Impacts of a Disease Management Program for Dually Eligible Beneficiaries

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The LifeMasters Supported SelfCare demonstration program provides disease management (DM) services to Florida Medicare beneficiaries who are also enrolled in Medicaid and have congestive heart failure (CHF), diabetes, or coronary artery disease (CAD). The population-based program provides primarily telephonic patient education and monitoring services. Findings from the randomized, intent-to-treat design over the first 18 months of operations show virtually no overall impacts on hospital or emergency room (ER) use, Medicare expenditures, quality of care, or prescription drug use for the 33,000 enrollees. However, for beneficiaries with CHF who resided in high-cost South Florida counties, the program reduced Medicare expenditures by 9.6 percent.

INTRODUCTION

Chronic medical conditions contribute disproportionately to increasing health care costs, morbidity, and mortality among Medicare beneficiaries. In 2001, while only one-half of all Medicare beneficiaries were treated for one or more chronic medical conditions, such as chronic obstructive pulmonary disease, diabetes, CAD, or CHF, this same group accounted for more than 95 percent all Medicare expenditures (U.S. Congressional Budget Office, 2005). Furthermore, numerous studies suggest that much of the high level of services used by beneficiaries with chronic illnesses would be unnecessary if physicians provided care consistent with evidencebased guidelines; patients practiced better self-care and adherence to recommended medication, diet, and exercise regimens; the numerous providers treating a patient with chronic illnesses communicated more clearly with each other and with the patient; and patients had adequate access to transportation, medications, and other social support services.

To address these issues, CMS has sponsored a series of demonstration programs for beneficiaries in the Medicare fee-forservice (FFS) program to test whether coordinated care or DM services can improve the quality of care and health of beneficiaries who have chronic health problems and whether they can reduce beneficiaries' health care spending. In 2002, CMS contracted with 15 small-scale programs to provide case management and DM services under the Medicare Coordinated Care demonstration. The programs each identified their own target population and intervention. Most of these programs enrolled fewer than 1.000 beneficiaries.

While these interventions provided CMS with valuable lessons on the promise of small scale, voluntary programs, some Federal policymakers sought to test population-based DM programs at a much larger scale, in a fashion similar to DM programs operating in the private sector. To this end, CMS initiated the Medicare Health Support (MHS) program to improve the quality of care and life for people living

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with multiple chronic illnesses. Eight MHS providers began operations between August 2005 and January 2006. Under this model, the programs are accountable for the outcomes of all beneficiaries in the assigned population, not only those who choose to engage with program staff.

Prior to MHS, CMS initiated a separate population-based demonstration, in January 2005, with LifeMasters as the program operator. The demonstration targets FFS beneficiaries who are enrolled in both Medicare and Medicaid (dual eligibles), reside in select Florida counties, and have CHF. CAD. or diabetes. Like MHS. this demonstration is large-scale and population-based. CMS prospectively identifies eligible beneficiaries, and those patients are randomly assigned to treatment and control groups (in a 5:2 ratio). LifeMasters receives a fixed monthly payment per treatment group patient and must reduce Medicare spending among its treatment group members relative to the control group by at least its fees or repay the difference to CMS, up to the full amount of its fees.

The LifeMasters program, which began 1 year before the MHS sites, provides important lessons from which newer initiatives can learn. Furthermore, the demonstration provides unique insights about the effectiveness of DM programs for improving quality of care and reducing Medicare expenditures for dually eligible beneficiaries with chronic illnesses, a particularly vulnerable and expensive group. The data presented here summarize an interim analysis of the effects of the LifeMasters demonstration program on both quality-of-care measures and Medicare service use and costs over the first 18 months of operation.

DESCRIPTION

LifeMasters began providing DM services in January 2005 to dually eligible beneficiaries in Florida who receive full Medicaid benefits (Table 1). As of September 2006, LifeMasters had enrolled more than 37,000 beneficiaries into its treatment group (Table 2).

Once randomized into the treatment group, a patient remains eligible if he or she continues to meet demonstration eligibility criteria. Patients in both the treatment and control groups who become ineligible after enrollment are disenrolled from the study and only their data for the months in which they were eligible are

Table 1

LifeMasters Supported SelfCare Demonstration Eligibility Criteria

At the time of enrollment, the following conditions must hold:

The beneficiary must be enrolled in both Medicare Parts A and B, and not be in a Medicare Advantage plan, other Medicare pre-paid health plan, or other Centers for Medicare & Medicaid Services (CMS) demonstration program.

Medicare must be the beneficiary's primary payer of medical services.

The beneficiary must have full Medicaid benefits.

The beneficiary cannot be enrolled in hospice care or classified as having end-stage renal disease (ESRD).

In the 12 months before enrollment, patients cannot have:

An inpatient psychiatric admission of more than 14 consecutive days.

Long-term nursing home residence.

An organ transplant.

During the followup period, patient observations are truncated at the end of the month when they first:

Fail to meet any of these eligibility criteria (with the exception of being classified as an ESRD patient and losing Medicaid eligibility). Move from the program's service area, as indicated in the Medicare enrollment files.

NOTES: All eligibility rules were assessed using Medicare claims or enrollment files. Long-term nursing residence is based on indicators provided by a CMS subcontractor, Fu Associates, showing that a beneficiary has been in a nursing home for at least 90 days. SOURCE: LifeMasters Supported SelfCare, San Francisco, CA. 2004.

included in the evaluation. Services are discontinued for disenrolled treatment group members, and the monthly fee payment to LifeMasters for them ceases. Control group members were not allowed to enroll in other CMS demonstrations while eligible for this program.

Once randomized into the treatment group. LifeMasters considers an eligible patient to be active unless he or she becomes ineligible or chooses to opt out of the demonstration or LifeMasters chooses to inactivate him or her for any reason (such as being unable to contact the patient, or patient's refusal to cooperate). Treatment group patients can opt out at any time, at which point they become inactive. LifeMasters does not receive any payment for inactive patients, but these patients remain in all analyses of program effects as long as they meet the program eligibility criteria. Only 8 percent of enrollees were inactivated during the first 18 months.

LifeMasters classifies active patients who are willing to participate fully in the intervention as mediated and patients who participate less than fully, but do not choose to opt out as instructional. Mediated patients participated fully by agreeing to accept telephone calls from LifeMasters nurse DM staff and measuring and reporting to LifeMasters their vital signs and symptoms. Instructional patients agreed only to receive a quarterly health magazine or an occasional telephone call from program staff. Through June 2006, one-third of enrollees were mediated for at least 1 month during their first 6 months of enrollment (Table 3). Thus, impacts of the demonstration are likely to be concentrated among this modest subset of active participants.¹

¹ Among patients enrolled through May 2005, mediated members differed from instructional ones on a number of characteristics, including age, race, disability, chronic medical conditions, and health care utilization. The intervention is primarily telephonic, but also has an in-person component. Specific DM services include educating patients about their medical conditions, helping patients adhere to physicians' treatment plans, and improving patients' self-care skills.

Staff

LifeMasters assigns each mediated patient his or her own nurse care manager because it believes that a patient becomes engaged, builds a relationship with the program, and learns self-care skills faster when he or she works exclusively with one nurse. This nurse remains the patient's care manager throughout their enrollment.² Nurses are responsible for assessing patient needs, providing patient education, and alerting physicians about important changes to patients' health. All of these care managers are registered nurses. These staff members are located in either the LifeMasters' San Antonio, Texas, nurse call center (nurse consultants), communicating with patients only by telephone, or in Florida (community nurses), meeting with patients in person as well as calling them.³ Patients classified as frail, based on a screening tool, are assigned a community nurse who visits them in their homes. Less frail patients are assigned a telephonic nurse consultant. LifeMasters also employs non-clinical staff to assist the nurses to collect patients' vital signs over the telephone and arrange ancillary community services for patients related to activities of daily living, such as meal delivery and home care services, as requested by nurses.

 $^{^2}$ LifeMasters reported that nurse turnover has been less than 5 percent since the start of the demonstration.

³ One-third of nurses who work with treatment group patients are community nurses while two-thirds are nurse consultants. Typical nurse caseloads are 150:1 for nurse consultants and 60:1 for community nurses.

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Months of Enrollment	Miami-Dade	Dade	Broward and Palm Beach	alm Beach	North Florida ¹	orida ¹	To	Total
	Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control
January to March 2005	5,200	2,103	Ι	Ι	Ι	Ι	5,200	2,103
April to June 2005	4,815	1,944	Ι	I	Ι	Ι	4,815	1,944
July to September 2005	193	76	4,466	1,787	2,357	950	7,016	2,813
October to December 2005	Ι	Ι	2,660	1,047	6,212	2,504	8,872	3,551
January to March 2006	Ι	I	230	91	7,134	2,837	7,354	2,928
April to June 2006	Ι	I	894	358	929	371	1,823	729
July to September 2006	1,287	515	Ι	Ι	706	283	1,993	798
Total	11,495	4,638	8,250	3,283	17,338	6,945	37,083	14,866

פ NOTE: Enrollees from April 2006-September 2006 were not included in analyses as we did not have adequate followup data for them at the time of this study. Urange, Seminore, and volusia. In

SOURCE: Mathematica Policy Research, Inc.: Data from LifeMaster's Enrollment File demonstration.

Number of Patients	32,555
Mean Number of Active Months per Patient	5.8
Mean Number of Months Mediated per Patient	1.5
Among the Mediated, Mean Number of Months Mediated Per Patient	4.4
Percentage of Patients Mediated	
) Months	67.0
to 3 Months	9.7
4 to 6 Months	23.3
Percentage of Patients with at Least 1 Contact (of Any Type)	79.8
Among Those with No Mediated Months	69.6
Among Those with 1 to 3 Mediated Months	99.9
Among Those with 4 to 6 Mediated Months	100.0
Mean Number of Contacts of Any Type, per Active Patient Month	1.1
Among Those with No Mediated Months	0.2
Among Those with 1 to 3 Mediated Months	1.4
Among Those with 4 to 6 Mediated Months	3.2
Distribution of Patients by Number of Contacts per Active Patient Month	
0	20.2
1 or Fewer	52.3
More Than 1, No More Than 3	16.3
More Than 3	11.3

LifeMasters Supported SelfCare Demonstration Progam Status and the Timing and Frequency of Contacts for Treatment Group Members in the First 6 Months of Enrollment

NOTES: Includes all patients enrolled through June 2008. The sample size is smaller here than for outcomes analyses because this table excludes people who were never activated by LifeMasters.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

Components

LifeMasters intervention components include patient assessment, care planning, routine nurse monitoring, patient self-monitoring, education, care coordination, and service arrangement. Unless otherwise noted, the descriptions of the LifeMasters intervention components refer to those activities, which are conducted only with mediated patients.

Assessment and Care Planning

LifeMasters uses patient assessments to determine health education needs and monitoring priorities for each patient. Assessments consist of asking enrollees disease-specific questions on symptoms, current medication use, recent utilization of medical services, and laboratory data (such as blood pressure, and cholesterol and HbA1c levels for diabetic patients). LifeMasters' initial assessment may be conducted in person or over the telephone. depending on how initial contact is made with each patient, and includes screens for frailty, cognitive ability, depression, and nutrition. After a nurse conducts an initial patient health history, the LifeMasters data system assesses the patient's level of clinical risk and develops an individualized care plan for the patient. When necessary, LifeMasters nurses also conduct reassessments as a part of routine monitoring. Thus, nurses could assess patients by telephone and in person over time.

Among active patients, 84 percent had at least one assessment contact after enrollment (not shown). Among those with assessment contacts, a much larger percentage were assessed via telephone (90 percent) than in person (53 percent) for enrollees enrolled during the first half of 2005. In each cohort, more than 50 percent of active patients with at least one assessment contact were assessed within 3 weeks of activation and about 70 percent within 6 weeks.

Routine Monitoring by Nurses

Registered nurses in the LifeMasters call center and in the community provide routine patient monitoring using tools designed by LifeMasters, with the frequency determined by patients' care plans. Nurses attempt to contact mediated patients as often as once a week and no less than every other week. as called for in the LifeMasters protocol, but LifeMasters staff report that some patients prefer less frequent contact. Instructional patients are contacted once per quarter. Typical monitoring tasks include collection of data from the patient, reassessment by the nurse, and followup of abnormal test results. These tasks are embedded in a data system designed by LifeMasters that prompt nurses to ask particular questions during monitoring calls; for in-person visits, nurses use hard copies of scripts.

About 80 percent of active patients received at least one contact in their first 6 months of enrollment. Patients had 1.1 contacts per active month, on average. The average number of contacts per month active was a function of the number of months in mediation. During each 6-month period we examined, enrollees with 4 or more months in mediation had 3.2 contacts per month, those with 1 to 3 mediated months had 1.4 contacts per month, and those with no mediated months had 0.2 contacts per month.

Patient Self-Monitoring

LifeMasters staff attempt to teach patients better self-management skills by instructing and encouraging them to monitor their health. LifeMasters expects patients to monitor and report certain vital signs, such as blood pressure, weight, and symptoms on a weekly basis. Patients can report these data either over the telephone (to a nurse, clinical service assistant, or LifeMasters' integrated voice response system) or via the Internet, though more than 90 percent report by telephone. If the nurse detects a clinical change that might present an immediate risk to the patient, the nurse will contact a physician. LifeMasters also provides patients with a variety of equipment and materials to assist them in monitoring their vital signs and symptoms.

Patient Education

Nurse case managers provide education to patients on the recognition of signs and symptoms of their disease; how to monitor vital signs; the cause of diseases; how to better adhere to diet, exercise, and medication regimens; and strategies to cope with chronic illness. When providing education to patients, nurses use predesigned scripts embedded in the LifeMasters data system that are geared towards educating patients on how to attain clinical goals.

Care Coordination

A primary component of the LifeMasters intervention is to teach patients how to

better communicate with their health care providers. (LifeMasters direct contact with physicians is relatively limited.) To accomplish this, nurses assist patients in preparing for physician office visits by encouraging them to ask questions about their care, to use journals provided by the program to write down questions for their doctors and document instructions from them, and to use medication lists to document the medications (prescription and over-the-counter) they use regularly.

LifeMasters reviews patients' self-reported medications use (including overthe-counter drugs) to confirm that drug utilization meets accepted clinical practice guidelines for CHF, CAD, and diabetes and patients are using the drugs properly. If LifeMasters identifies a problem with patient drug use (such as a potential drugto-drug interaction or poor adherence), the nurse contacts the patient's physician.

Service Arrangement

During the course of monitoring contacts, nurses may identify patients who need additional services beyond those provided by LifeMasters. Such services may include case management, safety assessments, transportation, meal delivery, spiritual care, and home health care services. Non-clinical staff will arrange for such services for patients, rather than simply referring them to an appropriate provider. LifeMasters will pay for meals, but does not pay for other services.

Program Redesign

As the second year of program operations came to a close, based on quarterly monitoring estimates of cost savings, Life-Masters negotiated with CMS to restrict its catchment area, beginning on March 1, 2007, to 7 of the original 11 demonstration counties—Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia. Furthermore, the redesigned target population includes only patients with CHF or two or more target chronic conditions (CHF, CAD, or diabetes). With the goal of increasing mediation rates to 30 percent by the end of 2007, LifeMasters reactivated 2.700 heart failure patients in the redesign counties who had been inactivated earlier.⁴ These beneficiaries were inactive anywhere from a few months to more than a year, depending on their enrollment month and initial level of engagement. The redesign also included many activities to increase mediation rates and intervention enhancements that were already under way.

METHODS AND DATA

The primary research sample included all beneficiaries enrolled as of March 2006 who met demonstration eligibility criteria at the time of enrollment, as noted in Table 1, regardless of whether they actively participated in the intervention, reflecting our intent-to-treat study design. Medical claims for services that occur during a patient's enrollment period are the only claims that are considered in constructing outcome measures.

Using data from the Medicare enrollment database and Medicare medical claims for January 2005-June 2006, we estimated program effects on hospital use (proportion with an admission and number of admissions), ER use (proportion with a visit and number of visits), and expenditures per member per month enrolled over the first 18 months of program operations. We also estimated impacts on these outcomes in the first 6 months, second 6

⁴ The program reactivated these enrollees because it believed that improvements to its engagement strategy would result in more mediated patients than earlier in the demonstration.

months, and first year after enrollment to examine changes in effects with the length of time enrolled, but focus primarily on the estimates for all enrollees over the full 18-month period of program operations. While some research has found that care coordination programs reduce readmissions during the 180 days after a discharge, those programs enrolled patients immediately after a discharge (Naylor et al., 1999; 2004). However, LifeMasters does not enroll patients exclusively at the time of a discharge.

We also evaluated a number of claimsbased quality-of-care measures in the first year of enrollment among patients enrolled through July 2005. Some of these outcomes, such as colon cancer screening or mammography, are general screening tests not specific to the targeted population in the program. Others are diseasespecific measures of the processes of care (for example, blood tests for lipid levels in patients with diabetes or CAD), or measurement of left ventricular ejection fraction in patients with CHF. Finally, we include adverse outcomes that are presumably preventable with high-quality outpatient care, such as hospitalizations for pneumonia or exacerbations of heart failure, or lower-extremity amputations in patients with diabetes. We also examined prescription drug utilization in 2005 using Florida Medicaid claims data in the first 6 months after enrollment for beneficiaries enrolled as of July 2005.

Using data obtained from a telephone survey of 613 enrollees (304 treatment and 309 control; conducted from July-November 2006), we also examined program effects on process of care, quality of life, adherence, and satisfaction with care measures across the treatment and control groups. The survey sample was selected from beneficiaries who enrolled in the LifeMasters program between May and October 2005. At the time they responded, beneficiaries had been enrolled from 10 to 19 months, with an average of 13.2 months.

To estimate program impacts on costs and health care utilization (ER and inpatient use), we conducted ordinary least squares regression for continuous variables and logistic regression for binary variables.⁵ We used a 0.05-significance level to test whether treatment-control differences were larger than are likely to be observed by chance. To examine whether or not the program had different impacts on beneficiaries who met its redesign criteria, we estimated treatment-control differences over the first 18 program months in average monthly Medicare expenditures for beneficiaries who met redesign criteria at enrollment. Independent variables used included treatment status, county at enrollment, age, sex, number and type of chronic medical conditions, Medicare disability status, race, ethnicity (Hispanic), pre-enrollment expenditures and hospitalizations, and number of providers in the vear before enrollment.

LifeMasters' large enrollment provides a high level of statistical precision for analyses. This precision can be misleading, however, because this is a populationbased program, meaning that impacts will be concentrated solely in the subset of the sample that actually receives the intervention. Thus, for example, we have 80 percent power to detect impacts on Medicare expenditures of \$98 per member per month (PMPM) enrolled over the first 18 months of program operations, or 5.4 percent of the control group mean (assuming two-tailed tests at the 0.05 significance level). However, if only one-third of the treatment group participates, the

⁵ Due to the small number of survey respondents, survey outcomes were not regression-adjusted. We also did not conduct regression analyses for quality-of-care outcomes.

real effect on these participants must be three times larger (about 16 percent of the control group mean) to be detectable with 80 percent power in our intent-to-treat analysis. Estimates for impacts on hospitalizations will be slightly less precise, with 80 percent power to detect effects of 6.9 percent of the control group mean for hospitalizations. Clearly, impacts on survey-based measures are measured with far less precision, given that only 613 patients were interviewed. For a binary outcome measure with a mean of 0.50, the minimum detectable effect with 80 percent power is about 11 percentage points, or 23 percent of the mean.

CHARACTERISTICS OF DEMONSTRATION ENROLLEES

LifeMasters enrolled an ethnically diverse mix of beneficiaries (Table 4), all of whom were dually enrolled in FFS Medicare and Medicaid. Among those enrolled through March 2006 (the first 15 months of program intake), about 30 percent of demonstration enrollees were age 65 or younger, and about 9 percent were age 85 or over. About one-third were male and just over one-half were White (non-Hispanic). Nearly one in five of enrollees were Hispanic. The mean number of months enrolled was 9.5 and one-quarter of enrollees were enrolled for more than 12 months.

Demonstration enrollees had multiple chronic medical conditions and were extensive users of Medicare Part B services. Three-quarters of all enrollees had pre-enrollment claims for three or more chronic medical conditions (out of the 15 that were defined for this analysis) in the 2 years before enrollment. The most common conditions included CAD (70 percent of patients), diabetes (64 percent), and chronic obstructive pulmonary disease (47 percent). Only 35 percent had CHF even though it was a primary target condition for the demonstration. Average Medicare expenditures in the 2 years before enrollment were \$1,250 to \$1,300 monthly, or more than \$15,000 annually; roughly twothirds of this was for Medicare Part B services. This is substantially higher than the average monthly cost of \$560 for all Medicare beneficiaries nationally in 2002 (Social Security Administration, 2005).

In general, the treatment and control groups were similar at enrollment, as one would expect for randomly assigned groups. The only statistically significant difference in pre-enrollment characteristics between the treatment and control groups was for Medicare expenditures. Treatment group members had average expenditures about 5 percent above those of the control group over the 2-year period preceding enrollment (\$1,309 for the treatment group, \$1,249 for the control group, p = 0.024). although neither the distribution of expenditures nor the number of hospitalizations was significantly different for the two groups (p = 0.471 and p = 0.840, respectively). To ensure that this preexisting difference did not lead to distorted estimates of program effects, we controlled for it in regression analyses.

INTERVENTION EFFECTS

Hospital Use

Over the first 18 months of program operations, treatment-control differences in the proportion of patients with a hospital admission and the average annualized number of admissions per year were small and not statistically significant (Table 5). The proportion with a hospital admission in the first year of enrollment was about 32 percent (not shown), modest for a population with these chronic medical

the LifeMasters Demonstration Through January 2006							
Characteristic	Treatment Group	Control Group	Treatment- Control Difference				
Demographic							
Average Age at Enrollment	68.4	68.4	-0.1				
Sex (Male)	33.9	34.0	-0.1				
Race							
White	55.3	54.7	0.6				
Black	23.9	24.3	-0.3				
Asian	1.5	1.5	0.0				
Dther ¹	19.2	19.5	-0.3				
Ethnicity (Hispanic)	17.0	17.5	-0.4				
Driginal Reason for Medicare—Disabled	43.4	43.1	0.4				
lumber of Months Enrolled Through June 2006							
Average Number	9.5	9.5	0.0				
6 Months or Less	29.2	28.9	0.3				
Nore Than 6 Months to 12 Months	44.8	45.1	-0.3				
Nore than 12 Months	26.0	26.1	-0.1				
Aedical Condition(s) at Enrollment							
Congestive Heart Failure (CHF) Only	4.2	4.2	0.0				
Coronary Artery Disease (CAD) Only	26.7	26.6	0.1				
Diabetes Only	24.2	24.2	0.1				
CHF + CAD	10.2	10.7	-0.5				
CHF + Diabetes	2.9	2.9	0.0				
CAD + Diabetes	19.2	19.0	0.2				
CHF + CAD + Diabetes	12.6	12.4	0.2				
Freated 2 Years Before Enrollment							
CAD	69.0	69.6	-0.5				
CHF	35.0	35.1	-0.1				
Diabetes	64.6	64.4	0.2				
Cancer	20.2	19.9	0.3				
Chronic Obstructive Pulmonary Disease	47.6	47.2	0.4				
Dementia (Including Alzheimer's Disease)	16.5	16.5	0.1				
Peripheral Vascular Disease	36.8	36.6	0.2				
Depression	26.3	27.1	-0.8				
Asthma	23.8	23.0	0.8				
lumber of Chronic Medical Conditions ²							
? or Less	27.0	27.2	-0.2				
3 or 4	34.8	34.8	0.0				
or More	38.2	38.0	0.2				
lumber of Patients	33,267	13,339	_				
lospitalizations							
Annualized Number 2 Years Before Enrollment ³							
Average	0.6	0.6	0.0				
	50.7 31.2	51.0 31.0	-0.3 0.2				
2 or More	18.1	18.0	0.2				
Had 1 or More in Each of the 2 Years Before Enrollment	15.7	16.3	-0.6				

Pre-Enrollment Characteristics of Treatment and Control Group Patients Randomly Assigned to the LifeMasters Demonstration Through January 2006

Refer to footnotes at the end of the table.

Table 4—Continued

Characteristic	Treatment Group	Control Group	Treatment- Control Difference
ER Use			
Annualized Number in the 2 Years Before Enrollment			
0	53.4	52.9	0.5
1	32.0	32.6	-0.5
2 or More	14.6	14.6	0.0
Had Visit in Year Before Enrollment	31.2	30.9	0.3
Expenditures Per Month in FFS During the 2 Years Before Enrollment			
Part A Medicare	\$456	\$443	\$13
Part B Medicare	852	806	46
Total Expenditures	1,309	1,249	59*
Medicare Expenditures per Month in FFS During the 2 Years Before Enrollment			
\$0 to \$250	26.4	26.7	-0.2
\$251 to \$500	18.3	18.2	0.0
\$501 to \$1,000	19.2	19.1	0.1
\$1,001 to \$2,000	17.8	18.5	-0.7
\$2,001 to \$3,000	8.2	8.0	0.2
More than \$3,000	10.1	9.5	0.6
Had Medicare Expenditures per Month in Top Quartile Both Years Before Enrollment ⁴	14.0	13.5	0.5
Physicians			
Average Number Billed in the Year Prior to Enrollment ⁵	12.2	12.1	0.2
Number of Patients	33,267	13,339	_

Pre-Enrollment Characteristics of Treatment and Control Group Patients Randomly Assigned to the LifeMasters Demonstration Through January 2006

* Difference between the treatment and control groups is significantly different from 0 at the 0.05 level, 2-tailed test.

¹ Other includes North American Native and other races.

² Chronic conditions measured included CAD, CHF, stroke, diabetes, cancer, chronic obstructive pulmonary disease, dementia, peripheral vascular disease, end-stage renal disease, depression, asthma, bipolar disorder, schizophrenia, coagulation disorders, sickle cell anemia, and HIV/AIDS.

³ Calculated as $12 \times (number of hospitalizations during 2 years before month of enrollment) <math>\div (number of months eligible)$. For example, if a beneficiary was eligible all 24 months and had 2 hospitalizations during that time, that beneficiary would have one hospitalization per year [(12×2) $\div 24$]. If another beneficiary was eligible 8 months during the previous 2 years and had 2 hospitalizations during those 8 months, that beneficiary would have [(12×2) $\div 8$], or 3 hospitalizations per year.

⁴ The quartile is calculated for the combined treatment and control groups in each year.

⁵ Calculated as the number of unique physician identification numbers.

NOTES: Percentages unless otherwise noted. FFS is fee-for-service. ER is emergency room.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

conditions. While 21 percent of all Medicare beneficiaries have a hospitalization in any given year (Centers for Medicare & Medicaid Services, 2007); among beneficiaries with CHF, the figure is typically about 40 percent (Kozak, Hall, and Owings, 2001).

ER Use

The proportion of patients with an ER visit was about 1 percentage point smaller for the treatment group than for the control group (26.6 versus 27.7 percent; p = 0.009). Though this difference is statistically significant, it suggests that the program's effect was very small. Furthermore, the estimated treatment-control difference in the average number of ER visits was not statistically significant at the 5 percent level (p = 0.084). For all other time periods examined (the first 6 months of enrollment, second 6 months of enrollment, and first year of enrollment), treatment-control differences in either the proportion of

Hospital and Outpatient Emergency Room Use, and Average Medicare Expenditures¹ Per Member Per Month Enrolled in the First 18 Months of LifeMasters Program Operations

Utilization	Treatment Group	Control Group	Treatment- Control Difference	Percent Difference	p-Value
Hospital Use					
Any Admission (Percent)	30.50	30.30	0.2	0.6	0.664
Average Annualized Number of Admissions per Year	0.71	0.71	0.0	-02.3	0.909
Outpatient Emergency Room Use					
Any Use (Percent)	26.60	27.70	-1.20	-4.2	0.009
Average Annualized Number of Visits per Year	0.54	0.57	-0.02	-4.7	0.084
Average Medicare Payments per Month in Fee-for-Service					
Part A	\$614	\$605	9	1.5	0.629
Part B	1,179	1,212	-34	-2.8	0.070
Total	1,793	1,818	-25	-1.4	0.365
Sample Size	33,267	13,339	_	_	_

¹ Regression adjusted.

NOTES: Observations are weighted according to the proportion of the followup period the sample member meets demonstration eligibility requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group. SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

patients with an ER visit or the average annualized number of ER visits per year were small and not statistically significant. Thus, impacts on ER use are at best very small.

Medicare Expenditures

Regression-adjusted Medicare expenditures PMPM over the first 18 program months for the treatment group were \$25 lower than control group costs, but this difference was not statistically significant (p = 0.365).⁶ To investigate the potential effect of outliers on our estimates, we calculated the treatment-control differences in trimmed means (with expenditures truncated at the 98th percentile). The treatment-control difference fell to \$7 and was not statistically significant (p = 0.742). Over the first 18 program months, the average monthly fee paid to LifeMasters per member month enrolled was \$162, so the program was far from cost neutral over this period.

To investigate whether or not the program had impacts on costs as it gained experience with enrollees, we estimated treatment-control differences in the first 6 months, second 6 months, and first year after enrollment (Table 6). Though treatment-control differences were not statistically significant for any of these periods, the trend suggested that impacts might be seen over a longer time period. For the months 7 to 12 after enrollment, average PMPM costs in the treatment group were 4.3 percent (p = 0.077) smaller than control group costs.

Patients with CHF are often regarded as the low-hanging fruit of DM programs; the target population for which favorable impacts are easiest for DM programs to demonstrate in a short time period. To test this hypothesis, we examined impacts on costs for patients with and without CHF who resided in the LifeMasters redesign region at enrollment. We chose this

 $^{^{6}}$ Unadjusted treatment-control differences in Medicare expenditures were essentially zero.

Average Medicare Expenditures¹ Per Member Per Month Enrolled in the First 6 Months, Months 7 to 12, and First Year After Enrollment in the LifeMasters Demonstration

	Number o	f Patients	Expenditures p per Month			
After Enrollment	Treatment Group	Control Group	Treatment Group	Control Group	Difference	<i>p</i> -Value
First 6 Months	28,871	11,602	\$1,627	\$1,632	-5	0.895
Months 7 to 12	10,891	4,389	2,356	2,464	-107	0.077
First 12 Months	11,530	4,642	2,288	2,372	-84	0.132

¹ Regression adjusted.

NOTES: Observations are weighted according to the proportion of the followup period the sample member meets demonstration eligibility requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group. Analyses include sample members enrolled early enough in program operations to potentially be observed for 6 or 12 months. For example, only patients enrolled in the demonstration on or before July 2005 were included in the first-year and 7-to-12-month results. Only patients enrolled by January 2006 were included in the 6-month results. The sample sizes for the first 12-month and second 6-month followup periods differ because some patients became ineligible (and hence were disenrolled) before the end of their 6-month of enrollment. The minimum detectable treatmentcontrol difference for the smallest sample is about \$171 at 80 percent power (assuming two-tailed tests at the 0.05 significance level). This is about 75 percent larger than for the entire research sample.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

subgroup of enrollees because their program experience was greater (12 to 18 months enrolled), on average, than enrollees outside of the redesign region (6 to 9 months enrolled) and because Medicare expenditures were much larger in this area, on average. Over the first 18 program months, average Medicare costs of the treatment group were nearly 10 percent lower (p = 0.008) than those of the control group among patients with CHF residing in the LifeMasters redesign catchment area at enrollment (Table 7). The treatmentcontrol differences for both Medicare Parts A and B services were about 10 percent of the control group mean. The absolute difference in costs (\$205) is 27 percent larger than the average monthly fee received by LifeMasters over the first 18 program months (\$162). Medicare expenditures of

Table 7	
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Analysis of Medicare Expenditures ¹ in the First 18 Program Months, for LifeMasters Enrollees
Residing in the Redesign Region at Enrollment, by Congestive Heart Failure (CHF) Status

Average Medicare Payments per Month in	Resides in Redesign Region at Enrollment		
Fee-for-Service	With CHF	No CHF	
Treatment	\$1,939	\$1,824	
Control	\$2,144	\$1,881	
Difference	-\$205	-\$57	
Percent Difference	-9.6	-3.0	
<i>p</i> -Value	0.008	0.207	
Sample Size			
Treatment	6,658	16,364	
Control	2,727	6,530	

¹ Regression adjusted.

NOTES: CHF is congestive heart failure. The seven Florida counties remaining in the redesign region are Alachua, Broward, Marion, Miami-Dade, Palm Beach, Seminole, and Volusia. Observations are weighted according to the proportion of the followup period the sample member meets demonstration eligibility requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group. Only patients enrolled by January 2006 were included in these analyses.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

the treatment and the control group were similar at the beginning of patients' enrollment periods and average monthly treatment group costs were not consistently smaller than control group costs until the fourth month after enrollment.

Quality-of-Care Outcomes

While LifeMasters had no overall impact on costs or utilization in the 18-month period examined, it may have been the case that intermediate outcomes would show some improvements in the quality of care received by enrollees, which could in time yield reductions in hospitalizations and costs. Furthermore, some policymakers might argue that if improvements in quality of care were sizable, expenditures for the program might be justifiable, even if no savings were generated. Thus, we examined a range of claims-based outcomes for evidence that disease-specific outcomes were better for treatment group members than for controls. In the first vear after enrollment, there were no significant treatment-control differences in 27 claims-based quality-of-care measures (Table 8), despite the fact that there was substantial room for improvement. For example, in both groups, only about 62 percent of patients with diabetes received HbA1c tests and less than one-half of these patients had claims for blood glucose self-monitoring supplies.

Satisfaction with Care Outcomes

In addition to claims-based measures, we examined a number of survey based outcomes that provide information on how the intervention was affecting patients' behavior, perceptions of care quality, and quality of life. For example, significantly more treatment than control group members reported that that a nurse, disease manager, or social worker helped them to arrange care (34.6 versus 21.2 percent, p < 0.001). In addition, among enrollees who needed help with transportation (about one-half of all enrollees), treatment group members were more likely to report that they received such help than control group members (85.1 versus 73.9 percent, p = 0.014). However, as noted on Table 9, there were no differences for other process-of-care measures, including those for educational activities that one might expect the program to pursue. Among survey measures of quality of life, adherence, and satisfaction with care, there virtually were no treatment-control differences (Table 10).⁷

Prescription Drug Utilization

To examine effects on prescription drug use, we constructed 15 general measures of and 23 disease-specific measures of prescription drug utilization (not shown). Across all of these outcomes over the first 6 months after enrollment. there were only two significant treatment-control differences, which suggests that these differences may be due to chance rather than to program impacts.⁸ In the first 6 months after enrollment, the proportion of treatment group members with one or more pharmacy claims is slightly, but significantly, larger than the proportion in the control group (91.6 versus 90.4 percent. p = 0.011). Despite the fact that all enrollees had CAD, CHF, or diabetes, use of clinically recommended cardiovascular medications, such as beta blockers, angiotensin-converting enzyme inhibitors. or statins, was not significantly different

 $^{^7}$ The measures on Tables 9 and 10 are a sample of more than 50 collected from survey respondents and representative of survey findings.

⁸ For this analysis, we only had access to 2005 pharmacy data. Our drug claims analysis was limited to patients enrolled through July 2005.

Claims-Based Quality-of-Care Measures in the First Year After Enrollment in the LifeMasters Demonstration

Measure	Treatment Group	Control Group	Treatment-Control Difference	<i>p</i> -Value
All Enrolled Patients				
Any Potentially Preventable Hospitalization ¹	9.9	10.7	-0.8	0.127
Preventive Care				
Colon Cancer Screening ²	6.7	6.7	0.0	0.994
Screening Mammography for Females ³	18.6	19.0	-0.4	0.625
Patients with Diabetes				
Number of Patients	7,476	3,012	—	_
Potentially Preventable Hospitalizations and Complications				
Any Cardiac Hospitalization ⁴	4.5	4.9	-0.3	0.470
Average Number Per 100 Patients	5.8	6.4	-0.7	0.352
Any Diabetes Hospitalization ⁵	2.2	2.3	-0.1	0.778
Average Number per 100 Patients	2.7	2.9	-0.2	0.735
Any Peripheral Vascular or Extremity Complication ⁶	28.7	28.6	0.1	0.928
Average Number per 100 Patients	38.1	37.5	0.7	0.693
Any Microvascular Complication ⁷	16.5	16.5	0.0	0.968
, ,	10.5	10.5	0.0	0.900
Preventive Care	F 7	1.0	0.0	0.000
Any Diabetes Education ⁸	5.7	4.9	0.8	0.093
Average Number of Diabetes Education Visits	0.5	0.4	0.1	0.094
Any Claims for Blood Glucose Self-Monitoring Supplies	47.8	46.7	1.1	0.331
Any Therapeutic Shoes	12.5	12.3	0.3	0.734
Any Eye Examination	62.1	62.3	-0.2	0.820
Any Podiatry Visit	38.1	37.1	1.0	0.356
Average Number of Podiatry Visits	1.3	1.2	0.1	0.413
Any Blood Test for Cholesterol or Lipids	80.7	80.6	0.1	0.898
Any Blood Test for Hemoglobin A1c (HbA1c)	62.6	61.5	1.1	0.320
Any Urine Test for Protein	16.2	16.5	-0.3	0.717
Patients with Congestive Heart Failure				
Number of Patients	4,168	1,700	—	—
Potentially Preventable Hospitalizations and Complications				
Any Hospitalization for Fluid/Electrolyte Problems ⁹	0.5	0.7	-0.2	0.410
Any Congestive Heart Failure Hospitalization	7.3	7.7	-0.5	0.557
Preventive Care				
Any Asessment of Left Ventricular Function	62.6	63.7	-1.0	0.461
Patients with Coronary Artery Disease				
Number of Patients	8,821	3,605	_	
Any Cardiac Hospitalizations	4.9	5.1	-0.2	0.710
Average Number of Cardiac Hospitalizations per 100 Patients	6.3	6.7	-0.4	0.535
Preventive Care				
Any Blood Test for Cholesterol or Lipids	80.6	80.7	-0.1	0.897

¹ Any hospitalizations for any of the conditions for which we search.

² Fecal occult blood testing, screening colonoscopy, sigmoidoscopy, or barium enema.

³ Females only: There were 2,757 control group members and 6,861 treatment group members.

⁴ Any hospitalizations for acute myocardial infarction, coronary artery bypass graft surgery, percutaneous transluminal angioplasty, or coronary artery stenting.

⁵ Any hospitalizations for diabetes with hyperosmolarity, diabetes with ketoacidosis, diabetes with other (non-hyperosmolar and non-ketotic) complications, diabetes with other (non-hyperosmolar and non-ketotic) coma, or diabetes without mention of complications.

⁶ Any hospitalizations or other services for femoral-bypass procedure, peripheral circulatory disorders, lower limb amputation, incision and drainage of bone cortex, skin and subcutaneous debridement for gangrene, cutaneous gangrene, leg cellulitis, diabetic arthropathy or neurological disorders, osteomyelitis, or incision and drainage below fascia.

⁷ Any hospitalizations, claims, or change in enrollment status for diabetic eye disease, laser treatment for diabetic eye disease, nephropathy, or new end-stage renal disease.

⁸ Any claims for individual or group diabetes outpatient self-management training services, or for education/training services, including diabetes diet training.

⁹ Any hospitalizations for hyperkalemia, hypernatremia, hypokalemia, hyponatremia, or other fluid/electrolyte problems.

NOTES: Percentages unless otherwise noted. Observations are weighted according to the proportion of the followup period the sample member meets demonstration eligibility requirements and is alive. Weights are normalized for treatment and control group members to sum to the number of observations in the group.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

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Table 9 Selected Process-of-Care Measures for LifeMasters Treatment and Control Group Members

Measure	Number of Patients	Treatment Group	Control Group	Difference	<i>p</i> -Value
			Perce	ent	
Service Arranging					
Nurse, Disease Manager, or Social Worker Helped Arrange Care	603	34.6	21.2	13.4	<0.001
Beneficiary Reported Being Able to Get Help With:					
Telephone	127	96.2	91.7	4.5	0.280
Transportation	316	85.1	73.9	11.1	0.014
Preparing Meals	212	89.0	87.2	1.8	0.695
Housework	372	79.6	78.5	1.1	0.789
Taking Medication	150	95.7	96.6	-0.9	0.785
Education					
Beneficiary Reported Being Taught How To:					
Follow a Healthy Diet	571	60.2	57.6	2.6	0.522
Exercise	548	49.6	46.5	3.1	0.466
Recognize Warning Signs to Seek Urgent Care	570	45.6	42.9	2.7	0.515
Among Those Reporting They Had Help From a Medical Professional Arranging Care, Beneficiary Received Material to Explain					
Condition or Treatment	182	66.1	37.7	28.4	<0.001

NOTES: Mean duration of enrollment of respondents was 13.2 months (range 10–19 months). Survey response rate was 71 percent.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

Table 10

Measures of Patient Quality of Life, Adherence, and Satisfaction With Care for LifeMasters Treatment and Control Group Members

Measure	Number of Patients	Treatment Group	Control Group	Difference	<i>p</i> -Value
			Percent		
Mental and Physical Health Status					
Primary Condition Interfered a Lot or Somewhat With Enjoyment of Life in the Last 4 Weeks	567	37.5	41.1	-3.6	0.379
Beneficiary Felt Primary Condition Placed a Burden on Family in the Past 4 Weeks	550	37.0	36.5	0.5	0.897
Beneficiary Felt Depressed About Living with Primary Condition in the Past 4 Weeks	572	39.8	38.6	1.2	0.766
Adherence and Health-Related Behavior					
Smoked in the Past 6 Months	613	16.1	15.9	0.3	0.930
Visited Doctor with List of Questions Most or All of the Time	582	50.5	43.1	7.4	0.073
Followed Healthful Eating Plan Most or All of the Time in Past 4 Weeks	502	66.8	68.2	-1.4	0.735
Exercised Regularly	579	50.9	54.4	-3.5	0.403

Refer to footnotes at the end of the table.

Table 10—Continued

induitiont and control aroup membere					
Measure	Number of Patients	Treatment Group	Control Group	Difference	<i>p</i> -Value
			Percent		
Satisfaction With Care Patient Ratings					
Providers Keeping in Touch with Each Other					
Excellent	559	36.9	34.6	2.3	0.575
Fair/Poor	559	13.6	12.1	1.5	0.602
Explanations of How to Take Medication					
Excellent	551	40.0	29.9	10.1	0.013
Fair/Poor	551	7.8	7.1	0.7	0.768
Explanations of Possible Side Effects					
Excellent	498	23.0	26.0	-3.0	0.434
Fair/Poor	498	20.6	18.0	2.6	0.469
Explanation of What to Expect from Conditions or Treatments					
Excellent	564	23.7	21.4	2.3	0.506
Fair/Poor	564	18.6	15.2	3.4	0.276
Explanation of Test Results					
Excellent	578	23.3	25.8	-2.4	0.496
Fair/Poor	578	14.8	13.6	1.3	0.659

Measures of Patient Quality-of-Life, Adherence, and Satisfaction With Care for LifeMasters Treatment and Control Group Members

NOTES: Mean duration of enrollment of respondents was 13.2 months (range 10–19 months). Survey response rate was 71 percent.

SOURCE: Esposito, D., Brown, R., Chen, A., Schore, J., and Shapiro, R., Mathematica Policy Research, Inc., 2008.

in the treatment group compared with the control group. However, 9 percent more (24.4 versus 22.4 percent, p = 0.018) treatment group members did have claims for non-statin antihyperlipidemic agents and other miscellaneous cardiovascular agents compared with the control group.

DISCUSSION

The evidence shows that the LifeMasters program had little overall effect on service utilization, cost, or quality of care outcomes over the first 18 months of program operation. However, estimates suggest that treatment group costs diverge from control group costs as the length of time since enrollment increases. The few scattered differences that are statistically significant and favorable to the treatment group (such as lower ER use and fewer enrollees taking no medications despite their serious chronic illnesses) are small, and not supported by similar treatment-control differences on related outcomes or other time periods. The only sizable treatmentcontrol difference appears among enrollees with CHF who reside in high-cost counties (defined by PMPM Medicare expenditures) around Miami.

In interviews we conducted, program staff indicated they felt that a number of unanticipated circumstances were responsible for the program's inability to improve health outcomes and reduce costs. Somewhat surprisingly, they reported neither the DM program LifeMasters had operated previously for the Florida Medicaid program nor its experience with commercial clients prepared the company for the volume of demonstration patients with low literacy, behavioral health problems, or the need for basic financial assistance. LifeMasters reported that they found these barriers to be particularly great for beneficiaries residing outside the Miami area. Furthermore, although staff anticipated that only some of the treatment group members in this population-based demonstration would be willing to work with program nurses (that is, become mediated), the actual mediation rate over the first 2 years (between 20 and 25 percent) was only about one-half of the expected rate. In part, this was due to difficulty locating a sizable proportion of the enrollees.

The results are still only for a relatively short period of time; it may well take longer than the average 9.5 months of exposure examined here. However, the low patient engagement rate does not bode well for the LifeMasters program or for other population-based DM programs for Medicare beneficiaries.

The 3-vear LifeMasters demonstration was scheduled to be completed by the end of 2007, but has been extended, based on some favorable trends in the data on the percentage of patients in mediation and favorable treatment-control differences for patients with CHF who reside in counties eligible for the redesign. During 2006, the program improved its rate of patient contacts (the percent of patients mediated in their first 6 months of enrollment rose from 9.3 to 18.2 percent over time: not shown) and increased the proportion of patients assessed within 6 weeks of enrollment (from 77.5 to 87.2 percent; not shown). In addition, the program has shown consistent evidence of favorable impacts on Medicare expenditures for members with CHF who resided in the redesign region. CMS and LifeMasters agreed to continue the demonstration for 1 year for the redesign population, with the possibility of extension for 2 additional years if the program continues to exhibit favorable effects for this group.

While these trends are favorable for this subpopulation, the simultaneous changes to the intervention and to the target population will make it difficult to determine which factor is responsible if any further growth in savings is observed for this subpopulation. That is, the concentration of effort on this subpopulation may enable the program to increase its effectiveness for them. Alternatively, impacts may grow simply because it takes longer exposure to the program to produce sizable effects. It is also possible that the difference observed for the redesign subgroup of the original target population is due to chance, since this subgroup was selected based on the observed favorable treatment-control differences over the first 21 months of operations. There are credible substantive reasons to think that this subpopulation may be the one for which true impacts are most likely to be achievable. and the treatment-control differences in expenditures did not begin to emerge until about the fourth month after enrollment. Furthermore, impacts might increase as the proportion of enrollees who are mediated and the average number of contacts per active enrollee rise. Nonetheless. it may still be true that LifeMasters has simply identified a subgroup of enrollees for which there is a chance treatment-control difference in expenditures and focused in on this group. As new enrollees are added to the demonstration during the extension period, no such favorable treatment-control difference would be expected to occur if the previous difference were due solely to chance.

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