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Clinical and Utilization Outcomes for a Heart Failure Care Support Program

A Matched-Cohort Study

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Abstract

Objective: To investigate the effect of a heart failure disease management program for patients ≥18 years of age enrolled in a commercial health plan.

Background: Disease management provides a framework for managing the chronic illness of large populations. Evaluating the comparative benefits of disease management program participation remains a central challenge for researchers, clinicians, and administrators. A growing consensus in the field of disease management is that more rigorous methodologies are required to assess program outcomes. However, many heart failure disease management programs have been evaluated by the use of non-experimental designs (pre-/post-methodologies), or matching and stratification methods that have been used with limited success.

Methods: To investigate the program effects of a heart failure care support program, we conducted a matched-cohort study on 521 participants using propensity scores. This methodology constructed matched samples of treated and control pairs for a wide range of observed characteristics and may reduce the bias in estimates of treatment effects to provide a relatively more accurate assessment of program outcomes. Administrative claims provided the source data for evaluating rates of hospitalizations, emergency department visits, and physician office visits. The study also included selected clinical indicators from administrative claims data to estimate the effects of program enrollment.

Results: Participants exhibited significantly fewer cardiac-related inpatient admissions and bed days compared with those for matched cohorts. A greater proportion of participants received cardiography testing and pneumococcal and influenza immunizations compared with matched cohorts. Participants experienced less use of medical services overall, suggesting that there were beneficial effects with monitoring and education for this group.

Conclusions: This study documents the beneficial outcomes of participation in a commercially delivered heart failure care support program. In those cases where controlled randomized clinical trials cannot be performed because of ethical, cost, or feasibility issues, the use of propensity scores provides an alternative for estimating treatment effects based on observational data.

Background

Chronic disease is the leading cause of illness, disability, and death in the US, affecting nearly 100 million Americans.[1] Heart failure alone affects nearly 4.9 million Americans, with another 550 000 newly diagnosed cases each year.[2] Although heart failure can occur in all people, its prevalence is highest in the elderly. Heart failure prevalence increases with age and approaches 10% of Americans >75 years old.[3] Because of the aging US population and increasing survival rates after diagnosis, the prevalence of heart failure is expected to increase 2- to 3-fold in the next decade[4,5] and remains one of the chronic diseases with the greatest morbidity and mortality rates.[6]

Currently, heart failure directly and indirectly contributes to approximately 285 000 deaths per year in the US.[2,7-10] Not only is it the number one cause of hospitalization for persons >65 years of age in the US,[11] considerable differences in efficiencies in care of heart failure, as measured by hospital length of stay, exist across hospitals. Despite treatment for heart failure, readmissions after discharge remain all too common, contributing to a poor quality of life. As such, the immense morbidity and mortality associated with

heart failure push medical costs in excess of $US20 billion per year.[7,12]

Although the costs of heart failure are high in terms of direct medical costs and quality of life, practical interventions exist for controlling and preventing many chronic conditions, including heart failure. Reducing risk factors is the most important part of any intervention aimed at reducing morbidity and mortality. Primarily, heart failure interventions must encourage smoking cessation, eating a low-fat, low-cholesterol diet, being physically active, effective treatment of hypertension, and use of effective medications, such as ACE inhibitors and β-adrenoceptor antagonists, all of which are currently underused in the treatment of heart failure.[13]

Heart Failure Disease Management

Disease management is an integrated, systematic approach to healthcare delivery that focuses on the population of patients with specific chronic diseases. These programs have the intended purpose of more effectively managing chronic conditions by providing printed educational materials on the chronic condition(s), Internet information, toll-free telephonic access for participants, and one-to-one consultations with a registered nurse. Information on a person's condition, associated comorbid conditions and potential complications related to disease management are used by physicians, nurses, and other healthcare professionals to more effectively support program participants.

One of the primary goals of disease management programs is to reduce, if not eliminate, unnecessary clinical visits through patient education and the use of clinical protocols. At the same time, disease management programs are designed to improve the quality of healthcare delivery. Ideally, these programs extend traditional approaches to healthcare cost containment by encouraging the improved coordination of care (e.g. physician care with pharmaceutical and institutional care), by maintaining a patient focus while providing all components of care and addressing caregiver issues.

To underscore the importance of disease management, in June 2000 the National Committee for Quality Assurance in the US announced its intentions to certify disease management programs. The intent of this certification process has been to help health plans, employers, and other groups determine which vendors will help them meet their goals of quality, accreditation, and overall health improvement.[14]

The aim of the current study is to investigate the health services utilization and clinical outcomes of a commercially delivered disease management program for patients with heart failure. Based on an analysis of administrative claims data, this study documents these outcomes up to a 15-month period following enrollment of members in the McKesson Heart Failure Care Support Advisor (HFCSA) Program.

Methods

Data Source

Under an agreement between Anthem Blue Cross and Blue Shield and McKesson Health Solutions, Anthem identified and referred high-risk members for enrollment into the McKesson HFCSA Program. The criteria used for this referral process included:

- health maintenance organization, point-of-service, and Medicare + Choice members who had an authorization for hospitalization where heart failure was one of the diagnoses;
- members from the above who were not engaged in a local heart failure program;
- members with heart failure who did not have a hospitalization;
- heart failure members at least 18 years of age with a valid phone number.

Anthem provides a population-based model of disease management for any health maintenance organization, point-of-service, or Medicare + Choice member with heart failure who agrees to participate in the Anthem Disease State Management Program. Members are identified either by disease-specific claims data, health risk assessment, or direct program referral, and are stratified for intervention based on comorbidity and hospitalization pattern. Educational mailings, immunization and health screening reminders, and pharmacy compliance education are provided and routinely evaluated for effectiveness. Members identified as noncompliant for health screenings receive additional educational mailings and automated voice messaging. In addition, high-risk heart failure members are offered the opportunity to participate in a telephonic education and monitoring support program.

Beginning in October 1999, McKesson registered nurses telephoned referred members to determine their interest in enrolling in the McKesson HFCSA Program. For the participants, McKesson Health Solutions customized a self-management intervention plan that included risk stratification, formal scheduled nurse education sessions, 24-hour access to a nurse counseling and symptom advice telephone line, printed action plans, workbooks, and individualized assessment letters, medication compliance reminders, vaccination reminders, and physician alerts about signs and symptoms of decompensation. In addition, physicians were notified of gaps between patient-reported practice and guideline recommendations.

Program coordination with physicians took place through letters, faxes, and phone calls. Communication was encouraged from the physicians back to the disease management nurse on recommendations for further counseling topics or clarification of patient-reported information. In addition, the disease management nurse communicated to the health plans' case managers for provision and coordination of plan benefit issues, such as durable medical

equipment procurement, mental health visit coordination, transportation difficulties, or financial barriers to adhering to physician recommendations. Communications to physicians and case managers occurred regularly. This was usually after each scheduled patient call. The interventions took place telephonically primarily in the participant's residence, though some participants did not have a telephone at home and a convenient community-based alternative was employed. The Agency for Health Care Policy and Research Clinical Practice Guideline, *Heart failure: evaluation and care of patients with left-ventricular systolic dysfunction*, published in 1994,[15] and the American College of Cardiology and the American Heart Association *Guidelines for the evaluation and management of heart failure*, published in 1995,[16] were the two principal guidelines used in the intervention.

In this retrospective, claims-based study, individual members were not identified by name or through the use of any additional information that would reveal identity. Medical and pharmacy claims data employed identification keys that were encrypted for all participants and nonparticipants. Participation in the McKesson HFCSA program was entirely voluntary, and all participants were notified of their right to opt out of the program at any time. Policies and procedures established at McKesson Health Solutions regarding data transfer, receipt, and analysis were compliant with The Health Insurance Portability & Accountability Act to protect the confidentiality and security of health data. Data transfer and analysis also adhered to a signed confidentiality agreement between Anthem Blue Cross and Blue Shield and McKesson Health Solutions.

As members participated in the HFCSA program, McKesson nurses administered telephonic surveys at 6 and 12 months to assess each participant's knowledge, behavior, and health status related to their heart failure condition. The improvement in patients' knowledge, behavior, and health status was expected to lead to changes in their medical service utilization. Following the receipt of administrative claims data covering the baseline and program periods, a matched-cohort study was conducted to evaluate group differences on selected clinical and healthcare utilization outcomes.

Study Population

Participants voluntarily self-selected program participation whereas nonparticipants did not complete a program enrollment because they could not be reached or chose to reject program participation. The Anthem referrals included 3149 members with heart failure. Participants were excluded according to various criteria, such as certain medical diagnoses and time enrolled in the plan (see Results section). A total of 521 participants remained in the analysis.

Clinical Assessment

Medical service utilization, prescription drug use, and procedures performed were determined from administrative medical and pharmaceutical claims. Medical service utilization included overall inpatient admissions and bed days, cardiac-related hospitalizations and bed days, overall emergency department visits, cardiac-related emergency department visits, institutional outpatient visits, and home health visits. Prescription drug use included ACE inhibitors, β-adrenoceptor antagonists, antihypertensives, diuretics, cardiac glycosides or antiarrhythmics, and antianginals. These drug classifications come from the US FDA and can be obtained at the FDA's website.[17] Procedures analyzed included glycosylated hemoglobin (HbA_{1c}) tests, lipid panels, influenza vaccination, pneumococcal vaccination, cardiography, echocardiography, cardiac catheterization, and myocardial imaging and perfusion. The Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes used in determining each category of procedures are listed in table I.

Study Design and Statistical Analysis

We used a 1 : 1 matched-cohort study design. The purpose of matching is to find a similar comparison group in terms of observable variables. For each disease management participant, a matched nonparticipant was chosen by matching on a propensity score.[18-22] Matching on a propensity score is a way of matching indirectly on many variables, instead of matching directly on each variable, which becomes increasingly difficult with added variables. A propensity score is a single variable comprised of the many variables for which a match is developed which tends to balance observed variables. As demonstrated by Rosenbaum and Rubin,[18] matching on a propensity score balances the many variables, in effect matching on all of those variables. Matching on a propensity score reduces a multivariate matching problem into a simpler univariate matching problem.

The regression equation used to generate a propensity score for participants and nonparticipants included demographic and comorbidity variables, medical services utilization, prescription drug use, and medical procedures. The independent variables in the equation included: gender, age, age ≥65 years, coronary artery disease (CAD) indicator, chronic obstructive pulmonary disease (COPD) indicator, hypertension indicator, diabetes mellitus indicator, inpatient visit indicator, inpatient length-of-stay, emergency department visit indicator, physician visit indicator, pharmacy prescription indicator, inpatient admission with heart failure as primary diagnosis, hospital length-of-stay where heart failure was primary diagnosis, emergency department visit with heart failure as primary diagnosis, cardiac-related inpatient admission, cardiac-related emergency department visit, number of inpatient readmis-

Table I. International Classification of Diseases (9th Edition) [ICD-9], Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes used to determine comorbidities and procedures performed

Variables	Codes
Comorbidities	
Coronary artery disease	First listed ICD-9 diagnosis in: 410.x, 411.x, 412.x, 413.x, 414.x, 433.x, 434.x, 435.x, 437.x, 440.x, 429.2 *or* CPT in 33530, 33542, 33572, 92996, 92975, 92977, 93940 *or* 33510 ≤ CPT ≤ 33523 *or* 33533 ≤ CPT ≤ 33536
Chronic obstructive pulmonary disease	Primary ICD-9 diagnosis between 491 and 496, inclusive *or* primary ICD-9 diagnosis in 493.2
Hypertension	Primary ICD-9 diagnosis between 401 and 405, inclusive
Diabetes mellitus	Primary diagnosis in 250.x or 357.2, 362.0, 362.01, 362.02, 366.41
Cardiac-related	Primary diagnosis in 428.x or 398.91, 402.01, 402.11, 402.91, 404.01
Procedures performed	
HbA_{1c} test	83036
Lipid panels	80061, 82465, 83718, 84478
Cardiography	93000 ≤ CPT ≤ 93278
Echocardiography	93303 ≤ CPT ≤ 93350
Cardiac catheterization	93501 ≤ CPT ≤ 93562
Myocardial imaging/perfusion	78414 ≤ CPT ≤ 78499
Influenza vaccination	90657, 90658, 90659, 90660, 90724, G0008
Pneumococcal vaccination	90669, 90732, G0009

HbA_{1c} = glycosylated hemoglobin.

sions, ACE inhibitor indicator, β-adrenoceptor antagonist indicator, antihypertensive indicator, diuretic indicator, cardiac glycoside indicator, antianginal indicator, α-adrenoceptor agonist/α-adrenoceptor antagonist indicator, HbA_{1c} test indicator, lipid test indicator, cardiography test indicator, echocardiography test indicator, cardiac catheterization test indicator, perfusion test indicator, influenza vaccination indicator, pneumococcal vaccination indicator, total medical claims expenditures, pharmacy claims expenditures, inpatient length-of-stay (squared), inpatient admissions (squared), total expenditures (squared), pharmacy expenditures (squared), and months in the program period. The variables race/ethnicity, renal function and blood pressure were not included in the propensity score because these measures were not present in the data sources used in the study.

Then, for each participant, a nonparticipant was chosen with the closest propensity score using the method of replacement as described by Dehejia and Wahba[22] whereby it is possible for a comparison group member to be selected more than once, which is beneficial in terms of bias reduction. The algorithm used for estimating the propensity scores in this study is outlined here.

1. Start with a parsimonious logit specification to estimate the score.

2. Statistical test: for all covariates, differences in means across treated and comparison units are not significantly different from zero.

a. If covariates are balanced between treated and comparison observations then stop.

b. If a covariate is not balanced with its comparison, modify the logit by adding interaction terms and/or higher-order terms of the covariate and re-evaluate.

The propensity score method of matching was used to find a suitable comparison cohort, which was similar at baseline to the treatment cohort. For every treatment cohort patient, a matched comparison cohort member with a history of heart failure was selected from nonparticipants, who were also members of Anthem. These members were matched according to a propensity score model based on demographic and comorbidity factors, medical service utilization, prescription drug use, and procedures performed. Nonparticipants were matched with participants based on an equivalent time period subsequent to the participants' program enrollment date. All treatment cohort patients who agreed to participate were enrolled in the McKesson HFCSA Program for a minimum of 3 months. Participants in the study could be enrolled up to a period of 24 months based on the length of their HFCSA program enrollment and corresponding plan eligibility. As shown

in table II, the average length of enrolment in the HFCSA program was approximately 15 months for the treatment group in the study period.

Once a comparison cohort was defined, variables were compared at baseline year to ensure the similarity of the two groups. Lastly, variables were compared during the program year between the two groups to estimate the treatment effects of the disease management program. The Kruskal-Wallis Test was used for comparison of variables between the treatment and comparison cohorts for both the baseline and program periods.

Table II. Baseline matching results for treatment cohort and matched cohort[a,b]

Factors	Treatment cohort	Matched cohort	p-Value
Demographics and comorbidities			
Number of people	521	521	NA
Average months enrolled in health plan (baseline)	11.8	11.71	0.115
Average months enrolled in health plan (study period)	14.9	15.3	0.153
% male	40.9	41.1	0.950
% >65 years of age	75.4	77.7	0.380
% with CAD	60.1	63.0	0.340
% with COPD	17.9	19.2	0.557
% with hypertension	51.2	53.4	0.495
% with diabetes mellitus	38.4	40.2	0.657
Medical service utilization			
Inpatient admits	394	401	0.603
Inpatient bed days	1585	1695	0.745
Institutional emergency room visits	277	291	0.768
Institutional outpatient visits	2780	2430	0.259
Cardiac-related inpatient admits	210	222	0.344
Cardiac-related inpatient bed days	878	978	0.437
Cardiac-related emergency department visits	28	28	0.329
Prescription drug use (% of patients)			
ACE inhibitor	40.5	39.9	0.850
β-Adrenoceptor antagonist	30.5	29.0	0.588
Antihypertensive	68.7	70.4	0.545
Diuretic	72.4	70.4	0.493
Cardiac glycoside or antiarrhythmic	31.7	30.3	0.639
Antianginal	37.2	35.5	0.562
Procedures performed (% of patients)			
HbA_{1c} test	26.1	27.4	0.624
Lipid panels	42.2	39.3	0.345
Cardiography	73.5	75.0	0.571
Echocardiography	43.8	45.3	0.618
Cardiac catheterization	20.9	23.4	0.333
Myocardial imaging/perfusion	25.1	24.0	0.666
Influenza immunization	50.5	49.7	0.804
Pneumococcal immunization	5.8	5.6	0.893

a Cohorts were matched using propensity scores.

b No statistically significant differences between cohorts at 10% level.

CAD = coronary artery disease; **COPD** = chronic obstructive pulmonary disease; **HbA_{1c}** = glycosylated hemoglobin; **NA** = not applicable.

Table III. Exclusion criteria

Exclusion	Treatment cohort	Matched cohort
Program report	Not listed as deceased, does not have condition, or medical exclusion in program report	NA
Treatment participation	<90 days of participation	NA
Cancer	If principal ICD-9 diagnosis was between 140 and 208.91 inclusive	Same as treatment cohort
AIDS	First listed ICD-9 diagnosis = 042.x, 279.x, 031.0	Same as treatment cohort
Transplants	If principal diagnosis in V42.4, V42.81, V42.1, V42.89, V42.0, V42.7, V42.6, V42.9, V42.89, V42.83, V42.82, 996.8 *or* CPT in (33935, 33945, 92997, 92998, 50340, 50360, 50365, 50370, 50380, 47135, 47136, 38230, 38231, 38240, 38241, 00580, 32850, 32854, 32852, 32851, 48160, 48550, 48554, 48556, 54680) *or* (50300 ≤ CPT ≤ 50320)	Same as treatment cohort
Renal failure/dialysis	If principal ICD-9 diagnosis was between 584 and 586, inclusive *or* principal ICD-9 diagnosis in 403.x *or* CPT in (36145, 90935, 90937, 90997, 90989, 90993, 90999) *or* (90918 ≤ CPT ≤90925) *or* (90945 ≤ CPT ≤90947)	Same as treatment cohort
SNF	Place of service listed as SNF or hospice	Same as treatment cohort
Expired	Discharge status listed as expired	Same as treatment cohort

CPT = Current Procedural Terminology; **ICD-9** = International Disease Classification (9th edition); **NA** = not applicable; **SNF** = skilled nursing facility.

Results

Of 3149 Anthem members initially referred to the McKesson HFCSA Program, 1898 either could not be reached by telephone or actively declined enrollment. A total of 1251 agreed to enroll by completing an initial assessment. To minimize the influence of outliers, most notably those associated with severe and catastrophic illness, patients with a Skilled Nursing Facility/Hospice claim or who were identified as having end-stage renal disease, dialysis, transplants, AIDS, or cancer were excluded from the study. In an effort to assure the continuity of data and sufficient time for outcomes measurement, we excluded members from the study who did not have a minimum of 3 months of plan enrollment before and after enrollment into the HFCSA program. These exclusions resulted in a final study participant group of 521. A complete listing of exclusion criteria is shown in table III.

Table II indicates that the program participants and matched cohort patients were closely balanced at baseline. Factors such as gender and age, for example, exhibit no statistically significant difference between groups in the baseline period. Based on the matching methodology, the groups are very similar in terms of the factors listed for medical services utilization, prescription drug use, and medical procedures performed.

It should be noted that the baseline data presented in table II are included to indicate the degree of matching between the treatment and matched cohort groups prior to the program intervention. Caution should be used in comparing values at baseline with those in the program period since the time periods are not equivalent and the claims data used to match patients in the baseline period may be absent from administrative data captured during the program period.

Table IV provides a comparison of measured outcomes between the participants and nonparticipants in the program period. The McKesson HFCSA Program appears to have had a favorable impact on participants' utilization of health services. There was a statistically significant difference between the groups for cardiac-related inpatient admissions and cardiac-related inpatient bed days ($p < 0.05$). Procedures that were performed more often in the treatment cohort than in the matched cohort included influenza immunizations ($p < 0.01$), cardiography ($p < 0.05$), and pneumococcal immunizations (not significant). A statistically significantly greater proportion of persons in the matched cohort group underwent a cardiac catheterization procedure during the program period, possibly indicating that members in this group experienced more episodes of cardiac symptoms (e.g. fatigue, chest pain, dizziness, shortness of breath) than members of the treatment cohort. Moreover, the proportion of program participants using ACE inhibitors, antihypertensives, and antianginals during the program period was higher than that of the matched cohort group, although these differences were not statistically significant. Such differences in key medication usage, although small, may have contributed to the differences observed in utilization of medical services.

There were a total of 4779 completed telephone contacts between the nurse counselors and participants during the program study period, the purpose of which was to perform ongoing

Table IV. Analysis period results

Factors	Treatment cohort	Matched cohort	p-Value
Number of people	521	521	NA
Medical service utilization			
inpatient admits	304	352	0.108
inpatient bed days	1246	1433	0.059
institutional emergency room visits	339	360	0.455
institutional outpatient visits	2949	2997	0.983
cardiac-related inpatient admits	100	158	0.005
cardiac-related inpatient bed days	382	699	0.001
cardiac-related emergency department visits	32	46	0.124
Prescription drug use (% of patients)			
ACE inhibitor	37.2	33.4	0.195
β-adrenoceptor antagonist	34.9	35.5	0.846
antihypertensive	66.8	63.7	0.298
diuretic	69.7	70.4	0.787
cardiac glycoside or antiarrhythmic	28.6	29.4	0.785
antianginal	34.4	31.9	0.392
Procedures performed (% of patients)			
HbA_{1c} test	32.6	33.6	0.742
lipid panels	51.1	50.3	0.804
cardiography	73.9	67.9	0.035
echocardiography	39.5	39.7	0.950
cardiac catheterization	8.3	13.4	0.007
myocardial imaging/perfusion	24.6	25.3	0.775
influenza immunization	54.5	45.3	0.003
pneumococcal immunization	11.7	8.4	0.080

HbA_{1c} = glycosylated hemoglobin; **NA** = not applicable.

monitoring, semi-annual and annual assessments. On average, each member received and participated in eight calls during the program period. Overall, these positive outcomes suggest that program participants were being carefully monitored and that this group was likely benefiting from standard preventive measures that reduce heart failure-related complications and unnecessary medical service utilization.

Discussion and Limitations

The current study has described a program established between McKesson Health Solutions and Anthem Blue Cross and Blue Shield, an independent licensee of the Blue Cross and Blue Shield Association, to provide select members with the McKesson HFCSA Program. The program, which is based on a comprehensive and integrated approach to care, is designed to improve patients' self-management skills through monitoring, education, and counseling. Members who enrolled and participated in the McKesson HFCSA Program had one-to-one consultations with a McKesson registered nurse, including ongoing and regularly scheduled monitoring for early signs of problems. After an initial assessment, each participating member was supported by individualized care plans that included appropriate levels of counseling and intervention. Additionally, McKesson nurses conducted a telephonic survey at 6 and 12 months to assess each participant's knowledge, behavior, and health status related to his/her cardiac condition. Overall, the program is designed to improve members' quality of life, improve clinical outcomes, and reduce costs associated with managing heart failure.

Disease management of heart failure in the outpatient setting has become increasingly feasible as a result of multiple interventions. The pharmacological and non-pharmacological interventions and understanding of the pathophysiology of heart failure disease have allowed an increasing number of patients to be managed in an ambulatory setting.[23-28] It has been shown by several investigators that a multidisciplinary approach using disease management nurses, frequent office visits, and phone contact systems have had a positive impact and improved the quality of life, reduced hospitalizations, and overall cost of medical service utilization for patients with heart failure.[29-32]

While the outcome measures used in this study have focused on health services utilization and identifiable clinical procedures secured through administrative claims data, the education and counseling of participants has also likely affected the measured program outcomes. For example, we noted that, through self-reports at 6- and 12-month intervals, participants experienced positive outcomes in terms of self-monitoring and adherence to physicians' treatment plans. Diet, weight monitoring, and recognition of the signs of worsening heart failure are critical factors that are affected directly by the educational component of the McKesson HFCSA Program.

The prescription drug use findings for ACE inhibitors in this study are largely unexpected. Specifically, the percentage of participants and nonparticipants using this class of drugs in the program period is lower than anticipated. Drugs that are commonly classified as ACE inhibitors, such as lisinopril, enalapril, and captopril are classified in the FDA classification system as antihypertensives. As such, the reported value of approximately 70% for participants in the antihypertensive classification may reflect more accurately the actual ACE inhibitor usage.

Although most disease management programs for heart failure seem to be effective in reducing hospital length of stay or readmission rates,[33,34] the impact is not always statistically significant[35]

and success may be related to severity of illness and the existence of comorbidities.[11,36] This study examined the comorbid conditions of diabetes, hypertension, COPD, and CAD and matched for these factors across groups in the baseline period based on the use of propensity score estimation.

We believe this study adds to previous research of heart failure disease management outcomes by moving beyond traditional pre-/post-evaluations with patients serving as their own controls, or health center-related studies that focus principally on clinic-based interventions. The use of propensity scores to generate equivalent treatment and control groups in a naturalistic setting is relatively new in the field of health outcomes research. Previous studies that have used propensity scores for evaluation purposes have focused on clinic-based outcomes and selection bias.[37-42] To date, few disease management programs have been evaluated based on the use of propensity scores.[43,44]

Many demographic and clinical variables were chosen and used in the propensity score estimation to balance variables between each group. However, although matching on a propensity score tends to balance observed variables, it does not balance unobserved variables like random assignment of treatment and comparison group members. As such, important unobserved variables may lead to selection bias. It is unknown which variables may be important in influencing a person's decision to participate in a disease management program or which unobserved variables influence the observed treatment outcomes. If the variables associated with selection are unobserved, then the only study design capable of controlling for selection bias is the random trial methodology.

Because the initial pool of referred members from Anthem was identified as high risk, and additional selection criteria were used in an effort to minimize confounding (i.e. exclusion of those patients with a severe medical condition such as end-stage renal disease), the results may not be generalizable to excluded patients or to a population of all persons diagnosed with heart failure. Additionally, because members were selected from a commercial health plan, the results may not be applicable to members from federal- and state-funded programs such as Medicaid.

The nature of our study resulted in a relatively small sample of program participants (although the 521 participants included here are still greater in number than those reported in some other studies).[45-47] The small sample size may have contributed to substantial variation in medical utilization, and this may have caused the large differences between treatment and matched cohort groups. In addition, the measured outcomes of this study were based on a program period of up to 15 months following enrollment. Given the chronic nature and progression of heart failure, including the potential to have an impact on the condition over a longer time period, the outcomes of the program may not have been fully captured. Follow-up studies on both medical services utilization and economic outcomes are required to get a more accurate assessment of the intermediate- to long-term effects of the McKesson HFCSA Program.

Conclusions

In summary, we found that participants in this study experienced significantly fewer cardiac-related hospital admissions and cardiac-related bed days compared with a matched cohort group. A significantly greater proportion of participants than matched cohort patients had influenza vaccinations. In addition, there were fewer overall invasive medical procedures in the participant group (e.g. relatively fewer cardiac catheterization procedures coincident with more routine electrocardiogram tests or electrocardiographic monitoring). The effect of a higher immunization rate for participants and a higher proportion of participants using antihypertensive medications during the program period may have contributed to a favorable clinical impact on utilization. The inferences drawn from this study are strengthened by the use of a propensity-scoring methodology that has established comparable groups at baseline and reduced bias in estimating treatment effects based on the current observational data.

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