary approach Helping Hearts is taking to improve patient health. It supports this approach by teaching patients to better understand the disease process and to recognize and respond to seminal symptoms, and through the daily use of a home monitoring device. Helping Hearts follows a standard CHF curriculum developed by Avera, based on CMS, American Heart Assocation, and American College of Cardiology guidelines, supported by materials from a pharmaceutical company and community education resources that address psychosocial issues and co-morbidities. Home monitoring allows care coordinators to assess the effectiveness of their teaching, encourages patients to be more adherent to treatment, and provides opportunities for reinforcement of education concepts such as self-management. If a patient is not learning, the care coordinator will continue to reinforce educational concepts with the patient and may consult other program staff about alternative education strategies. Among the 57 patients enrolled in Helping Hearts during its first six months, 81 percent had received at least one contact for self-care or disease-specific education, and more than half (58 percent) had at least one contact during which the case manager explained medications.

Improving Communication and Coordination. The program also seeks to improve patients' health by teaching them to communicate more effectively with their physicians and to arrange for their own care. Care coordinators teach patients when to contact their physicians using the results of home monitoring. When abnormal readings occur, the care coordinator calls

the patient and asks him or her about their signs and symptoms. The care coordinator will teach the patient how to determine whether he or she needs to call their physician and will encourage the patient to do so, if appropriate. In order to motivate self-management, care coordinators usually do not intervene on behalf of their patients, but they will make doctor appointments for their patients when the patients are reluctant to do it themselves. Care coordinators also teach patients how to ask their physician questions, through role-playing or by helping patients make a list of questions to ask their doctor during the visit.

Care coordinators seek to make patient care more timely by regularly communicating pertinent, patient-specific information to patients' physicians primarily through trended home-monitoring reports. To improve coordination and ensure that care is in line with published CHF treatment guidelines, care coordinators also phone physicians to remind them that a patient is due for a test or preventive care, to follow up with them on abnormal monitoring results, or to report changes in patient health status or symptoms that need attention. Care coordinators occasionally suggest changes to medications when CHF guidelines recommend them.

Care coordinators also aim to improve coordination by tracking patients' adverse events (mostly hospitalizations) through home monitoring, and by working with hospital staff, physicians, patients, and their caregivers to prevent reoccurrences. When a patient does not record his or her vital signs or has an abnormal reading and cannot be reached by phone, the care coordinator calls the patient's designated emergency contact person. When a patient is hospitalized, the care coordinator contacts the patient in the hospital. The care coordinator talks to the patient's hospital nurse or case manager to make sure the patient gets the follow-up care he or she needs (for example, a particular test) upon discharge, calls the physician to report the adverse event and ask him or her if the patient's course of treatment will change, and works with the patient and his or her caregiver to determine why the event occurred and develops a plan to prevent other occurrences.

Increasing Access to Services. Although Helping Hearts refers patients to a wide variety of services (or, if necessary, arranges services on their behalf), increasing patients' access to services is not a major activity of the program. The services that staff reported that they have referred patients to or arranged for most frequently during its first year were transportation and home health care. In addition, Helping Hearts has access to Avera McKennan Hospital's community resource lists, which catalog all the resources and services that patients admitted to the hospital have been referred to across the program's entire service area. The cost of prescription medications has been a barrier to adherence for many patients, and Helping Hearts has tried to eliminate this barrier by assisting patients in finding medication assistance programs to apply for and guiding them through the process. The program does not pay for services or resources other than the home monitoring device, and refers patients who need help paying for care-related goods and services to Avera McKennan's Development Foundation, which assists patients with limited financial resources.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

We developed preliminary estimates of the effect of Helping Hearts on Medicare service use and costs, but caution that these estimates are not necessarily indicative of the true effects of the program over a longer period. On average, Medicare reimbursements were about $3,000 over

the first two months for both the treatment and control groups (or about $1,500 per month). About a fifth of each group had a hospitalization during that period. It is too soon to tell whether the intervention ultimately will result in reduced hospital service use and total costs and improved patient health.

CONCLUSION

Program Strengths and Unique Features. The Helping Hearts program appears to have many of the features associated with effective care coordination:

- The program targets patients hospitalized for CHF, a high-cost diagnosis, and, as a result, has ***enrolled patients with high health care costs*** in the year before enrolling. About a third of these patients were enrolled during the month after a hospital discharge—an especially vulnerable time.

- Care coordinators administer a ***comprehensive, in-person assessment*** and use it to develop individualized care plans. Care coordinators use the care plan to guide telephone monitoring contacts and patient progress toward goals.

- The program ***monitors patients' daily vital signs*** using a home monitoring device, as well as by regular telephone calls. When a patient's vital signs are outside monitoring parameters or the patient does not record his or her data, the care coordinator immediately contacts the patient, allowing the care coordinator to know right away about adverse events.

- The program's educational intervention focuses on teaching patients to be better self-managers and to communicate more effectively with their physicians. The ***disease-specific curriculum can be customized to individual patients' needs*** and is supplemented with materials that address lifestyle issues and co-morbidities.

- The program primarily facilitates communication and coordination among patients and their physicians by ***teaching patients to coordinate their own care***. Abnormal home-monitoring readings provide care coordinators an opportunity to teach patients when to contact their doctor, but also alerts them to adverse events. Care coordinators ***call the physician to update*** him or her when a patient's condition changes or an adverse event occurs, as well as ***sending home-monitoring trend reports*** regularly and before the patient's appointments.

- Helping Hearts' current care coordinators are ***baccalaureate-prepared registered nurses***, and all have extensive experience caring for and educating cardiac patients. Each care coordinator receives additional CHF patient education training during orientation.

- The program aims to support physicians' medical management of their patients, requiring only that physicians approve patient participation, ***specify home-monitoring parameters, review home-monitoring trend reports, and respond to care coordinators' patient-specific requests***. Staff report that physicians are satisfied with trend reporting and the services care coordinators provide their patients.

- The program seeks to ***improve physicians' prescribing of heart failure medications*** by performing a ***medication review*** for each treatment group patient when they enroll in the program. Staff report that a few physicians have changed their patients' treatment regimens in response to the medication review.

- Finally, while the program does not provide financial incentives to staff to achieve particular patient outcomes or program goals, it does ***reimburse physicians for reviewing the trend reports*** in the program by paying them $30 per month for each treatment group patient.

Potential Barriers to Program Success. Helping Hearts' primary challenge is to enroll enough patients to achieve some economies of scale and still be able to demonstrate effects on outcomes. The program fell short of its year-one enrollment target; as of this writing, it still has not met its target despite having made some changes to eligibility criteria. Initially, the program believed the shortfall resulted from a high number of patients being served by referring hospitals living outside the service area and the restrictiveness of requiring a primary diagnosis of CHF. However, tripling the number of counties in the program service area and taking beneficiaries with primary *or secondary* CHF diagnoses has helped only modestly. The program also noted a higher than anticipated patient refusal rate, both active and passive. Lack of data makes it difficult to determine the relative importance of these factors (or whether there is some other reason for the shortfall)—though not having physicians more actively involved in encouraging patients to enroll (either by sending beneficiaries letters signed by physicians, or having physicians introduce the program to them during visits) likely contributed to patient refusal rate.

A second potential barrier to Helping Hearts' success is the absence of a process to collect and generate reports on patient outcomes (for example, patient self-care, clinical indicators, and adverse events) to help program administrators determine whether the intervention is attaining its broad objectives, such as increasing patient adherence. Such reports would also indicate whether particular procedures are working better than others and might suggest approaches to improving performance. Reports of patient outcomes could also provide valuable feedback to care coordinators. Although the program's Access database appears to track at least some of these outcomes, such as physicians prescribing of ACE inhibitors and beta blockers, the system is not equipped to generate formal reports. This problem grows as program enrollment grows. As of early April 2004, the program had enrolled 271 treatment group members, more patients than a program can monitor effectively without a good reporting system.

INTRODUCTION

The Medicare Coordinated Care Demonstration, mandated by the Balanced Budget Act of 1997, is testing a range of models aimed at improving the care of chronically ill beneficiaries with Medicare fee-for-service coverage. Fifteen programs are participating in the demonstration sponsored by the Centers for Medicare & Medicaid Services (CMS). The programs—hosted by organizations as diverse as hospital systems, disease management providers, and retirement communities—are serving patients in 16 states and the District of Columbia. Mathematica Policy Research, Inc. (MPR) is evaluating the national demonstration through both impact and implementation analyses.[1]

This report is one of a series that will describe each program during its first year of implementation and provide preliminary estimates of its impact on Medicare service use and costs. First, it briefly describes the data and methodology used in this series of reports and presents an overview of the program that is the focus of this report. It then addresses the following questions: Who enrolls in the program? To what extent does the program engage physicians? How well is the program implementing its approaches to improving patient health and reducing health care costs? What were enrollees' Medicare service use and costs during its first months of operation? The report concludes with a discussion of the program's strengths and unique features, as well as potential barriers to program success.

This report describes Avera Research Institute's Medicare Coordinated Care Demonstration project, called "Helping Hearts."[2] Avera Research Institute is a department within the Avera

[1]The CMS Medicare Case Management Demonstration for Congestive Heart Failure and Diabetes Mellitus is also part of the MPR evaluation. Appendix Table A.1 lists all demonstration programs and locations.

[2]For a more detailed description of the Avera Research Institute demonstration's implementation plans and early experiences, see Aliotta et al. (2004).

McKennan Hospital and University Health Center, in Sioux Falls, South Dakota. The Helping Hearts program, which began enrollment in June 2002, enrolls Medicare beneficiaries with congestive heart failure (CHF).

DATA SOURCES AND METHODOLOGY

Implementation Analysis. The evaluation's implementation analysis uses information gathered during telephone interviews with program staff conducted approximately three months after the program began enrolling patients, as well as in-person interviews conducted about six months later. For each program, one of three MPR implementation team members conducted the telephone and in-person interviews using semi-structured protocols covering the following topics: organization and staffing; targeting and patient identification; program goals; care coordination activities (such as assessment, patient education, and service arranging); physician attitudes toward the program and program interventions with physicians; quality management; record keeping and reporting; and financial monitoring. Use of the protocols ensured that each interviewer collected as consistent a set of information for each program as possible, while allowing the interviewer to explore specific issues of importance to each program. The structure of the protocols will also make synthesizing findings across programs more efficient. MPR staff reviewed written materials each program provided, including the program's proposal to CMS, its operational protocol, materials it provided to patients and physicians, and the forms used in its operation. (Appendix Table A.2 contains a full list of documents reviewed for this report.) This analysis also includes an examination of data each program collected specifically for the evaluation, describing care coordinator contacts with patients, patient disenrollment, and any goods and services the program purchased for patients during its first six months of operation.

Participation Analysis. The evaluation uses Medicare claims and eligibility data to estimate the number of beneficiaries in Helping Hearts' service area who were eligible for the

program and the percentage who actually enrolled during the program's first six months of operations. Beneficiaries are identified as eligible if, for any month between June and December 2002, they (1) lived in the program's service area, (2) were enrolled in Medicare Parts A and B, (3) had Medicare as the primary payer, (4) were not in a Medicare managed care (Medicare + Choice) plan, and (5) met the program's target diagnosis and service use requirements (described in detail in Appendix B). The midpoint of the six-month enrollment period examined in this analysis—September 15, 2002—is used as a pseudo-enrollment date for nonparticipants; the actual enrollment date is used for participants. Participants and eligible nonparticipants were then compared with respect to demographic characteristics, diagnoses, and utilization histories to determine the extent to which participants are typical of the pool of eligible beneficiaries.

Impact Analysis. This report also presents early impact estimates based on key study outcomes. The evaluation's impact analysis is based on the random assignment of consenting, eligible Medicare beneficiaries to either receive the program intervention in addition to their regular Medicare benefits or to receive only their regular Medicare benefits as usual. Comparison of outcomes for the two groups will yield unbiased estimates of the impact of care coordination. Disenrollees are not excluded from the analysis sample because doing so would introduce unmeasured, preexisting differences between the treatment and control groups that random assignment is meant to avoid.

The report provides two types of comparisons of estimated treatment and control group means for Medicare-covered service use and costs. The first uses outcomes measured over the first two months after random assignment for beneficiaries who enrolled in the program during its first four months. The second compares treatment and control group means for each calendar month after program startup, using all sample members enrolled through the end of each month, to observe any trends in treatment-control differences over time.

In this report, the impact of the program's intervention is estimated as the simple difference in mean outcomes between treatment and control patients. T- and chi-squared tests are used to establish whether differences are statistically significant. The next round of site-specific reports will use regression to adjust for any chance baseline differences between the two groups that arose despite random assignment. (Appendix B describes in more detail the methods used to obtain Medicare data, construct variables, and choose analysis samples.)

The treatment-control comparisons presented in this report may not reflect the true long-term impacts of the program, for several reasons. First, the comparisons are based on a relatively small sample (only patients enrolling during the first four months of program operations). Second, the outcomes are measured too soon after patient enrollment to expect programs to be able to have sizable impacts. (The timetable for the evaluation's first Report to Congress defined the observation period for this report.) Third, program interventions may change over time as staff gain more experience with the specific patients they have enrolled. Finally, if programs change their eligibility criteria or the type of outreach they conduct, they may enroll different types of patients over time.

Despite these shortcomings, the treatment-control differences are presented to provide some limited feedback to the programs on how the two groups compare. Later analyses will examine Medicare service use and cost impacts over a longer time and will include all enrollees during the program's first 12 months. These analyses will also examine patient outcomes based on telephone interviews with treatment and control group members. Interview-based outcomes include the receipt of preventive health services, general health behaviors, self-management, functioning, health status, and satisfaction with care, as well as disease-specific behaviors and health care.

OVERVIEW OF HELPING HEARTS

Program Organization and Relationship to Physicians. The nonprofit Avera Research Institute is a department within Avera McKennan Hospital and University Health Center (AMH/UHC), a 429-bed regional medical facility in Sioux Falls, South Dakota. Avera Research Institute is responsible for conducting and coordinating research studies throughout the region on behalf of AMH/UHC. AMH/UHC, also a nonprofit organization, is the largest of four hospitals belonging to Avera Health, a rural health care delivery system based in Sioux Falls that operates more than 100 health care facilities in Iowa, Minnesota, Nebraska, North Dakota, and South Dakota. Avera Research Institute did not have a prototype program for Helping Hearts, although AMH/UHC operates a short-term health management program for a working-age managed care population with cardiovascular disease and diabetes. Avera Research Institute based Helping Hearts on the American College of Cardiology/American Heart Association Guidelines for the Evaluation and Management of Chronic Health Failure in the Adult (Hunt et al. 2001).

Helping Hearts staff are located on the AMH/UHC main medical campus. The medical director, who does not have daily oversight of the program, is housed in Avera Research Institute's central office. The program director, care coordination supervisor, care coordinators, and research associates are located in an office nearby. The care coordination supervisor is responsible for day-to-day operations, and the research associates are responsible for enrolling patients and data management. After a year of operation, the program had 3.5 full-time-equivalent care coordinators spread across four staff and two full-time research associates. When Helping Hearts reaches full enrollment (350 treatment group patients), the program anticipates care coordinator caseloads of 88 patients each.

Most physicians with patients participating in Helping Hearts are not affiliated with AMH/UHC, but some are familiar with Avera Research Institute's staff. At the end of its first

year, 210 physicians were participating in Helping Hearts. Only about 10 percent had worked with Avera Research Institute on prior research projects, and only 30 percent are employed by AMH/UHC. On the other hand, most are familiar with the Avera Health system.

Early in the demonstration, the care coordination supervisor established a physician advisory council for the program to build support for the program and to familiarize physicians with the program who practice farther away from Sioux Falls. The council includes cardiologists, internists, and family practice physicians affiliated with Avera Health. Initially, the council met semi-monthly to discuss the program's practice model. The council currently meets semi-annually to review program progress and to update program staff on changes in heart failure guidelines. Council physicians also help promote the program to their peers by giving presentations to Sioux Falls area physicians on CHF guidelines. In addition, council physicians enabled the care coordination supervisor to give a presentation about Helping Hearts at an October 2003 symposium in Sioux Falls attended by about 300 physicians and other health care professionals. Council members also report to the program about participating physicians satisfaction with the program, based on informal professional conversations.

Primary Approaches. Helping Hearts has adopted two main approaches to improving patient health and reducing health care costs: (1) improving patient adherence to treatment recommendations, and (2) improving communication and coordination among patients and physicians. The program aims to improve patients' ability to adhere to treatment recommendations and recognize and respond to seminal symptom changes by providing each patient with a home monitoring device, the output of which is reviewed daily by a care coordinator. The program seeks to improve communication and coordination by teaching patients to manage their own care and effectively communicate with their physicians.

Although Helping Hearts does not focus its primary effort on changing physicians' clinical practice, it does aim to improve the prescribing of heart failure medications by providing each treatment group patient's physician with a pharmacist's medication review when the patient enrolls.

Target Criteria and Patient Identification. To be eligible for Helping Hearts, the program requires that patients have been hospitalized for CHF (or related diagnosis). (See Appendix B for the exact conditions and ICD-9 codes included.) Patients must have had a hospitalization either (1) with a primary diagnosis for a target condition in the year prior to May 1, 2002, or (2) with a primary or secondary diagnosis for a target condition after May 1, 2002. In addition, the patient's CHF severity must be New York Heart Association Class II, III, or IV (that is, have mild to severe difficulty in performing daily living activities). Beneficiaries must reside in the program's defined service area, which includes 71 counties in Iowa, Minnesota, Nebraska, and South Dakota covering 48,000 square miles. As in all 16 demonstration programs, beneficiaries must meet CMS's insurance payer and coverage requirements for the demonstration: (1) be enrolled in Medicare Parts A and B, (2) not be in a Medicare managed care plan of any kind, and (3) have Medicare as their primary payer. The program excludes beneficiaries who are younger than 65, are senile, have active psychiatric disorders, have renal disease treated with dialysis, have a life expectancy of less than six months for a condition other than CHF, or live in a skilled nursing facility. (See Appendix B for a detailed description of Helping Hearts eligibility criteria, including a list of the 71 counties in its service area.)

The program identifies patients primarily through lists generated by approximately 20 hospitals and 40 clinics in the service area based on DRG codes for heart failure. Although lists differ in content by facility, they generally include the patient's name, contact information, Medicare number, date of birth, primary care physician's name, diagnosis code, and date of

hospitalization.[3] A research associate checks each referral for Medicare eligibility. The research associate then contacts the patient's physician to explain the program and asks him or her to participate and refer the patient. If the physician determines that the patient is appropriate for the program, the physician's office staff fills out the patient referral form, which includes a checklist of the program's eligibility criteria (see Appendix C for the physician referral form).[4] Upon receipt of the form (including severity of CHF), the research associate checks the remaining eligibility criteria listed on the form. When eligibility is confirmed, a research associate telephones those patients, describes the program, and tells them that their physician recommended them for the program. If a patient is interested in participating, the research associate sends the patient a packet containing a program brochure, an informed consent form, a medical records release form, and a return envelope. Within a week, the research associate will follow up with the patient by phone to answer questions and obtain verbal informed consent. The patient mails the informed consent and medical records release forms to the program.[5] The research associate sends the medical records release form to the referring hospital to verify diagnosis at hospitalization.[6] The research associate then sends the patient's data to MPR for randomization.[7]

[3]Clinics are less likely to have the date of hospitalization, so the program obtains this information from the hospital at which the patient was admitted after the patient signs a medical records release form.

[4]Physicians are not expected to fill out the entire referral form. For example, the research associate checks off that the patient has given informed consent after the physician returns the form to the program.

[5]The research associate will, at the request of the patient, pick up the informed consent and medical records release forms from patients residing in the Sioux Falls area.

[6]The program has electronic access to the medical records of patients hospitalized at Avera McKennan Hospital. For all other referring hospitals, the hospital must verify the admission diagnosis.

[7]Originally, care coordinators were responsible for enrollment, and the research associates helped with paperwork. However, as care coordinators' caseloads increased, research associates took primary responsibility for enrolling patients. Care coordinators, on occasion, participate in the enrollment process when research associates need help making calls to eligible patients.

Although the program has identified almost all of their patients by reviewing lists provided by hospitals and clinics, it has received a small number of referrals from physicians and discharge planners. The program has actively encouraged referrals from physicians who already have patients participating in the study by sending them extra referral forms and an update letter from the program's medical director. In addition, the program has sent physicians flyers containing an endorsement from a participating physician (see Appendix C for the physician marketing letter and flyer). The program has also made presentations to hospital and clinic staff, particularly at facilities in the Sioux Falls area, to explain and promote the program. In addition, the program has received a handful of self-referrals and has made some attempts to market Helping Hearts. For example, the program has been featured in newspaper articles and several AMH/UHC publications.

Assessment, Care Planning, and Monitoring. Following random assignment to the treatment group, each patient is assigned a care coordinator based on their geographic location. The care coordinator conducts an assessment of each patient in his or her home. About a year after program operations began, however, the program contracted with a home care agency for their nurses to conduct some assessments in order to cut down on travel costs to more distant areas.[8] (Some patients are 250 to 400 miles away from their care coordinator.) Only three patients had been assessed by a home care nurse a month after this contract began, primarily because the program had enrolled so few distant patients within that time.

Avera Research Institute modeled its assessment tool after the OASIS home care assessment which, in addition to a physical assessment, covers medical history, psychosocial status, availability of social support, financial resources, home safety, functional status, and

[8]The program first contracted with a home care agency in Hendricks, Minnesota. As of April 2004, the program has contracts with home care agencies in Aberdeen and Gregory, South Dakota.

medications. The assessment also reviews educational needs using a questionnaire about CHF developed specifically for the program (see Appendix C for the CHF questionnaire). The program uses some standard tools to assess the patient, including the SF-36 Health Survey and the Beck scale for anxiety and depression. The care coordinator evaluates patient caregivers using the Zarit Caregiver Burden Scale. The assessment usually takes one to two hours to complete and includes setting up and teaching patients how to use the home monitoring device. The care coordinator will assist the patient in recording and transmitting the patient's first set of vital signs. The results of the assessment are documented on paper.

Between June and December 2002, the first six months of program operation, 57 patients enrolled and were randomly assigned to the Helping Hearts treatment group (Table 1). Among the treatment group patients, 88 percent (50 of 57) had at least one contact for assessment; among those contacted for assessment, 64 percent had their first contact within two weeks of random assignment. The program's goal is to assess all patients within two weeks of enrollment. The delays in performing assessments have usually been due to difficulty in scheduling, since some patients live a considerable distance from their care coordinator.

The program does not conduct formal reassessments (that is, repeat all the initial assessment tools). However, the program does repeat the SF-36 and the Beck scale every six to twelve months and administers the CHF questionnaire every year. The program considers every contact with the patient as an opportunity to reassess patient status less formally. In addition, when a patient reports symptoms, home monitoring results that are outside the parameters established by the physician, or an adverse event such as a hospitalization, the care coordinator reassesses the patient using portions of the assessment tool she deems appropriate to address the patient's immediate needs. Reassessments are documented on paper.

TABLE 1

CARE COORDINATOR CONTACTS WITH PATIENTS DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	57
Number of Patients with at Least One Care Coordinator Contact	50
Total Number of Contacts for All Patients	1,508
Average Number of Contacts per Patient	30
Number of Care Coordinators Contacting Patients[b]	6
Among Those Patients with at Least One Contact:	
Percentage of contacts care coordinator initiated	98.6
Percentage of contacts by telephone	95.8
Percentage of contacts in person at patient's residence	3.4
Percentage of contacts in person elsewhere	0.8
Of All Patients Enrolled, Percentage with Assessment Contact	87.7
Among Those Patients with an Assessment, Percentage of Patients Whose First Assessment Contact Is:	
Within a week of random assignment	32.0
Between one and two weeks after random assignment	32.0
More than two weeks after random assignment	36.0
Of All Patients Enrolled, Percentage of Patients with Contacts for:	
Routine patient monitoring	78.9
Monitoring abnormal or missed home-monitoring readings	86.0
Providing emotional support	45.6
Providing disease-specific or self-care education	80.7
Explaining tests or procedures	21.1
Explaining medications	57.9
Identifying need for non-Medicare service[c]	3.5
Identifying need for Medicare service	8.8
Monitoring services[d]	26.3
Average Number of Patients Contacted per Care Coordinator	5.0
Average Number of Patient Contacts per Care Coordinator	150.8

Source: Avera program data received January 2003 and updated July 2003. Covers six-month period beginning June 4, 2002 and ending November 30, 2002.

[a]Number of patients enrolled in the treatment group as of November 30, 2002.

[b]Includes four care coordinators and two research associates.

[c]Includes assistance applying for public programs.

[d]Care coordinators follow up with patients to ensure the receipt of referred services, services the patient had been receiving prior to program startup, and contracted visits made by home care nurses.

The care coordinator develops an individualized care plan for the patient, based primarily on the assessment, which includes a list of goals, interventions by problem area (such as heart failure, diabetes, stress, and loneliness), recommendations about changing behavior, expected outcomes or milestones to be achieved in attaining goals, and educational materials required. Physicians participate in the care planning process by completing a "plan of care" form which the program sends to the physician upon patient assignment to the treatment group (see Appendix C for the physician's plan of care form). Physicians indicate weight and diet restrictions for the patient and set parameters for home monitoring which include values for blood pressure, pulse, and oxygen saturation. The form also allows physicians to designate the frequency at which they wish to receive home monitoring trend reports (for example, once a week, once every other week, or once a month). Patients and/or their caregivers participate in the care planning process by identifying problems they would like to address. Care plans are documented on paper using a form combined with the assessment tool (see Appendix C for assessment and care planning form).[9] Physicians receive a copy of the care plan.

As mentioned, the program monitors patients primarily through home monitoring, using the HomMed Sentry Monitoring System to collect and analyze, on a daily basis, such patient vital signs as weight, pulse, blood pressure, and oxygen saturation. At a scheduled time each day, the patient will be prompted by the HomMed device to take his or her vital signs and answer up to 10 subjective questions about their health status.[10] Data are transmitted to the program by wireless pager or telephone modem to the HomMed central monitoring station. The care

[9]Care plans were formerly documented in Canopy's case management software, but the program has switched to a paper-based documentation system due to length of time data entry takes in Canopy.

[10]Care coordinators program the monitor to ask questions specific to each patient's needs. Patients are asked an average of three to five questions each day out of a possible list of 25 questions.

coordinators document these readings on paper, generate trend reports using the HomMed software, and send trend reports to the physician on a basis determined by the physician. When a patient's vital signs fall outside the parameters set by their physician, the care coordinator calls the patient and assesses his or her signs and symptoms.[11] The care coordinator will also forward a copy of the abnormal readings to the patient's physician, confirm receipt of the report, and follow up with the physician to see if any changes need to be made to the care plan. The monthly maintenance fee per patient for the HomMed device is $90, not inclusive of cellular phone usage.

In addition to following up on abnormal monitor readings, care coordinators monitor patients regularly by telephone at a frequency based on length of enrollment. Care coordinators contact patients by telephone on a weekly basis for the first six weeks, and twice a month thereafter. During routine monitoring contacts, the care coordinator will: assess the patient's physical status; evaluate the patient's progress toward attaining care plan goals; identify educational needs and teach, if warranted; provide positive reinforcement for treatment adherence; and identify needs for services. Care coordinator contact with patients is almost entirely telephonic following the assessment; however, care coordinators do visit patients when there is a problem with the monitoring device or, occasionally, when a home monitoring indicates that a patient's blood pressure is abnormally high. The program has home care nurses

[11]If the program does not receive the physician's plan of care containing home monitoring parameters prior to the receipt of the first monitoring results, the program uses pre-set parameters based on the American College of Cardiology/American Heart Association heart failure treatment guidelines.

make these visits in the same three areas in which the program has home care nurses perform assessments.[12]

Of the 57 patients enrolled during the first six months of operation, 50 patients had at least one contact with a case manager. Most patients (79 percent) had a contact for routine monitoring, and 86 percent had a contact for an abnormal or missed home-monitoring reading. Patients averaged 30 contacts each during this period. Care coordinators initiated almost all contacts (99 percent), and most contacts (96 percent) were conducted by telephone. Only 21 out of 1,508 contacts were initiated by patients. Staff reported that some patients contact their care coordinators when they are going out of town and after doctor's appointments. About half (46 percent) of patients had a contact in which they received emotional support (Table 1).

Staffing and Program Quality Management. Maintaining and improving care quality and ensuring that programs attain their goals both require that staff have adequate qualifications, training, and supervision and that management has the tools and support to monitor program progress toward the program's goals. Helping Hearts prefers their care coordinators to be baccalaureate-prepared registered nurses. After a year of operation, the program had four care coordinators, each with 10 years or more of nursing experience. Each of the care coordinators had cardiology experience, and one had a background in geriatric nursing as well. Upon hire, each care coordinator completed an orientation that began with a self-assessment examination of the coordinator's skills. The care coordination supervisor conducts the orientation and educates care coordinators on such program-specific topics as research standards, problem identification, assessment, home monitoring, interventions, patient education, outcome measurement, and

[12]Two to three percent of the program's patients temporarily move away from the service area for several months at a time ("snowbirds"). Helping Hearts continues to manage these patients by telephone, and patients take their HomMed devices with them.

documentation. After orientation, the care coordination supervisor provides individual and group training sessions on an as-needed basis, including CHF-related updates on medication and dietary information. She also periodically sends care coordinators to seminars on disease management. In addition, she arranges for staff from Avera McKennan Hospital—including social workers, dietitians, pharmacists, physical therapists, home care staff, sleep study staff, and fitness trainers—to provide training when needed. For example, the care coordination supervisor has invited dieticians to give presentations to the care coordinators.

To evaluate care coordinator performance, the supervisor goes on assessment visits and listens to care coordinators' phone calls. The care coordination supervisor also randomly reviews case files on a weekly basis. She also meets weekly with the care coordinators and research associates.

The program evaluates its approach to patient care during its weekly staff meetings, which include the program director, care coordination supervisor, care coordinators, and research associates. At these meetings, staff discuss their approach and sometimes suggest changes to improve the care of individual patients (for example, alternative education strategies for a patient who is not learning). The program director and medical director also meet on a weekly basis to discuss the program's procedures and enrollment.

Since it was in the process of developing an Access database to collect and store information on its activities, the program, after a year of operation, was not generating formal reports to monitor the effectiveness of its intervention. In the meantime, the program has been using a paper-based system to document program activities. Helping Hearts previously used a commercial case management software to document care coordination activities and help care coordinators determine when to contact patients, but program staff found the software inefficient. For example, care coordinators reported that it took them twice the time to input the assessment

to the case management program that it did to perform the assessment. When the Access database is complete, the program will use it to generate enrollment statistics and reports of patient contacts and selected patient outcomes (such as quality of life and CHF knowledge) for the purpose of monitoring the effectiveness of their intervention.

WHO ENROLLS IN THE PROGRAM?

As with many care coordination programs, enrollment has been much lower than anticipated. Expanding the program's service area from 25 counties to 71 counties increased enrollment only modestly. Nevertheless, Helping Hearts appears to have enrolled patients with high health care expenditures and the expected rate of hospitalization. Staff report that patients are satisfied with the program, and program data show no voluntary disenrollment during its first six months.

Enrollment After One Year. After one year of operation, Helping Hearts had enrolled 157 patients in the demonstration treatment group and 161 in the control group (MPR weekly enrollment report, week ending June 8, 2003), about 40 percent of the 788 beneficiaries Avera Research Institute had planned to enroll during its first year.[13] The program attributes its enrollment shortfall to initial difficulties in identifying eligible patients within the program's service area and a high refusal rate among eligible patients. Some patients were reluctant to join the program because they felt uncomfortable sharing personal information.

Early in the demonstration, Avera Research Institute reported that many patients referred to the program by participating hospitals and clinics lived outside the program's service area due to

[13]Given Helping Hearts' shortfall in enrollment, Avera Research Institute reduced its original enrollment target of 788 treatment group members to 350, as of April 2003. The program anticipates increasing its care coordinator staff to 4.0 full-time equivalents.

patients coming to the hospital from outlying areas for tertiary care.[14] As a result, Helping Hearts requested that CMS allow it to expand its service area, first in September 2002 when it expanded from its original 25 counties to 50 counties, and again in September 2003, to add another 21 counties, bringing the total to 71. During the months following the initial addition of 25 counties, enrollment increased from roughly 20 patients per month during the program's first three months, to about 30 patients per month during the subsequent year (October 2002 through September 2003). However, enrollment reverted to roughly 20 patients per month during the six months following the addition of another 21 counties (October 2003 through March 2004).

The program believes that a high patient refusal rate also played a significant role in its enrollment shortfall. Staff report that approximately two-thirds of eligible patients initially contacted by the program's research associate actively declined to participate in the program. Patients who refused often said they were too busy or not interested, wanted to discuss the program with their doctor before deciding, or felt the home monitoring would be too burdensome. Program staff also believe that many patients refused because they do not think of themselves as having heart failure or are unaware of their diagnosis. A substantial number of patients also passively refused to participate in the program. Of those patients initially contacted who requested that the program send its written materials, more than a third could not be contacted for telephone followup, refused to participate upon followup, or simply did not return the necessary forms to the program.

Percent of Eligible Beneficiaries Participating. To gain another perspective on the appeal of the program to beneficiaries, the evaluation simulated the program's eligibility criteria using

[14]The program believes it received between 3,000 and 5,000 referrals during its first year. It did not keep data describing its patient identification process consistently over time. Thus, we are unable to assess the relative importance of ineligibility and patient refusals as factors affecting the program's enrollment shortfall.

Medicare enrollment and claims data to estimate the percent of eligible beneficiaries who chose to participate in Helping Hearts. (Appendix B contains a detailed description of the simulation.) This simulation identified 6,022 beneficiaries eligible for the program between June and December 2002, the program's first six months of operation. That is, they met CMS's three demonstration-wide Medicare requirements, lived in the program's service area,[15] and met the program's diagnostic and service use criteria.[16] During the same six months, 100 "eligible" beneficiaries enrolled in the demonstration (about 1.7 percent of the 6,022 eligible beneficiaries).[17] (See Tables B.2 and B.3.)

Comparison of Participants and Eligible Nonparticipants. Medicare enrollment and claims data show that program participants and eligible nonparticipants differed in terms of age and Medicaid eligibility, but were similar with respect to sex and race (Table 2). Program participants were two and a half years younger, on average, because they were less likely to be age 85 or older. Forty to 45 percent of each group was male and under 2 percent were nonwhite.

[15]The program had a 50-county service area during the first six months of operations. The 47 counties the program had reported to us before the data pull are listed in Appendix B, Table B.1, as well as the three counties that were omitted.

[16]Between June and December 2002, 121,316 beneficiaries were living in the program's service area. Of those, 12,263 (10 percent) would have been ineligible for the program because they did not meet one of CMS's demonstration-wide criteria. Of the remaining 109,053 beneficiaries who met these criteria, 6,022 (6 percent) also met the program's diagnostic and service use criteria at some point during the six-month intake window, and they had none of its exclusion criteria (to the extent they could be simulated with the Medicare data). (See Table B.2.)

[17]In fact, 116 beneficiaries actually enrolled in the program during its first six months. When estimating the participation rate, the evaluation excludes enrollees with incorrect Health Insurance Claim (HIC) numbers on MPR's enrollment file, and those who did not meet the Medicare demonstration-wide criteria or the program's geographic, diagnostic, utilization, or exclusion criteria (as measured with Medicare data). These enrollees were excluded from the participation analyses in order to use a consistent definition of eligibility for the numerator and denominator of the ratio. (Beneficiaries with invalid HIC numbers may well be eligible, but the beneficiaries' Medicare data could not be obtained to assess that, so they were excluded. The HIC numbers have since been corrected.) This leaves 100 known *eligible* participants. Over two-thirds of the reduction was due to participants living outside the service area during the enrollment month or having reported an invalid HIC number. The comparison of participants to eligible nonparticipants in Table 2, however, excludes only participants with invalid HIC numbers and those who did not meet Medicare demonstration-wide requirements, leaving 111 participants. Thus, the comparison more closely reflects the differences between all actual participants and those who were eligible to participate but did not.

TABLE 2

CHARACTERISTICS OF ALL PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING THE FIRST SIX MONTHS OF PROGRAM ENROLLMENT
(Percentages, Unless Otherwise Noted)

	Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Age at Intake			
Average age (in years)	79.1	81.5	***
Younger than 65	0.0	0.0	
65 to 74	26.1	20.3	
75 to 84	51.4	42.8	*
85 or older	22.5	37.0	***
Male	45.1	41.2	
Nonwhite	1.8	1.4	
Original Reason for Medicare: Disabled or ESRD	6.3	8.2	***
State Buy-In for Medicare Part A or B	7.2	19.6	***
Newly Eligible for Medicare (Eligible Less than Six Months)	0.9	0.0	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	99.1	100.0	***
Medical Conditions Treated During Two Years Before Month of Intake[c]			
Coronary artery disease	78.2	66.4	***
Congestive heart failure	97.3	91.7	**
Stroke	27.3	32.1	
Diabetes	46.4	33.3	***
Cancer	24.6	23.5	
Chronic obstructive pulmonary disease	66.4	52.1	***
Dementia (including Alzheimer's disease)	2.7	7.0	*
Peripheral vascular disease	22.7	21.8	
Renal disease	20.0	16.8	
Total Number of Diagnoses (number)	3.9	3.4	***
Days Between Last Hospital Admission and Intake Date[b]			
No hospitalization in past two years	0.9	0.0	***
0 to 30	32.7	12.7	***
31 to 60	14.6	10.1	
61 to 180	30.9	30.5	
181 to 365	15.5	31.8	***
366 to 730	5.5	14.9	***

TABLE 2 *(continued)*

	Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Annualized Number of Hospitalizations During Two Years Before Month of Intake[b,c]			
0	2.7	1.4	
0.1 to 1.0	47.3	53.2	
1.1 to 2.0	26.4	28.5	
2.1 to 3.0	13.6	11.0	
3.1 or more	10.0	5.9	*
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[b]			
Part A	$1,035	$986	
Part B	$463	$393	
Total	$1,499	$1,376	
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[b]			
$0	0.0	0.1	
$1 to 500	17.3	28.4	**
$501 to 1,000	32.7	24.8	*
$1,001 to 2,000	25.5	24.7	
More than $2,000	24.6	22.0	
Number of Beneficiaries	**111**	**5,505**	

Source: Medicare Enrollment Database and National Claims History File.

Note: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is September 15, 2002, the midpoint of the six-month enrollment period examined.

[a]Participants who do not meet CMS's demonstration-wide requirements for the demonstration or had an invalid HIC number on MPR's enrollment file are excluded from this table because we do not have Medicare data showing their reimbursement in the fee-for-service program. Members of the same households as the research sample members are included.

[b]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[c]Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001, would be captured in the measure defined by month of enrollment, but not in the measure based on the day of enrollment.

*Difference between participants and eligible nonparticipants significantly different from zero at the .10 level, two-tailed test.

**Difference between participants and eligible nonparticipants significantly different from zero at the .05 level, two-tailed test.

***Difference between participants and eligible nonparticipants significantly different from zero at the .01 level, two-tailed test.

Helping Hearts participants were less likely to be eligible for Medicaid as well as Medicare: 7 percent were eligible for Medicaid as compared with 20 percent of eligible nonparticipants.

Participants and eligible nonparticipants were more likely to have certain chronic health conditions. Almost all participants (97 percent) had been treated for CHF—Helping Hearts' primary target diagnosis—during the two years prior to enrolling as compared with 92 percent of eligible nonparticipants.[18] Seventy-eight percent of participants had been treated for coronary artery disease, 66 percent for chronic obstructive pulmonary disease, and 46 percent for diabetes. Among nonparticipants, these rates were lower—66 percent, 52 percent, and 33 percent, respectively.

Avera Research Institute enrolls most participants within a year after a hospitalization. (Its target criteria requires participants to have had a hospitalization for CHF anytime after May 1, 2001.) During the year prior to enrollment, 94 percent of participants had a hospitalization in the fee-for-service setting, and had monthly Medicare expenditures of $1,499. By comparison, only 85 percent of nonparticipants had a hospitalization in the prior year and their average monthly reimbursement was $1,376. Participants were also much more likely to have had a hospitalization in the month before intake, with 33 percent of participants and 13 percent of nonparticipants hospitalized.

When developing the cost estimate for the program's waiver application, MPR estimated that Medicare costs would average $1,479 per month for eligible beneficiaries who did not

[18]All of the participants Avera enrolled and all of the nonparticipants included in the simulation had one of Avera's target conditions. However, not all participants and nonparticipants are shown as having heart failure in Table 2 because the standard definition used by the evaluation to measure CHF for all MCCD programs contains different ICD-9 codes than those used by Avera. In additional to CHF, Avera targets several additional diagnoses including: artherosclerosis, thyotoxicosis, cardiomyophathy, ill defined descriptions and complications of heart disease, rheumatic fever with heart involvement, and symptoms involving the cardiovascular system. Similarly, none of the participants or nonparticipants had any of Avera's exclusion conditions (including senility). However, three percent of participants and seven percent of nonparticipants are shown as having dementia in Table 2 because the standard definition the evaluation uses for dementia differs from that used by Avera.

participate in Helping Hearts. It thus appears that the program has enrolled patients who are just as costly as planned, with average monthly costs of $1,499 prior to enrollment.

Satisfaction and Voluntary Disenrollment. Anecdotal information collected by the care coordinators suggests that patients and their caregivers are satisfied with the Helping Hearts program. Several family members reported that they feel less anxious about a relative knowing that he or she is being monitored by a nurse. Some patients, especially those living alone, said the program gives them a sense of security. Others like having the monitor to remind them to take their medications. The staff believes that the program works best for those patients who are non-adherent to treatment and do not report signs and symptoms to their physician.

Patients may stay in the Helping Hearts program for the duration of the demonstration (that is, until June 2006). Among the 57 patients receiving the Helping Hearts intervention who enrolled during the first six months of operation, just under half (44 percent) had been enrolled 10 weeks or less during those six months, while most others (47 percent) had been enrolled between 11 and 20 weeks during the period. No patients voluntarily disenrolled during the first six months of the program. Only four patients disenrolled for other reasons. One patient died, and another lost program eligibility because he moved into a nursing home. Two disenrolled for "other" reasons; the program did not track specific reasons for those coded as "other" (Table 3).

TO WHAT EXTENT DOES THE PROGRAM ENGAGE PHYSICIANS?

While the importance to program success of engaging eligible beneficiaries is self-evident, the importance of engaging physicians may be less so. Care coordinators must develop trusting, collaborative relationships with primary care physicians in order for physicians to feel comfortable communicating important information to them about their patients. For example, care coordinators need physicians to tell them about medication changes, new problems

TABLE 3

DISENROLLMENT FOR PATIENTS ENROLLED DURING FIRST SIX MONTHS

Number of Patients Enrolled[a]	57
Length of Enrollment as of October 15, 2002 (Percentage of All Enrollees)	
10 weeks or less	43.9
11 to 20 weeks	47.3
21 or more weeks	8.8
Mean Length of Enrollment (Weeks)	11
Number of Patients Who Disenrolled	4
Number Who Disenrolled Because:	
Patient died	1
Patient lost program eligibility[b]	1
Patient initiated disenrollment	0
Unspecified reason	2
Number Disenrolling:	
Within a week after random assignment	0
Between 1 and 4 weeks	3
Between 5 and 12 weeks	1
More than 12 weeks	0

Source: Avera program data received January 2003 and updated July 2003. Covers six-month period beginning June 4, 2002 and ending November 30, 2002.

[a]Number of patients ever enrolled in the treatment group through November 30, 2002.

[b]Patients can lose program eligibility for the following reasons: joined a managed care plan, Medicare no longer primary payer, have become senile or developed an active psychiatric disorder, developed renal disease treated with dialysis, have a life expectancy of less than six months for a condition other than CHF, moved to a nursing home, or moved out of the program's service area.

identified during office visits, or areas for additional patient education. Physicians also need to feel that information they get from the care coordinators is credible and warrants their attention (for example, regarding problems in the home environment that affect patients' health, functional deficits that patients do not tell physicians about, or reminders about providing preventive care). A trusting, respectful relationship will also facilitate care coordinators' access to physicians when urgent problems arise, and it will facilitate communication and coordination across medical care providers (Chen et al. 2000). Moreover, to increase acceptance of care

coordination among physicians in general, care coordinators of course need to engage physicians.

Helping Hearts is promoted to physicians as a management tool that will help them make better-informed decisions about patient care and thus make their care delivery more efficient. The program seeks to supplement physicians' medical management of their patients, but also to have physicians cooperate with care coordinators when specific patient problems arise. The program further aims to improve physicians' prescribing of heart failure medications by providing them with a medication review and recommendations when each treatment group patient enrolls.

Relationship Between Care Coordinators and Physicians. Helping Hearts aims to make physician practice more efficient by providing physicians with timely medical information from the patient's home monitoring device. The program expects care coordinators to "assist, rather than interfere" with physicians' medical management of their patients (for example, by providing additional patient education or by referring patients to needed non-Medicare services). Program expectations for physicians, therefore, are limited to: (1) approving patient participation, (2) specifying home monitoring parameters and the frequency of trend reporting, (3) responding to care coordinators' telephone calls when abnormal home monitoring readings or adverse events occur, and (4) reviewing trend reports for home monitors that care coordinators send.

Helping Hearts has adopted two primary strategies to promote cooperation between physicians and care coordinators: (1) having care coordinators conduct introductory conferences with physicians, and (2) providing physicians with home monitoring trend reports and a stipend for reviewing them. Care coordinators meet with physicians in person when the program enrolls their first patient, in order to explain the program's model of care coordination and describe the program's expectations of them. After this conference, contact between care coordinators and

physicians is almost exclusively by telephone and is limited to reporting abnormal trends in home monitoring readings and changes in patient health status (for example, following up when the patient experiences an adverse event). After the introductory conference, Helping Hearts also communicates with physicians by providing them with trend reports of home monitoring results at a frequency requested by the physician, as well as before patient appointments (see Appendix C for the HomMed trend report). These reports are sent by mail or more often by fax. To encourage physicians to review the reports, the program pays them a monthly stipend of $30 per treatment group patient.

Efforts to engage physicians appear to have succeeded within the program's limited expectations. Physicians have cooperated by approving patients for participation in the program. Most physicians specify home monitoring parameters within a week of receiving the plan of care form. Program staff also report that physicians are generally responsive to, and return, care coordinators' phone calls.

Improving Practice. Although changing clinical practice is not a primary focus of Helping Hearts, it does seek to improve physicians' prescribing heart failure medications by having a pharmacist from its multidisciplinary team review the medications of each treatment group patient when the patient enrolls. The program sends the patient's physician the results of a medication review that compares the patient's current medications with the CHF medication guidelines of the American College of Cardiology and the Heart Failure Society of America. The program states in the cover letter for the review that its suggestions "are provided to support [the physician's] clinical judgment" and acknowledges that physicians may have access to patient information that the care coordinator does not, which might contraindicate its recommendations (see Appendix C for the medication review letter and form). Although the program does not track whether physicians are making the recommended changes, anecdotally,

staff report that a few physicians have changed their patient's treatment regimen in response to the medication review. Physicians who do not change their treatment often explain to the care coordinators why no change was made, often based on information the program was not aware of.

Staff reported, based on anecdotes, that physicians were highly satisfied with the program and its ability to deliver timely data on patients who are difficult to manage. One physician the program selected for us to interview said that he decided to participate in the program because he was having difficulty monitoring some patients who were neglecting their treatment and becoming sicker: "My patients are more stable because of the program." One physician endorsed the program in a Helping Hearts brochure distributed to physicians with potential study patients, saying that the program "has been very helpful in managing some of my sickest patients," and that it has made patients, "more inclined to follow their medicinal program" (see Appendix C for the physician marketing flyer). The physician further remarked that access to the trend reports and care coordinators' phone calls when a patient's condition changes helped him make "much more informed management decisions."

HOW WELL IS THE PROGRAM IMPLEMENTING TASKS TO ACHIEVE ITS GOALS?

Improving patient adherence to treatment recommendations is the primary approach Helping Hearts is taking to improve patient health. It supports this approach by teaching patients to better understand the disease process and to recognize and respond to seminal symptoms and through the daily use of a home monitoring device. The program hopes to improve patient health by improving communication and coordination among patients and their physicians. The program intends to accomplish this by teaching patients how to communicate more effectively with their physicians and by providing physicians with monitoring device trend reports.

Improving Patient Adherence. In order to help patients adhere more closely to their treatment regimens, care coordinators educate patients and their caregivers to better understand CHF and how to manage its symptoms on their own. Education begins prior to the in-home assessment when the care coordinator mails the patient a pamphlet on CHF and a CHF knowledge pretest. The care coordinator's first priority during the assessment visit is to make sure the patient is aware of the diagnosis, since some patients may not have been told specifically that they have CHF, or they may not remember that they have been told. Second, the care coordinator begins to educate the patient about CHF during the assessment and assesses what the patient knows about CHF by reviewing the CHF pamphlet with him or her. The care coordinator also verbally assesses the patient's readiness to change his or her behavior—for example, by asking if the patient had thought about losing weight or quitting smoking—and asks the patient how he or she prefers to learn: by demonstration, visually, or aurally. Based on the results of the pretest, the assessment, and observations of the patient's readiness to change, the care coordinator develops recommendations for specific educational interventions. The education plan is incorporated into the patient's care plan. The care coordinator then uses the care plan to document achievements in patient knowledge and behavior, as well as keep track of educational materials (for example, pamphlets, books, and audio and video tapes) given to patients.

The education intervention was developed by Avera, and is based on a standard CHF curriculum based on CMS, American Heart Association, and American College of Cardiology guidelines, supported by materials published by a pharmaceutical company. The intervention covers topics in three areas: (1) effective and appropriate use of medical care resources (for example, when to call your physician); (2) disease-specific knowledge and symptom management; and (3) the importance of adherence to treatment. The curriculum followed by the care coordinators is a flexible one that allows the care coordinators to omit parts that are not

applicable to a particular patient. Although the curriculum is disease-specific, care coordinators address psychosocial problems (such as stress and loneliness) and co-morbidities (such as diabetes) using supplemental materials.[19] For example, care coordinators might reinforce a diet for a patient who is adherent to the medication regimen but who consumes foods high in sodium; or they might reinforce exercise for an inactive patient. Helping Hearts does not exclude patients with sensory deficits, but they do exclude patients with dementia. For such patients the program works with the patient's caregiver. For example, one care coordinator is educating a deaf patient through the patient's daughter who translates for her mother. The program had not served any non-English speaking patients after one year of operation.

The program provides care coordinators with some training on providing patient education. During orientation, the care coordination supervisor teaches care coordinators how to provide heart failure education. All the care coordinators have several years' experience providing education to either cardiac or geriatric patients.

The program supplements the education provided by care coordinators when community resources are available to the patient. To address patients' educational needs, care coordinators have referred patients throughout the service area to cardiac and pulmonary rehabilitation programs. They have also referred patients to community education classes on diabetes and counseling with a nutritionist or dietician. The program also educates patients' caregivers and has sent them to the Care Givers workshop at the Heart Hospital in Sioux Falls. The program reported that it has encountered no problems in finding community education resources for patients residing in areas that are more rural. The program assesses whether teaching has been effective through observation of home monitoring data and patients' self-reported behavior, as

[19]The program had no information about the reading level of these materials.

well as reviewing the results of the CHF questionnaire and SF-36 Health Survey. One care coordinator said monitoring was a great incentive for patients to be adherent to their treatment regimen because "they know someone will call them if they're not." Another care coordinator reported that one of her patients "feels that he catches things early with the scale and having [the care coordinator] educate him." Care coordinators also listen to patients' reports of their behavior during telephone contacts, in order to assess whether education has worked. For example, one patient told her care coordinator she ate a lot of Chinese food, but seemed unaware of its high sodium content. After the care coordinator educated the patient about sodium intake, the patient ate less sodium and her weight decreased. Finally, the program measures the effectiveness of its educational intervention by repeating the CHF knowledge test annually and by assessing quality of life every six months to a year using the SF-36 Health Survey. The program reviews these outcomes for individual patients to reevaluate their educational needs.

If the program finds that a patient is not learning, the care coordinator will work with the patient to overcome educational barriers. For example, a care coordinator continually reinforced educational messages to a patient with low cognition to improve the patient's understanding of CHF, an approach which the patient's physician reported had improved his adherence to treatment. The care coordinator may also consult other care coordinators, the care coordination supervisor, or the medical director about alternative strategies. In some cases, however, the care coordinator revises her educational goals for the patient or moves on to another goal.

Among the 57 patients enrolled in Helping Hearts during its first six months, the majority had received at least one contact for self-care or disease-specific education (81 percent) and more than half had at least one contact during which the care coordinator explained medications (58 percent). A smaller proportion of patients (21 percent) had at least one contact during which the care coordinator explained tests or procedures (Table 1).

Helping Hearts appears to have implemented a patient education strategy that should result in improved patient adherence to treatment recommendations. The care coordinators have some experience providing patient education, and the program provides additional patient education training. The program's standardized curriculum can be customized to each patient based on his or her specific problems (including co-morbidities and lifestyle issues). Home monitoring allows care coordinators to assess whether their teaching has been effective, encourages patients to be more adherent to treatment, and provides opportunities for reinforcement of education concepts such as self-management. If a patient is not learning, the care coordinator will consult other program staff about alternative education strategies. Whether patients are actually taking in educational messages and changing their behavior will be more evident from the evaluation's analyses of patient and physician surveys and of Medicare claims data.

Improving Communication and Coordination. Another of the program's approaches to improving patient health is to teach patients to communicate more effectively with their physicians and arrange for their own care. The program also aims to improve coordination primarily by providing clinical information to physicians on a regular basis, which will help them make better, more timely decisions about their patients' treatment.

Care coordinators teach patients when to contact their physicians using the results of home monitoring. When abnormal readings occur, the care coordinator calls the patient and asks him or her about their signs and symptoms. The care coordinator will teach the patient how to determine whether they need to call their physician and encourage them to do so if appropriate. The care coordinator will follow up with the patient and physician's office to check on whether the patient has made an appointment. In order to motivate self-management, care coordinators usually do not intervene on behalf of their patients, but they will make doctor's appointments for their patients when the patients themselves are reluctant to do so.

Care coordinators also teach patients how to communicate better with their physicians and get the information they need to follow their treatment regimen during doctor visits. Care coordinators will teach patients how to ask their physician questions through role-playing or by helping patients make a list of questions to ask their doctor during the visit.

Care coordinators seek to make patient care more timely by regularly communicating pertinent, patient-specific information to patients' physicians primarily through home-monitoring trend reports. These reports are mailed or faxed to the physician: (1) as part of routine monitoring at a frequency determined by the physician, (2) before scheduled office visits, and (3) when patients have adverse events.

To improve coordination and ensure that care is in line with published CHF treatment guidelines, care coordinators phone physicians to remind them that a patient is due for a test or preventive care, to follow up with them on abnormal monitoring results, or to report changes in patient health status or symptoms that need attention. As mentioned, all physicians receive a pharmacist's review of their patients' medications when patients are first enrolled. Care coordinators occasionally suggest changes to medications when CHF guidelines recommend them.

Further, care coordinators aim to improve coordination by tracking patients' adverse events (mostly hospitalizations) through home monitoring and working with hospital staff, physicians, patients, and their caregivers to prevent reoccurrences. When a patient does not record his or her vital signs or has an abnormal reading and cannot be reached by phone, the care coordinator calls the patient's designated emergency contact person. In some cases, the patient or caregiver calls the care coordinator directly to report an adverse event. The care coordinator documents the unplanned event by filling out a "serious adverse event" form and inputting it to the HomMed central database as free-text note. When a patient is hospitalized, the care coordinator: contacts

the patient in the hospital; talks to the patient's hospital nurse or case manager to make sure the patient gets the follow-up care he or she needs (for example, a particular test) upon discharge; and calls the physician to report the adverse event and ask him or her if the patient's course of treatment will change. The care coordinator works with the patient and his or her caregiver to determine why the event occurred and develops a plan to prevent further occurrences.

Helping Hearts possesses several features that are meant to improve care coordination and communication among patients and their physicians. First, abnormal home-monitoring readings provide care coordinators with an opportunity to teach patients when they should contact their doctor. Second, home monitoring alerts care managers to adverse events, which prompts them to follow up with the patient to prevent recurrences and with health care providers to ensure that post-hospital care is coordinated. Third, care coordinators keep physicians informed of patient clinical indicators by regularly sending them home monitoring trend reports that assist them in making timely, well-informed decisions. And, finally, care coordinators keep physicians up to date by calling them when a patient's condition changes or an adverse event occurs. The program, however, seems not to have an approach to identifying medication problems (such as polypharmacy), which may occur after enrollment, or to helping patients resolve conflicting advice from different physicians.

Increasing Access to Services. Although Helping Hearts refers patients to a wide variety of services (or, if necessary, arranges services on their behalf), increasing access to services is not a major focus of the program. The services that staff referred patients to or arranged for most frequently during the program's first year were transportation and home health care. Helping Hearts has access to Avera McKennan Hospital's community resource lists covering the program's entire service area, which catalogs all the resources and services that patients admitted

to the hospital have been referred to. The program also has lists of community resources in rural areas collected during previous research in these areas.

The cost of prescription medications has been a barrier to adherence for most program patients, a barrier the program tries to eliminate by referring patients to state and pharmaceutical medication assistance programs. Care coordinators follow up with these patients to ensure that patients receive the assistance they need. These programs, however, are limited, with some patients finding it difficult to secure additional assistance when they run out of medications. Helping Hearts refers these patients to Avera McKennan's Development Foundation, which assists patients with limited financial resources.

The program does not pay for services or resources other than the home monitoring device. During its first six months of operation, it leased home monitoring equipment for 47 patients (82 percent of those enrolled; data not shown).[20] Care coordinators referred only two patients (3.5 percent) to Medicare-covered services or arranged services for them, and only five patients (8.8 percent) to non-Medicare-covered services (Table 1). Care coordinators followed up with more than a quarter of patients (26.3 percent) to ensure the receipt of referred services, services the patient had been receiving prior to program startup, and contracted visits made by home care nurses.

WHAT WERE ENROLLEES' MEDICARE SERVICE USE AND COSTS?

This report provides preliminary estimates of the effect of Helping Hearts on Medicare service use and expenditures. These early estimates must be viewed with caution, as they are not likely to be reliable indicators of the true effect of the program over a longer period. Due to lags in data availability, analysis for this report included only an early cohort of enrollees (those

[20]The remaining 18 percent were newly enrolled and had not yet received their home monitoring device.

enrolling during the first four months of program operation), and allowed observation of their experiences during their first two months in the program. The estimates thus include patients' experiences only during the program's first six months of operation, when staff still may have been fine-tuning the intervention. Moreover, the program may enroll patients with quite different characteristics over time.

During the first two full months after random assignment, total Medicare Part A and B reimbursements for the treatment group, exclusive of demonstration payment, were $3,189 ($1,595 per month), on average, compared with $2,533 ($1,267 per month) for the control group (Table 4). The difference between these two estimates is not statistically significant.[21] About a fifth of each group had a hospitalization during that period. The CMS per-member, per-month payment to the program averaged $298, slightly less than the negotiated monthly rate of $316.[22] The sample size enrolled during the first four months is too small to allow us to draw even preliminary conclusions about early program effects.

The evaluation also examined monthly trends in treatment-control differences from June through December 2002, the first six months of program operation (Table 5). Again, the sample enrolled in these months is too small to draw inferences about program effects. The table is included only to demonstrate the types of analyses the evaluation will conduct in the future.

CONCLUSION

Research over the past decade suggests, but is by no means conclusive, that successful care coordination has a number of features. These include effective patient identification, a well-

[21]As would be expected with random assignment, the treatment and control groups were statistically similar. See Appendix B.

[22]The per-member, per-month payment charged by the program is $316, or $632 over the two-month period. The slightly lower means in Tables 4 and 5 may have resulted from billing errors, payment delays, or payment adjustments for patients who disenrolled.

TABLE 4

MEDICARE-COVERED SERVICE USE DURING THE TWO MONTHS AFTER THE MONTH OF RANDOMIZATION, FOR EARLY ENROLLEES

	Treatment Group	Control Group	Difference[a]	
Inpatient Hospital Services				
Any admission (percent)	19.4	20.6	–1.1	
Mean number of admissions	0.31	0.21	0.10	
Mean number of hospital days	2.42	1.18	1.24	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	11.1	17.7	–6.5	
Not resulting in admission	5.6	8.8	–3.3	
Total	16.7	23.5	–6.9	
Mean number of emergency room encounters				
Resulting in admission	0.14	0.18	–0.04	
Not resulting in admission	0.08	0.09	0.00	
Total	0.22	0.26	–0.04	
Skilled Nursing Facility Services				
Any admission (percent)	2.8	2.9	–0.2	
Mean number of admissions	0.03	0.06	–0.03	
Mean number of days	0.42	1.35	–0.94	
Hospice Services				
Any admission (percent)	0.0	0.0	0.0	
Mean number of days	0.00	0.00	0.00	
Home Health Services				
Any use (percent)	13.9	14.7	–0.8	
Mean number of visits	1.56	2.50	–0.94	
Outpatient Hospital Services[b]				
Any use (percent)	58.3	55.9	2.5	
Physician and Other Part B Services[c]				
Any use (percent)	97.2	100.0	–2.8	
Mean number of visits or claims	10.5	9.4	1.1	
Mortality Rate (Percent)	0.0	0.0	0.0	
Total Medicare Reimbursement[d]				
Part A[e]	$2,058	$1,476	$582	
Part B	$1,132	$1,057	$74	
Total	$3,189	$2,533	$656	
Reimbursement for Care Coordination[f]	$596	$0	$596	***
Number of Beneficiaries	**36**	**35**		

TABLE 4 *(continued)*

Source: Medicare National Claims History File.

Note: Sample includes those enrolled during the first four months of program operations. Participants were excluded from this table if they had an invalid HIC number on MPR's enrollment file, were identified as a member of the same household as a research sample member, or did not meet Medicare coverage and payer requirements (defined as having Medicare as a secondary payer, being in Medicare managed care plan, or not having Part A and Part B coverage) during the month of randomization. Patient-months were excluded if the participant did not meet the above Medicare coverage and payer requirements that month, or had died in a previous month.

"Percents with any medical encounter type" are the percent of treatment or control group members who have at least one encounter of a particular type; "mean numbers of medical encounter types" are the average number of encounters of a particular type per treatment or control group member.

[a]The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the controls) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventative care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

Due to rounding, the difference column may differ slightly from the result when the control column is subtracted from the treatment column.

[b]Includes visits to outpatient hospital facilities as well as emergency room visits that do not result in an inpatient admission. Laboratory and radiology services are also included.

[c]Includes diagnostic laboratory and radiology services (including pathologist and radiologist services) from nonhospital providers, suppliers and devices, mammography, ambulance, covered medications, blood, and vaccines.

[d]Does not include reimbursement for care coordination services provided by demonstration programs.

[e]Includes reimbursement for inpatient, skilled nursing facility, hospice, and all home health care (including that paid under Medicare Part B). Excludes reimbursement for care coordination services provided by demonstration programs.

[f]This is the average amount paid to the program as recorded in the Medicare claims data for the two months following randomization. The difference between the recorded amount and two times the amount the program was allowed to charge per-member-per-month may reflect billing errors, delays, or payment adjustments for patients who disenrolled.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.
**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.
***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

TABLE 5

MONTHLY MEDICARE SERVICE USE FOR PARTICIPANTS WHO ENROLLED DURING THE FIRST SIX MONTHS OF PROGRAM OPERATIONS

	Group	Jun 02	Jul 02	Aug 02	Sep 02	Oct 02	Nov 02
Cumulative Enrollment Through Month End	Treatment	2	7	26	37	45	56
	Control	1	8	22	34	43	52
Mean Number of Beneficiaries Enrolled Who Meet Medicare Coverage and Payer Requirements and Are Alive That Month	Treatment	2	6	25	36	44	55
	Control	1	8	22	33	42	51
Average Medicare Reimbursement During the Month[a]	Treatment	$107	$2,072	$1,999	$1,840	$2,036	$1,509
	Control	$5,061	$6,344	$3,482	$1,700	$809	$1,236
Average Reimbursement for Care Coordination During the Month[a,b]	Treatment	$316	$316	$303	$298	$287	$281
Whether Admitted to Hospital This Month[a] (Percentage)	Treatment	0.0	33.3	20.0	19.4	15.9	14.5
	Control	0.0	62.5	31.8	9.1	4.8	17.6
Treatment - Control Difference[c]							
Average Medicare Reimbursement[a]		–$4,954 ***	–$4,272	–$1,482	$140	$1,226 *	$273
Average Reimbursement for Medicare plus Care Coordination[a]		–$4,638 ***	–$3,957	–$1,179	$438	$1,513 **	$554
Percentage Hospitalized[a]		0.0	–29.2	–11.8	10.4	11.1 *	–3.1

Source: Medicare National Claims History File.

[a]Participants were excluded if they died in a previous month or failed to meet the Medicare coverage and payer requirements during the month of randomization or the month examined—that is, if they were in a Medicare managed care plan, had Medicare as a secondary payer, or did not have both Part A and Part B coverage. Participants were also excluded entirely from this table if they had an invalid HIC number on MPR's enrollment file.

TABLE 5 *(continued)*

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[b]This is the average amount paid to the program as recorded in the Medicare claims data. The difference between the recorded amount and the program's approved per-member-per-month fee may reflect billing errors, delays, or payment adjustments for patients who disenrolled.
[c]The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the controls) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventative care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.
**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.
***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

designed and structured intervention, highly qualified staff, physician buy-in, and financial incentives aligned with program goals.

First, to generate net savings over a relatively short period, effective programs tend to target high-risk people. These people may include those with recognized high-cost diagnoses such as heart failure, but also those with prevalent geriatric syndromes such as physical inactivity, falls, depression, incontinence, misuse of medications, and undernutrition (Rector and Venus 1999; and Fox 2000).

Second, successful programs tend to have a comprehensive, structured intervention that can be adapted to individual patient needs. Key features include a multifaceted assessment whose end product is a written care plan that can be used to monitor patient progress toward specific long- and short-term goals and that is updated and revised as the patient's condition changes; and a process for providing aggregate- and patient-level feedback to care coordinators, program leaders, and physicians about patient outcomes (Chen et al. 2000). Another critical aspect is patient education that combines the provision of factual information with techniques to help patients change self-care behavior and better manage their care, as well as addressing affective issues related to chronic illness (Williams 1999; Lorig et al. 1999; Vernarec 1999; Roter et al. 1998; and Aubry 2000). Finally, successful programs tend to have structures and procedures for integrating fragmented care and facilitating communication among providers, to address the complexities posed by patients with several comorbid conditions, and, when necessary, to arrange for community services (Chen et al. 2000; Bodenheimer 1999; and Hagland 2000).

The third and fourth characteristics that have been associated with successful programs are having highly trained staff, and having actively involved providers. Strong programs typically have care coordinators who are baccalaureate-prepared nurses or who have case management or

community nursing experience. They also tend to have the active support and involvement of patients' physicians (Chen et al. 2000; and Schore et al. 1999).

Finally, periodic feedback during the demonstration period can motivate providers and care coordinators and enable the program to modify or intensify the intervention if it appears that it is not having the expected effect on intermediate or ultimate outcome indicators. Financial incentives can help to encourage physicians and program staff to look for creative ways both to meet patient goals and reduce total health care costs (Schore et al. 1999).

Program Strengths and Unique Features. Avera Research Institute's Helping Hearts program appears to possess many of the features associated with effective care coordination:

- The program targets patients hospitalized for CHF, a high-cost diagnosis; as a result, it has ***enrolled patients with high expected health care costs*** in the year before enrolling. About a third of these patients were enrolled within two months after hospital discharge, a time when these patients may benefit most from care coordination, service arrangement, and education and may be the most receptive to advice about self-care.
- Care coordinators administer a ***comprehensive, in-person assessment*** and use it to develop individualized care plans. To inform the care plan, care coordinators consult with the patient, the patient's caregiver, the patient's primary care physician, and other program staff. Care coordinators use the care plan to monitor telephone contacts and guide the patient toward his or her goals.
- The program ***monitors patients' daily vital signs*** using a telephonic home monitoring device. When a patient's vital signs are outside the parameters set by their physician, the care coordinator will contact the patient. Patients also receive telephone calls. Contact between care managers and patients following assessment is maintained primarily by telephone.
- The program's educational intervention focuses on teaching patients to be better self-managers and to communicate more effectively with their physicians. The ***disease-specific curriculum can be customized to the needs of individual patients*** and is supplemented with materials that address lifestyle issues and co-morbidities. Care coordinators assess whether patients have learned by examining ***trends in monitoring readings*** and responses to a CHF questionnaire and the SF-36.
- The program primarily facilitates communication and coordination among patients and their physicians by ***teaching patients to coordinate their own care***. Abnormal home-monitoring readings provide care coordinators opportunities to teach patients

when to contact their doctor, but also to alert them to adverse events. Care coordinators ***call the physician to update*** him or her when a patient's condition changes or an adverse event occurs, as well as ***send home monitoring trend reports*** regularly and before the patient's appointments. Care coordinators work with the patient to determine why adverse events occurred and to develop a plan that will prevent other occurrences.

- Helping Hearts' current care coordinators are ***baccalaureate-prepared registered nurses***, and all have extensive experience caring for and educating cardiac patients. Each care coordinator receives additional CHF patient education training during orientation.

- The program makes ***limited demands on physicians*** because it aims to support their medical management of patients. The program requires only that physicians approve patient participation, ***specify home-monitoring parameters, review home-monitoring trend reports and respond to patient-specific requests*** from the care coordinator. Care coordinators hold introductory conferences with physicians to promote cooperation and ask physicians how often they would like to receive home monitoring trend reports. Staff report anecdotally that physicians are satisfied with trend reporting and the services care coordinators provide their patients.

- The program seeks to ***improve physicians' prescribing of heart failure medications*** by performing a ***medication review*** for each treatment group patient when the patient enrolls in the program. The program provides physicians with these recommendations in a tactful manner to support their medical decision making. Although the program does not track whether physicians are making the recommended changes, staff report that a few physicians have changed their patient's treatment regimen in response to the medication review.

- Finally, while the program does not provide financial incentives to staff to achieve particular patient outcomes or program goals, it does ***reimburse physicians for reviewing the trend reports*** in the program by paying them $30 per month for each patient they have in the treatment group.

Potential Barriers to Program Success. The primary challenge of Helping Hearts is to enroll enough patients to achieve some economies of scale and still be able to demonstrate effects on outcomes. The program fell short of its year-one enrollment target; after two years, it has still not met its target despite making some changes to eligibility criteria. Initially, the program believed the shortfall resulted from a high number of patients being served by referring hospitals but living outside the service area and from the restrictiveness of requiring a primary diagnosis of CHF. However, tripling the number of counties in the program service area and

taking beneficiaries with primary *or secondary* CHF diagnoses helped only slightly. The program also noted a higher than anticipated patient refusal rate, both active and passive. The program's lack of data makes it difficult to determine the relative importance of these factors (or whether there is some other reason for the shortfall), although not having physicians more actively involved in encouraging patients to enroll (either by sending beneficiaries letters signed by physicians, or having physicians introduce the program to them during visits) likely contributed to the high refusal rate.

A second potential barrier to Helping Hearts' success is the absence of a formal process to collect and generate reports on patient outcomes (for example, patient self-care, clinical indicators, and adverse events) to help program administrators determine whether the intervention is attaining its broad objectives, such as increasing patient adherence. Such reports would also indicate whether particular procedures are working better than others and might suggest approaches to improving performance. Reports of patient outcomes could also provide valuable feedback to care coordinators. Although the program's Access database appears to track at least some of these outcomes, such as physicians prescribing of ACE inhibitors and beta blockers, the system is not equipped to generate formal reports. This problem grows as the program grows. As of early April 2004, the program had enrolled 271 treatment group members, more patients than a program can effectively monitor outcomes for without a good reporting system.

Plans for the Second Site-Specific Report. A second report covering Avera Research Institute's activities over the first two years of operation will be prepared in mid-2005. That report will focus more heavily on program impacts, estimated from both survey and Medicare claims data. It will describe changes made to the program over time, as well as the reasons for

those changes and staff impressions of the reasons for the program's successes and shortcomings.

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APPENDIX A

ADDITIONAL TABLES

TABLE A.1

DEMONSTRATION PROGRAMS PARTICIPATING IN THE EVALUATION

Host Organization	Organization Type	Service Area	Targeted Diagnoses
Avera Research Institute/Avera McKennan Hospital and University Health Center	Hospital	49 counties in South Dakota and 22 contiguous counties in Minnesota, Nebraska, and Iowa	CHF and related diagnoses
Carle Foundation	Integrated delivery system	11 counties in east central Illinois and 2 counties in west central Indiana	Heart conditions Diabetes Chronic lung disease
CenVaNet	Provider of care coordination services owned by hospitals and physicians	Richmond, Virginia, metropolitan area	Heart conditions Diabetes Chronic lung disease Cerebrovascular disease
Charlestown Retirement Community	Part of Erickson Retirement Communities	2 retirement communities in the Baltimore, Maryland, metropolitan area[a]	Heart conditions Diabetes COPD
CorSolutions	Provider of disease management services	Harris, Fort Bend, Bruzoria, and Montgomery counties, Texas (Houston area)	CHF
Georgetown University Medical School	Academic institution in partnership with Medstar, owner of Georgetown University Hospital and Washington Hospital Center	Washington, DC, and parts of Maryland and Virginia	CHF
Health Quality Partners	Provider of quality improvement services	Four counties in eastern Pennsylvania	Heart conditions Diabetes Asthma Moderate to severe hyperlipidemia or hypertension
Hospice of the Valley	Hospice	Maricopa County, Arizona (greater Phoenix)	CHF COPD Cancer Neurological conditions

TABLE A.1 *(continued)*

Host Organization	Organization Type	Service Area	Targeted Diagnoses
Jewish Home and Hospital Lifecare System	Long-term care provider, in partnership with the medical practices of St. Luke's and Mt. Sinai hospitals as referral sources	Manhattan and the Bronx, New York City	Heart conditions Diabetes Chronic lung disease Cancer Liver disease Stroke or other cerebrovascular disease Psychotic disorder Major depressive or anxiety disorder Alzheimer's or other cognitive impairment
Lovelace Health Systems	Integrated delivery system	Albuquerque metropolitan statistical area (Bernalillo, Valencia, and Sandoval counties in New Mexico)	CHF Diabetes
Medical Care Development	Consortium of 17 Maine hospitals hosted by a health services research organization	Rural areas of Maine	Heart conditions
Mercy Medical Center/North Iowa	Hospital	Rural areas of Iowa	CHF Chronic lung disease Liver disease Stroke Vascular disease Renal failure
QMed	Provider of disease management services	2 counties in northern California	CAD
Quality Oncology, Inc.	Provider of disease management services	Broward county, Florida	Cancer
University of Maryland Medical School	Academic institution	Baltimore, Maryland, metropolitan area, two counties in western Maryland, four in eastern Maryland, and two in Pennsylvania	CHF
Washington University School of Medicine	Academic institution in partnership with American Healthways, a disease management services provider	St. Louis, Missouri, metropolitan area	No specific diagnoses targeted[b]

TABLE A.1 *(continued)*

Note: Each program's service area and targeted diagnoses refer to its first year of operations.

Heart conditions may include congestive heart failure (CHF); coronary artery disease (CAD); atrial fibrillation; and ischemic, hypertensive, or other heart diseases. Chronic lung disease includes asthma and chronic obstructive pulmonary disease (COPD). Neurological conditions include stroke, Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis.

[a]Charlestown added a third retirement community in April 2003.

[b]Washington University uses an algorithm developed by its demonstration partner, American Healthways, to target Medicare beneficiaries who are likely to become clinically unstable and to require hospitalization during the next 12 months.

TABLE A.2

LIST OF DOCUMENTS REVIEWED FOR THIS REPORT

Avera McKennan Clinical Research Protocol, Helping Hearts Research Study, Protocol 001 (dated September 24, 2001, amended March 17, 2003)
"Heart Failure Research Study" presentation Powerpoint slides (delivered October 3, 2003)
Patient anecdotes provided by Avera staff (dated March 4, 2004)

APPENDIX B

METHODS USED TO ANALYZE PARTICIPATION AND PROGRAM IMPACTS

This appendix describes the methods and data sources used to analyze participation and treatment-control service use and reimbursement differences using Medicare data.

METHOD FOR CALCULATING PARTICIPATION RATE AND PATTERNS

We measured the proportion and types of beneficiaries attracted to the program by calculating the participation rate and patterns. The participation rate was calculated as the number of beneficiaries who met the program's eligibility criteria and actually participated during the first six months of the program's operations, divided by the number who met the eligibility criteria. The six-month window spanned 179 days, from June 4, 2002, through November 30, 2002. We explored patterns of participation by comparing eligible participants and eligible nonparticipants, noting how they differed on demographics, reason for Medicare eligibility, and costs and use of key Medicare services during the previous two years.

Approximating Program Eligibility Criteria

We began by identifying the program's eligibility criteria, reflecting CMS's insurance coverage and payer criteria for all programs and Avera Research Institute's (ARI's) specific criteria. CMS excluded beneficiaries from the demonstration who were not at risk for incurring full costs in the fee-for-service (FFS) setting because they (1) were enrolled in a Medicare managed care plan, (2) did not have both Part A and B coverage, or (3) did not have Medicare as the primary payer.

In addition to the Medicare coverage and payer requirements, ARI applied program-specific criteria to identify the target population. Table B.1 summarizes these criteria, which were approved by CMS and by the Office of Management and Budget (Brown et al. 2001). The program confirmed these criteria in spring 2003. The approved criteria differ slightly from a referral form used by the program's participating physicians. Table B.1 indicates the eligibility

TABLE B.1

ELIGIBILITY CRITERIA

Inclusion Criteria	Hospital admission for either (1) primary CHF (Class II, III, or IV) in the year prior to program startup, or (2) primary or secondary CHF anytime after the program started. ICD-9 Codes: 428, 428.1, 428.9, 440.9, 391.91, 402.91, 404.91, 404.93, 402.11, 402.01, 398.91, 429.1, 429.4, 242.9, 425.7, 404.01, 404.03, 404.11, 404.13, 785.50, 785.51
Exclusion Criteria	Meets any of these seven criteria: - Class I CHF - Severe psychiatric conditions - Senility/dementia - Life expectancy of less than 6 months - Lives in a nursing home - Renal Disease requiring dialysis - Under 65
Providers/Referral Sources	Avera McKennan Hospital, self-referral, Regional Cardiac Rehabilitation Program, Avera McKennan Home and Community Services, Avera McKennan physician clinics, other family practice clinics, cardiologists at North Central Heart Institute, Central Plains Clinic and USD University Physicians, Avera McKennan's Prestige Plus Seniors' Program
Geographic location	Original locations: 25 counties: Iowa: Clay, Dickenson, Emmet, Lyon, O'Brien, Osceola, Sioux Minnesota: Cottonwood, Jackson, Lincoln, Lyon, Murray, Lac Qui Parle, Nobles, Pipestone, Rock, Yellow Medicine South Dakota: Brookings, Lake, Lincoln, McCook, Minnehaha, Moody, Turner, Union CMS later approved an additional 22 counties (October 2002): Iowa: Plymouth South Dakota: Aurora, Beadle, Bon Homme, Charles Mix, Clark, Clay, Codington, Davison, Douglas, Deuel, Grant, Gregory, Hamlin, Hand, Hanson, Hutchison, Jerauld, Kingsbury, Miner, Sanborn, Yankton CMS actually approved 25 counties in October 2002 but ARI did not report 3 (Brule, Day, Tripp) to Mathematica in time for the data pull. In addition, ARI added 21 more counties in March of 2003, after the period analyzed for this report. March 2003 additions, 21 counties: South Dakota: Brown, Buffalo, Campbell, Edmonds, Faulk, Hughes, Hyde, Jones, Lyman, Marshall, McPhearson, Potter, Roberts, Spink, Stanley, Sully, Walworth Nebraska: Boyd, Cedar, Dixon, Knox

criteria as implemented by ARI. To be considered for the program's demonstration, beneficiaries must have had a hospital admission for either (1) primary CHF (Class II, III, or IV) in the year prior to program startup, or (2) primary or secondary CHF anytime after the program started. Along with the diagnosis criteria, at the time of enrollment beneficiaries could not: (1) have Class I CHF, (2) have severe psychiatric conditions, (3) have senility, (4) have a life expectancy of less than six months, (5) be a resident of a nursing home, (6) have renal disease requiring dialysis, or (7) be younger than 65.

We could approximate most of ARI's criteria using Medicare data with some exceptions that lead us to overestimate the actual number of eligible nonparticipants. We were unable to observe the complete diagnostic history for beneficiaries who had not been in FFS Medicare during the full two years before the 6-month enrollment window.[1] In addition, we did not limit eligible beneficiaries to people who had used specific hospitals or doctors who refer patients to the program, making our estimates potentially overstate the true number of people ARI would have approached about participating. We could not approximate five of ARI's exclusion criteria using Medicare data: (1) have Class I CHF, (2) have severe psychiatric conditions, (3) have a life expectancy of less than six months, (4) have renal disease requiring dialysis,[2] or (5) reside in a nursing home. To identify whether a beneficiary met the utilization (hospital admission) or exclusion criteria at any point during the 6-month enrollment window, we identified hospital discharges for the target diagnoses from May 1, 2001 and ending November 30, 2002. The estimates used the inclusion criteria approved by CMS and by the Office of Management and

[1]Among the 111 beneficiaries who enrolled in the first six months, who had valid Health Insurance Claim (HIC) numbers reported and who met CMS's insurance requirements at intake, 3.6 percent were enrolled in Medicare FFS 12 or less of the previous 24 months before they enrolled in the demonstration; 0.9 percent of participants were in FFS less than 6 of the 24 months before enrolling.

[2]This exclusion criteria was omitted because it was not included in criteria approved by CMS and by the Office of Management and Budget. It will be included in the second site specific report.

Budget, requiring a primary or secondary diagnosis of CHF over the entire time period. ARI actually required beneficiaries to have a hospitalization for primary CHF if the hospitalization occurred in the year before program startup (and allowed the hospitalization to be for a primary or secondary diagnosis after program startup). Finally, ARI did not report three counties (Brule, Day, and Tripp) to MPR in time for the data pull. Due to all of these differences, the estimates will overstate the number of eligibles.

Identifying Health Insurance Claim (HIC) Numbers and Records of Participants and All Beneficiaries

Medicare claims and eligibility data and data submitted by the program were used to identify participants and eligible nonparticipants. For all participants, we used the Medicare enrollment database (EDB) file to confirm the HIC numbers, name, and date of birth submitted by the program when beneficiaries were randomized. We identified potentially eligible nonparticipants by identifying the HIC numbers of all Medicare beneficiaries who were alive and living in the catchment counties during the six-month enrollment window. Initially, two years of Denominator records (2000-2001) and one year of HISKEW records (2002) were used to identify people living in the catchment counties at any time in the 2000-2002 period. HIC numbers of potentially eligible nonparticipants and all participants together formed a "finder file." The finder file was used to gather data on the beneficiary's state and county of residence during the 6-month enrollment period, as well as to obtain eligibility information from the EDB. Using this information, we limited the sample to people living in the catchment area at any point during the six-month enrollment window. This finder file was also used to make a "cross-reference" file to ensure that we obtained all possible HIC numbers the beneficiary may have been assigned. This was done using Leg 1 of CMS's Decision Support Access Facility. At the

end of this step, we had a list of HIC numbers for all participants, as well as all beneficiaries living in the catchment area during the six-month enrollment period.

Creating Variables from Enrollment and Claims Data

We obtained eligibility information from the EDB and diagnostic and utilization data from the National Claims History (NCH). All claims files were accessed through CMS's Data Extract System. At the end of June 2003, we requested Medicare claims from 2000 through 2002. We received all claims that were updated by CMS through March 2003. This allowed a minimum of a four-month lag between a patient's receipt of a Medicare-covered service in the last month we examined—November 2002—and the appearance of the claim on the Medicare files.[3]

Medicare claims and eligibility information were summarized as monthly variables from June 2000 through November 2002, for a total of 30 months. This enabled us to look at the eligibility status and the use of Medicare-covered services during any month in the two years before the program's start, to analyze participation in the first six months of program operation and to analyze treatment-control differences in Medicare service use and reimbursement following enrollment.

The EDB file provided us the information with which to construct measures of beneficiaries' demographic characteristics (age, sex, race), dates of death, original reason for Medicare entitlement, Medicare managed care enrollment, Part A and B coverage, whether Medicare was the primary payer, and the state buy-in proxy measure for enrollment in Medicaid.

[3]Occasionally, the HIC number in the cross-reference file was not in the EDB file that we used. Because data from the EDB were needed for the analyses, such beneficiaries were dropped from the sample. One reason for differences between the HIC numbers in the EDB and cross-reference files was that the two files were updated at different times. CMS created the cross-reference file using the unloaded version of the EDB, which was updated quarterly. We extracted data using the production version of the EDB, which was updated every night.

The Medicare claims data in the NCH files were used to construct measures of Medicare-covered service use and reimbursement by type of service (inpatient hospital, skilled nursing facility, home health, hospice, outpatient hospital, and physician and other Part B providers). When the services spanned months, the monthly variables were allocated based on the number of days served in that month as documented in the CLAIM FROM and CLAIM THRU dates. The length of stay for a month represented actual days spent in the facility in that month; costs were prorated according to the share of days spent in each month. Ambulatory visits were defined as the unique counts of the person-provider-date, as documented in the physician/supplier and hospital outpatient claims. Durable medical equipment (DME) reimbursements were counted in other Part B reimbursements. A small number of negative values for total Part A and Part B reimbursements during the past two years occurred for some of the demonstration programs. Any negative Part A and Part B amounts were truncated to zero. The few patients with a different number of months in Part A and Part B were dropped from the analysis of reimbursement in the two years before intake.

When we examined a beneficiary's history from the month during which they were randomized, we used the actual date of randomization for participants and a simulated date of randomization for nonparticipants, picked to be September 15, 2002, or roughly the midpoint of the six-month enrollment window.

Defining Eligible Nonparticipants and Eligible Participants

We used target criteria information to whittle the group of beneficiaries who lived in the catchment area down to those who met the program's eligibility criteria, which we could measure using the Medicare data. Tables B.2 and B.3 illustrate the exclusions used to identify the sample of eligible participants and nonparticipants used to analyze participation patterns.

TABLE B.2

SAMPLE OF ALL ELIGIBLE BENEFICIARIES FOR PARTICIPATION ANALYSIS

Sample	Number
Full Sample of Eligible Beneficiaries Who Live in Catchment Area One or More Months During the First Six Months of Enrollment	121,316
Minus those who:	
During 6-month enrollment period, either (1) were always in a Medicare managed care plan, or (2) never had Medicare Part A coverage, or (3) never had Medicare Part B coverage, or (4) Medicare was not primary payer during one or more months	–12,263
Did not have one or more of the target diagnoses on any claim during the two years before the program started or during the six-month enrollment window	–90,461
Did not have a hospitalization for the target condition from May 2001 through November 2002	–11,808
Met at least one of the exclusion criteria during the two years through November 2002	–762
Eligible Sample	**6,022**[a]

[a]Tables 2 and B.4 also exclude beneficiaries if they did not have a hospitalization between May 1, 2001 and intake (September 15, 2002, the midpoint of the six-month enrollment period, for eligible nonparticipants). This reduces the eligible sample to 5,604.

We identified 121,316 beneficiaries who lived in ARI's catchment area at some point during the first six months of enrollment (Table B.2). We then excluded 12,263 beneficiaries (10.1 percent) who did not meet the insurance requirements set by CMS for participation in the program during one or more months during the six-month enrollment window. Another 90,461 of the remaining beneficiaries (74.6 percent of all area beneficiaries) were dropped from the participation sample, since they were not treated for one or more of the target diagnoses the program identified as necessary for inclusion during the two years before the program began or during the first six months of enrollment. Sixty-three percent of the remaining beneficiaries (11,808 beneficiaries) did not meet the utilization requirement we measured (hospital admission) from May 1, 2001 through November 30, 2002 (which includes the period from May 2001 until

the end of the six-month enrollment window). Finally, 762 beneficiaries were identified as having at least one of ARI's exclusion criteria, leaving us with a sample of 6,022 beneficiaries we estimated would have been eligible to participate in ARI's program.

ARI randomized 116 beneficiaries during the first six months of operation (Table B.3). Of these, four (about 3 percent) could not be matched to their Medicare claims data due to problems with their reported HIC numbers and were therefore excluded from the participation sample.[4] ARI randomized seven beneficiaries who had addresses on the EDB that were outside its catchment area. We excluded these cases from the participation analysis to maintain comparability to the eligible nonparticipants sample. We also excluded one participant who did not meet CMS's requirements for participation in the program during the month of intake. All participants had at least one claim for a target diagnosis during the two years before the program began or the first six months of the program but four beneficiaries were dropped for not meeting the utilization criteria from May 2001 through November 2002. Lastly, no participants met any of the program's exclusion criteria during this time. Thus, among the 116 participants randomized by ARI into the program, after exclusions, 100 were included in the calculation of the participation rate as eligible participants.

ARI's participation rate for the first six months of enrollment is calculated as the number of participants who met the eligibility requirements (100), divided by the number of eligibles who live in the catchment area (6,022), or 1.7 percent.

[4]This number includes both beneficiaries with invalid HIC numbers reported and those whose claims we could not obtain when we extracted the files due to the way the Medicare files are created (described in footnote 3). Those with incorrect HIC numbers may well be eligible, but we could not obtain the Medicare data for them to assess that; so there were excluded. HIC numbers have since been corrected and those beneficiaries will be included in the final report.

TABLE B.3

SAMPLE OF ELIGIBLE PARTICIPANTS FOR PARTICIPATION ANALYSIS

Sample	Treatment Group	Control Group	All
Full Sample of Participants Randomized During the First Six Months of Enrollment	57	59	116
Minus those who:			
Had an invalid HIC number on MPR's enrollment file	–0	–4	–4
Not in geographic catchment area during the month of intake	–2	–5	–7
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–1	–0	–1
Did not have one or more of the target diagnoses on any claim during the two years before the program started or during the six-month enrollment window	–0	–0	–0
Did not have a hospitalization for the target condition from May 2001 through November 2002	–4	–0	–4
Met at least one of the exclusion criteria during the two years through November 2002	–0	–0	–0
Eligible Sample	**50**	**50**	**100**[a]

Note: The number of sample members reported as excluded at each point reflects *people in the previous line* who did not meet the additional eligibility criteria according to Medicare data. Thus, the table applied sequential criteria. The program actually used patient self-reports of diagnosis and service use. The total number of people who failed to meet a particular exclusion criterion may have been greater than the number reported in this table for program criteria that we could not fully assess using claims data (for example, reading level).

[a]Table B.4 also excludes participants who did not have a hospitalization between May 1, 2001 and intake. This reduces the number of eligible participants to 99.

Table B.4 describes the characteristics of the 99 participants who were enrolled by ARI during the first six months and who appear to meet ARI's eligibility requirements, as measured in Medicare data, and the 5,505 eligible nonparticipants.[5] Table B.4 is identical to Table 2 in the text, except that the sample of participants in Table B.4 has been restricted to the beneficiaries who meet the eligibility criteria according to Medicare claims data. Because more than 90 percent of the participants are included in this table, the results are similar to those in Table 2.

B. METHOD FOR CALCULATING TREATMENT-CONTROL DIFFERENCES

Sample sizes are too small, and the follow-up period too short, to estimate program impacts. Comparing the treatment and control groups on mean outcomes, however, provides an early indication of potential effects. The analysis draws on the data and the variables constructed for the participation analysis but is restricted to the program's participants (treatments and controls). The cost of the intervention was estimated as the amount CMS paid to ARI for the treatment group patients, using G-coded claims in the physician claims file.

Treatment – Control Differences

We used two approaches to estimate treatment-control differences in Medicare-covered service use and cost outcomes. First, we estimated differences over a two-month follow-up period for all people ARI randomized during the first four months of enrollment. The four-month enrollment window covers June 4, 2002 through October 1, 2002. The follow-up time

[5]Beneficiaries were identified as eligible when calculating the participation rate if they met the target criteria anytime during the six-month enrollment window. For the comparison of eligible participants and nonparticipants, we excluded beneficiaries if they did not meet the criteria before their intake date (fixed at three months after the program began enrollment (that is, the middle of the six-month window) for eligible nonparticipants).

TABLE B.4

CHARACTERISTICS OF ELIGIBLE PARTICIPANTS AND ELIGIBLE NONPARTICIPANTS DURING THE FIRST SIX MONTHS OF PROGRAM ENROLLMENT
(Percentages, Unless Otherwise Noted)

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
Age at Intake			
Average age (in years)	79.5	81.5	**
Younger than 65	0.0	0.0	
65 to 74	23.2	20.3	
75 to 84	54.6	42.8	**
85 or older	22.2	37.0	***
Male	46.5	41.2	
Nonwhite	2.0	1.4	
Original Reason for Medicare: Disabled or ESRD	6.1	8.2	***
State Buy-In for Medicare Part A or B	7.1	19.6	
Newly Eligible for Medicare (Eligible Less than Six Months)	0.00	0.02	
Enrolled in Fee-for-Service Medicare 6 or More Months During Two Years Before Intake	100.0	100.0	
Medical Conditions Treated During Two Years Before Month of Intake[b]			
Coronary artery disease	79.8	66.4	***
Congestive heart failure	97.0	91.7	*
Stroke	28.3	32.1	
Diabetes	46.5	33.3	***
Cancer	24.2	23.5	
Chronic obstructive pulmonary disease	66.7	52.1	***
Dementia (including Alzheimer's disease)	3.0	7.0	
Peripheral vascular disease	23.2	21.8	
Renal disease	22.2	16.8	***
Total Number of Diagnoses	3.9	3.4	
Days Between Last Hospital Admission and Intake Date[b]			
No hospitalization in past two years	0.0	0.0	
0 to 30	35.4	12.7	***
31 to 60	14.1	10.1	
61 to 180	29.3	30.5	
181 to 365	16.2	31.8	***
366 to 730	5.1	14.9	***

TABLE B.4 *(continued)*

	Eligible Demonstration Participants (Treatments and Controls)[a]	Eligible Nonparticipants	
0	2.0	1.4	
0.1 to 1.0	46.5	53.2	
1.1 to 2.0	25.3	28.5	
2.1 to 3.0	15.2	11.0	
3.1 or more	11.1	5.9	**
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[b]			
Part A	$1,067	$986	
Part B	$456	$393	
Total	$1,523	$1,376	
Distribution of Total Medicare Reimbursement per Month Fee-for-Service During One Year Before Intake[b]			
$0	0.0	0.1	
$1 to 500	15.2	28.4	***
$501 to 1,000	33.3	24.8	*
$1,001 to 2,000	26.3	24.7	
More than $2,000	25.3	22.0	
Number of Beneficiaries	**99**	**5,505**	

Source: Medicare Enrollment Database and National Claims History File.

Note: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is September 15, 2002, the midpoint of the six-month enrollment period examined.

[a]Participants who do not meet CMS's demonstration-wide requirements for the demonstration, or who had an invalid HIC number on MPR's enrollment file, are excluded from this table because we do not have Medicare data showing their reimbursement in the fee-for-service program. Members of the same households as the research sample members are included.

[b]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[c]Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001 would be captured in the measure defined by month of enrollment but not in the measure based on the day of enrollment.

*Difference between eligible participants and eligible nonparticipants significantly different from zero at the .10 level, two-tailed test.

**Difference between eligible participants and eligible nonparticipants significantly different from zero at the .05 level, two-tailed test.

***Difference between eligible participants and eligible nonparticipants significantly different from zero at the .01 level, two-tailed test.

covered the two calendar months after the month of randomization. For example, for a beneficiary randomized on June 25, we examined outcomes in July and August.

Second, we estimated treatment – control differences by calendar month over the first six months of ARI's enrollment to look at how cost-effectiveness might vary over the life of a program. One might expect programs to have little effect at first, since it takes time for patients to be assessed, the program to become fully functional, the patients to adopt case managers' recommendations, and these behavior changes to affect the need for health care. Analyzing costs by program month will allow us to examine such patterns. For each month from June 2002 through November 2002, we identified the patients who were enrolled in ARI's coordinated care program and analyzed their Medicare-covered service use. For example, a person randomized in June would be present in June through November, provided that person is eligible and alive in each month.[6] Someone randomized in July would not be part of the calculations for June but would be included in July through November, again provided that the person is eligible during those months.

The sample used to analyze treatment and control outcomes differs from that used to analyze participation. Like the participation analyses, we excluded from the analysis sample randomized individuals for whom we have an invalid HIC number, because we could not obtain their Medicare claims data. We also excluded those people who enrolled but were ineligible for the demonstration according to CMS's insurance criteria (as determined from data on the EDB). However, we also excluded beneficiaries flagged as a household member of a participant, since

[6]Patients were excluded as ineligible during months when we could not observe their full costs (when they were enrolled in a Medicare managed care plan for the full month).

they were not part of the research sample and thus were not used for the outcomes analysis.[7] Also, in contrast to the participation analyses, participants who did not meet the program's target criteria according to the claims and EDB data were not excluded from the outcomes analyses. Given this, of the 75 people randomized in the first four months of ARI's demonstration, the sample for analyzing treatment-control differences contained 71 people. For the six-month sample, 111, or 96 percent of the 116 randomized people, were included in the final sample (Table B.5). In addition to excluding beneficiaries, we excluded months during which we could not observe the beneficiaries' full costs in fee-for-service (described in footnote 5).

TABLE B.5

SAMPLES FOR TREATMENT-CONTROL COMPARISONS

	First Four Months	First Six Months
Number of beneficiaries who were randomized	75	116
Minus Those Who:		
Were members of the same household as research sample members	–0	–0
Had invalid HIC numbers on MPR's enrollment file	–3	–4
In a Medicare managed care plan, or did not have Medicare Part A and B coverage, or Medicare is not primary payer during the month of intake	–1	–1
Number of usable sample members	**71**	**111**

[7]Household members were excluded from treatment-control comparisons to keep the two groups balanced. Household members were assigned to the same experimental status to avoid the contamination that might occur if one person in the household was in the treatment group and another was in the control group. As a result, we expected to find fewer household members in the control group than in the treatment group, since household members have less incentive to join the demonstration if they know a household member has already been assigned to the control group and they will not receive care coordination.

Integrity of Random Assignment

Eligible applicants to the program were randomly assigned to the treatment or control group. To assess whether random assignment successfully produced treatment and control groups with similar baseline characteristics, we used two-tailed t-tests and chi-squared tests to compare the two research groups. Table B.6 presents the baseline characteristics for both the four-month and the six-month sample.

Under random assignment, we expect the treatment and control groups to have similar characteristics. Due to the small number of beneficiaries in both the four- and six-month samples, there were statistically significant differences in several baseline characteristics for the four-month sample: (1) the proportion of beneficiaries who were treated for diabetes in the two previous years, (2) the total number of nine medical conditions treated during the two years before intake, and (3) the proportion of beneficiaries in two of ARI's 47 county catchment area. For the six-month sample, there were also four statistically significant differences: the proportion of beneficiaries who were treated for diabetes in the two previous years and the proportion of beneficiaries in 3 of ARI's 47 county catchment area. We would expect some differences to occur due to the small samples and the number of characteristics examined. Thus, none of the differences in this small, early sample create any cause for concern.

Sensitivity Tests

To assess outcomes, we calculated Medicare-covered service use and cost in the two months after the month of randomization. For example, for an individual who was randomized in the month of June, we tabulated the individual's outcomes in July and August. To examine whether our results were affected by not including costs and services that occurred closer to the randomization date, we conducted a sensitivity analysis examining outcomes for three months—during the month the individual was randomized, as well as the two months after randomization

TABLE B.6

CHARACTERISTICS OF TREATMENT AND CONTROL GROUPS
IN THE RESEARCH SAMPLE ENROLLED DURING
THE FIRST FOUR MONTHS AND SIX MONTHS
OF PROGRAM ENROLLMENT

	Four-Month Sample			Six-Month Sample			
	Treatment Group	Control Group	Total Research Sample	Treatment Group	Control Group		Total Research Sample
Age at Intake							
Average age (in years)	79.2	79.3	79.3	79.7	78.6		79.1
Younger than 65	0.0	0.0	0.0	0.0	0.0		0.0
65 to 74	27.8	25.7	26.8	21.4	30.9		26.1
75 to 84	50.0	48.6	49.3	57.1	45.5		51.4
85 or older	22.2	25.7	23.9	21.4	23.6		22.5
Male	47.2	45.7	46.5	41.1	49.1		45.0
Nonwhite	0.0	2.9	1.4	1.8	1.8		1.8
Original Reason for Medicare: Disabled or ESRD	0.0	2.9	1.4	3.6	9.1		6.3
State Buy-In for Medicare Part A or B	5.6	5.7	5.6	8.9	5.5		7.2
Newly Eligible for Medicare (Eligible Less than Six Months)	2.8	0.0	1.4	1.8	0.0		0.9
Enrolled in Fee-for-Service Medicare Six or More Months During Two Years Before Intake	97.2	100.0	98.6	98.2	100.0		99.1
Medical Conditions Treated During Two Years Before Month of Intake[a]							
Coronary artery disease	82.9	77.1	80.0	78.2	78.2		78.2
Congestive heart failure	97.1	94.3	95.7	98.2	96.4		97.3
Stroke	34.3	22.9	28.6	27.3	27.3		27.3
Diabetes	57.1	34.3	* 45.7	56.4	36.4	**	46.4
Cancer	25.7	31.4	28.6	23.6	25.5		24.5
Chronic obstructive pulmonary disease	71.4	62.9	67.1	67.3	65.5		66.4
Dementia (including Alzheimer's disease)	2.9	2.9	2.9	3.6	1.8		2.7
Peripheral vascular disease	28.6	22.9	25.7	21.8	23.6		22.7
Renal disease	25.7	14.3	20.0	21.8	18.2		20.0
Total Number of Diagnoses (number)	4.3	3.6	* 3.9	4.0	3.7		3.9

TABLE B.6 *(continued)*

	Four-Month Sample			Six-Month Sample		
	Treatment Group	Control Group	Total Research Sample	Treatment Group	Control Group	Total Research Sample
Days Between Last Hospital Admission and Intake Date[a]						
No hospitalization in past two years	0.0	0.0	0.0	1.8	0.0	0.9
0 to 30	34.3	34.3	34.3	36.4	29.1	32.7
31 to 60	5.7	17.1	11.4	10.9	18.2	14.5
61 to 180	37.1	31.4	34.3	29.1	32.7	30.9
181 to 365	14.3	14.3	14.3	14.6	16.4	15.5
366 to 730	8.6	2.9	5.7	7.3	3.6	5.5
Annualized Number of Hospitalizations During Two Years Before Month of Intake[a,b]						
0	2.9	2.9	2.9	3.6	1.8	2.7
0.1 to 1.0	45.7	45.7	45.7	47.3	47.3	47.3
1.1 to 2.0	25.7	37.1	31.4	20.0	32.7	26.4
2.1 to 3.0	14.3	11.4	12.9	18.2	9.1	13.6
3.1 or more	11.4	2.9	7.1	10.9	9.1	10.0
Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]						
Part A	$907	$868	$888	$931	$1,140	$1,035
Part B	$437	$457	$447	$447	$480	$463
Total	$1,344	$1,325	$1,335	$1,378	$1,620	$1,499
Distribution of Total Medicare Reimbursement per Month in Fee-for-Service During One Year Before Intake[a]						
$0	0.0	0.0	0.0	0.0	0.0	0.0
$1 to 500	20.0	11.4	15.7	18.2	16.4	17.3
$501 to 1,000	34.3	37.1	35.7	32.7	32.7	32.7
$1,001 to 2,000	17.1	34.3	25.7	23.6	27.3	25.5
More than $2,000	28.6	17.1	22.9	25.5	23.6	24.5
Location During Program Intake Period						
Iowa						
Clay	5.6	2.9	4.2	3.6	1.8	2.7
Dickinson	5.6	5.7	5.6	5.4	5.5	5.4
Emmet	2.8	2.9	2.8	1.8	1.8	1.8
Lyon	5.6	0.0	2.8	3.6	0.0	1.8
O Brien	0.0	0.0	0.0	0.0	0.0	0.0
Osceola	0.0	0.0	0.0	0.0	0.0	0.0
Sioux	0.0	2.9	1.4	0.0	1.8	0.9
Plymouth (16740)	5.6	11.4	8.5	5.4	7.3	6.3

TABLE B.6 *(continued)*

	Four-Month Sample				Six-Month Sample			
	Treatment Group	Control Group		Total Research Sample	Treatment Group	Control Group		Total Research Sample
Minnesota								
Cottonwood	0.0	0.0		0.0	0.0	0.0		0.0
Jackson	0.0	0.0		0.0	0.0	1.8		0.9
Lincoln	5.6	0.0		2.8	3.6	0.0		1.8
Lyon	0.0	0.0		0.0	0.0	3.6		1.8
Murray	0.0	0.0		0.0	0.0	0.0		0.0
Lac Qui Parle	0.0	5.7		2.8	1.8	3.6		2.7
Pipestone	0.0	0.0		0.0	0.0	0.0		0.0
Yellow Medicine	2.8	2.9		2.8	1.8	3.6		2.7
Nobles (24520)	0.0	2.9		1.4	0.0	1.8		0.9
Rock	8.3	0.0	*	4.2	5.4	0.0	*	2.7
South Dakota								
Brookings	0.0	0.0		0.0	0.0	0.0		0.0
Lake	36.1	34.3		35.2	33.9	38.2		36.0
Lincoln	2.8	0.0		1.4	3.6	0.0		1.8
McCook	0.0	2.9		1.4	0.0	1.8		0.9
Minnehaha	0.0	0.0		0.0	0.0	0.0		0.0
Moody	0.0	2.9		1.4	1.8	1.8		1.8
Turner	2.8	0.0		1.4	1.8	0.0		0.9
Aurora	0.0	0.0		0.0	1.8	0.0		0.9
Beadle	0.0	0.0		0.0	0.0	0.0		0.0
Bon Homme	2.8	0.0		1.4	1.8	1.8		1.8
Charles Mix	0.0	0.0		0.0	0.0	1.8		0.9
Clark	0.0	0.0		0.0	0.0	0.0		0.0
Clay	2.8	2.9		2.8	1.8	1.8		1.8
Codington	0.0	2.9		1.4	0.0	1.8		0.9
Davison	0.0	0.0		0.0	0.0	0.0		0.0
Douglas	0.0	0.0		0.0	1.8	1.8		1.8
Deuel	0.0	0.0		0.0	0.0	0.0		0.0
Grant	0.0	2.9		1.4	0.0	1.8		0.9
Gregory	2.8	0.0		1.4	5.4	0.0	*	2.7
Hamlin	0.0	0.0		0.0	0.0	1.8		0.9
Hand	0.0	0.0		0.0	0.0	0.0		0.0
Hanson	0.0	2.9		1.4	0.0	1.8		0.9
Hutchinson	8.3	0.0	*	4.2	5.4	0.0	*	2.7
Jerauld	0.0	0.0		0.0	0.0	0.0		0.0
Kingsbury	0.0	0.0		0.0	1.8	0.0		0.9
Miner	0.0	2.9		1.4	0.0	1.8		0.9
Sanborn	0.0	0.0		0.0	0.0	0.0		0.0
Union	0.0	0.0		0.0	1.8	0.0		0.9
Yankton	0.0	0.0		0.0	3.6	0.0		1.8
Outside catchment area	2.8	8.6		5.6	3.6	9.1		6.3
Number of Beneficiaries	**36**	**35**		**71**	**56**	**55**		**111**

TABLE B.6 *(continued)*

Source: Medicare Enrollment Database and National Claims History File.

Notes: The intake date used in this table is the date of enrollment for participants. For eligible nonparticipants, the intake date is September 15, 2002, the midpoint of the six-month enrollment period examined.

Participants who do not meet CMS's demonstration-wide requirements, had an invalid HIC number on MPR's enrollment file, or were identified as a member of the same household as a research sample member were excluded from this table.

[a]Calculated among beneficiaries with six or more months in Medicare fee-for-service in the two years before intake. (See Note, above, concerning intake date definition.)

[b]Calculated as 12 x (number of hospitalizations during two years before month of intake) / (number of months eligible). For example, if a beneficiary was in fee-for-service all 24 months and had two hospitalizations during that time, they would have one hospitalization per year [(12 x 2) / 24]. If another beneficiary was in fee-for-service eight months during the previous two years, and had two hospitalizations during those eight months, they would have [(12 x 2) / 8], or three hospitalizations per year. The estimate of the proportion with no hospitalization in the two years before the month of intake may differ slightly from the proportion with no hospitalization in the two years before the date of intake because the two measure slightly different periods. Someone enrolled on September 20, 2003, whose only hospitalization in the preenrollment period occurred on September 5, 2003, would not be counted as hospitalized during the 24 months before the month of intake. Conversely, someone hospitalized on September 25, 2001, would be captured in the measure defined by month of enrollment, but not in the measure based on the day of enrollment.

ESRD = end-stage renal disease.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.

**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.

***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

(Table B.7). The results were largely similar to those for outcomes measured over the two-month period (text Table 4). The only difference is that Medicare reimbursements were lower for the treatment group than the control group when using the three-month period, and higher for the treatment group using the two-month period. In both cases, the difference was not statistically significant. Thus, the results are not sensitive to how the month of randomization is treated.

TABLE B.7

MEDICARE-COVERED SERVICE USE DURING THE MONTH OF RANDOMIZATION AND THE FOLLOWING TWO MONTHS FOR EARLY ENROLLEES

	Treatment Group	Control Group	Difference[a]	
Inpatient Hospital Services				
Any admission (percent)	33.3	42.9	–9.5	
Mean number of admissions	0.61	0.63	–0.02	
Mean number of hospital days	4.33	3.97	0.36	
Emergency Room Services				
Any emergency room encounters (percent)				
Resulting in admission	16.7	25.7	–9.1	
Not resulting in admission	13.9	17.1	–3.3	
Total	27.8	34.3	–6.5	
Mean number of emergency room encounters				
Resulting in admission	0.19	0.37	–0.18	
Not resulting in admission	0.17	0.26	–0.09	
Total	0.36	0.63	–0.27	
Skilled Nursing Facility Services				
Any admission (percent)	2.8	8.6	–5.8	
Mean number of admissions	0.03	0.11	–0.09	
Mean number of days	0.42	1.80	–1.38	
Hospice Services				
Any admission (percent)	0.0	0.0	0.0	
Mean number of days	0.00	0.00	0.00	
Home Health Services				
Any use (percent)	16.7	17.1	–0.5	
Mean number of visits	1.69	3.97	–2.28	
Outpatient Hospital Services[b]				
Any services (percent)	66.7	62.9	3.8	
Physician and Other Part B Services[c]				
Any use (percent)	100.0	100.0	0.0	
Mean number of visits or claims	17.4	18.7	–1.2	
Mortality Rate (Percent)	0.0	2.9	–2.9	
Total Medicare Reimbursement[d]				
Part A[e]	$3,329	$3,958	–$629	
Part B	$1,725	$2,157	–$432	
Total	$5,053	$6,115	–$1,062	
Reimbursements for Care Coordination[f]	$903	$0	$903	***
Number of Beneficiaries	**36**	**35**		

TABLE B.7 *(continued)*

Source: Medicare National Claims History File.

Note: Sample includes those enrolled during the first four months of program operations. Participants were excluded from this table if they had an invalid HIC number on MPR's enrollment file, were identified as a member of the same household as a research sample member, or did not meet Medicare coverage and payer requirements (defined as having Medicare as a secondary payer, being in Medicare managed care plan, or not having Part A and Part B coverage) during the month of randomization. Patient-months were excluded if the participant did not meet the above Medicare coverage and payer requirements that month or had died in a previous month.

"Percents with any medical encounter type" are the percent of treatment or control group members who have at least one encounter of a particular type; "mean numbers of medical encounter types" are the average number of encounters of a particular type per treatment or control group member.

[a]The direction of the treatment-control difference does not by itself signify whether the program is "effective." That is, for some outcomes a statistically significant negative difference (such as lower hospitalization rates for the treatment group than for the controls) suggests that the program is working as intended. However, a positive difference for other outcomes, such as number of physician visits, does not necessarily mean the program is ineffective or having adverse effects, because the program may encourage patients to see their physician more regularly for preventative care or to obtain recommended laboratory tests for their target conditions than they would have in the absence of the demonstration.

Due to rounding, the difference column may differ slightly from the result when the control column is subtracted from the treatment column.

[b]Includes visits to outpatient hospital facilities as well as emergency room visits that do not result in an inpatient admission. Laboratory and radiology services are also included.

[c]Includes diagnostic laboratory and radiology services (including pathologist and radiologist services) from nonhospital providers, suppliers and devices, mammography, ambulance, covered medications, blood, and vaccines.

[d]Does not include reimbursement for care coordination services provided by demonstration programs.

[e]Includes reimbursement for inpatient, skilled nursing facility, hospice, and all home health care (including that paid under Medicare Part B). Excludes reimbursement for care coordination services provided by demonstration programs.

[f]This is the average amount paid to the program as recorded in the Medicare claims data fro the month of randomization and the two following months. The difference between the recorded amount and three times the amount the program was allowed to charge per-member-per-month may reflect billing errors, delays, or payment adjustments for patients who disenrolled.

*Difference between treatment and control groups significantly different from zero at the .10 level, two-tailed test.
**Difference between treatment and control groups significantly different from zero at the .05 level, two-tailed test.
***Difference between treatment and control groups significantly different from zero at the .01 level, two-tailed test.

APPENDIX C

SELECTED PROGRAM DOCUMENTS

Physician referral form

Physician marketing letter and flyer

CHF questionnaire

Physician’s plan of care form

Assessment and care planning form

HomMed trend report

Medication review letter and form