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# Does the Collaborative Model Improve Care for Chronic Heart Failure?

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**Background:** Organizationally based, disease-targeted collaborative quality improvement efforts are widely applied but have not been subject to rigorous evaluation. We evaluated the effects of the Institute of Healthcare Improvement's Breakthrough Series (IHI BTS) on quality of care for chronic heart failure (CHF).

**Research Design:** We conducted a quasi-experiment in 4 organizations participating in the IHI BTS for CHF in 1999–2000 and 4 comparable control organizations. We reviewed a total of 489 medical records obtained from the sites and used a computerized data collection tool to measure performance on 23 predefined quality indicators. We then compared differences in indicator performance between the baseline and postintervention periods for participating and nonparticipating organizations.

**Results:** Participating and control patients did not differ significantly with regard to measured clinical factors at baseline. After adjusting for age, gender, number of chronic conditions, and clustering by site, participating sites showed greater improvement than control sites for 11 of the 21 indicators, including use of lipid-lowering and angiotensin converting enzyme inhibition therapy. When all indicators were combined into a single overall process score, participating sites improved more than controls (17% versus 1%,  $P < 0.0001$ ). The improvement was greatest for measures of education and counseling (24% versus –1%,  $P < 0.0001$ ).

**Conclusions:** Organizational participation in a common disease-targeted collaborative provider interaction improved a wide range of processes of care for CHF, including both medical therapeutics and education and counseling. Our data support the use of programs like the IHI BTS in improving the processes of care for patients with chronic diseases.

**Key Words:** quality improvement, collaboratives, congestive heart failure

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More than 5 million patients in the United States suffer from chronic heart failure (CHF), making it one of the most common reasons for hospitalization and the cause of 300,000 deaths annually.<sup>1,2</sup> More than 5% of the annual health care budget in the United States is devoted to the treatment of this condition.<sup>2</sup> Pharmacologic treatment can prolong life and reduce the symptoms of CHF.<sup>3–7</sup> In addition, patient education—particularly with regard to the close monitoring of diet, weight, and exercise—can reduce hospitalizations.<sup>8</sup>

Despite the prevalence of CHF and the promise of treatment, there are significant gaps in the quality of care that CHF patients receive. Studies have shown that only 59% of discharged CHF patients have had their ventricular ejection fraction measured, a crucial diagnostic evaluation, and as few as 14% have received target doses of angiotensin-converting enzyme inhibitors (ACEIs), a mainstay of CHF treatment. Patient education is particularly problematic. As few as 6% of patients have received counseling about weight monitoring.<sup>9,10</sup>

Improving the quality of care for CHF patients has proven to be challenging. Nurse- or case manager-based CHF disease management programs have shown great promise but focus on controlling costs and reducing readmission rates as much as improving processes and outcomes.<sup>11–13</sup> Facility- or physician-based audit/feedback strategies have failed to improve quality indicators<sup>14</sup> and at best have modestly improved 30-day mortality rates.<sup>15</sup> In any case, CHF disease management programs are not commonly used among physician organizations. This may be the result of poor information technology infrastructures or insufficient external incentives<sup>16</sup> or, as social theories of provider behavior suggest, the

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lack of provider input in the construction of quality improvement interventions.<sup>17,18</sup>

In response to these challenges, researchers at the MacColl Institute have developed an innovative way of caring for patients with chronic disease, called the Chronic Care Model (CCM). It aims to foster productive interactions between prepared, proactive practice teams and well-informed, motivated patients. Provider roles, standards of care, and treatment aims are explicit and evidence-based. Care management is linked to a patient registry, which provides reminders, data collection, scheduling of care, and performance data to caregivers. Patients are supported through self-management education, participatory goal-setting, and written care plans.<sup>19,20</sup>

Implementing a multifaceted quality improvement program such as the CCM can be difficult for organizations that lack previous experience. Organizationally based, disease-targeted collaboratives have been advocated as a way to help providers share experience and rapidly learn how to improve quality at their home institution. One such effort is the Institute for Healthcare Improvement (IHI) Breakthrough Series Collaboratives (BTS). With funding from The Robert Wood Johnson Foundation and participating organizations, the IHI promoted the Chronic Care Model (CCM) in 3 BTS collaboratives.

Although the use of this collaborative method is widespread,<sup>21</sup> it has not undergone rigorous controlled evaluations. Previous evaluations have relied on data collected by the participating sites and historical controls, which are subject to potential biases.<sup>22–24</sup> One randomized trial in preventive care showed little effect.<sup>25</sup> Thus, we undertook an evaluation of the effect of the IHI BTS on quality of care for CHF patients in 4 different types of participating health care organizations using predefined quality indicators.

## METHODS

### Overview

We evaluated the effect of IHI BTS, a collaborative group training program designed to improve the quality of chronic disease care, on the overall quality of care for CHF patients in 4 organizations participating in the program and 4 comparable control organizations. We used a computerized chart abstraction tool to review medical records for patients at each site and measure performance on 23 CHF quality-of-care indicators. We then tested the effect of participation in IHI BTS by comparing differences in indicator performance between the baseline and postintervention periods for participating and nonparticipating organizations. The overall design of our study was quasi-experimental because of the difficulties inherent in recruiting sites for randomization at either the site or patient level in organizationally based quality improvement evaluations.<sup>26</sup> Further details of the

evaluation design and the collaboratives have been published previously.<sup>27</sup>

### Site Recruitment

All 14 sites participating in the IHI BTS Collaborative for Chronic Heart Failure from May 1999 to June 2000 were eligible for our study. Seven sites volunteered to participate, but 2 sites failed to recruit any patients in the baseline period and another site did not have access to combined outpatient and inpatient records. The remaining 4 sites included a private outpatient hospital cardiology clinic, a public hospital general medicine clinic, a health plan, and a cardiology physician group. For each of these sites, we identified control sites that had not participated in the collaborative but were otherwise comparable organizations with respect to structural characteristics reported by site leaders. For the 2 hospital clinics, the control sites included different clinics within the same regional hospital organization; for the health plan, a different region served as the control site; for the physician group, the control site was a nearby cardiology group. All participating and control sites received approval from their Institutional Review Boards to join the study.

### Collaborative Intervention

Provider teams from the participating organizations attended a series of 3 IHI national collaborative training sessions designed to promote rapid changes in CHF care based on the Chronic Care Model.<sup>19,28</sup> To participate in the training sessions, the organizations had to demonstrate leadership commitment and pay a \$12,500 fee. The teams consisted of a group leader (usually a physician) and a day-to-day manager (usually a nurse). During the training sessions, national CHF experts and experts in quality improvement guided the teams in studying, testing, and implementing systematic improvements in essential CHF care processes.

In the periods between the training sessions, the teams recruited other providers from their respective organizations to participate in rapid-cycle quality improvement interventions. The team representatives who had attended the learning sessions worked together for 12 months, sharing information on their progress via phone and email. Structural and process improvements spanned 6 areas: self-management support, delivery system redesign, decision support, information support, community linkages, and health system support. Participating organizations averaged 42 different change efforts each. Examples included the development of a patient registry, effective diagnoses emphasizing the measurement of ejection fractions, effective medication use emphasizing angiotensin converting enzyme (ACE) inhibition, regularly scheduled follow-up appointments, and patient education and activation for self-care. However, each team was free to implement specific quality improvement interventions as they

saw fit. Further detail on the types of changes is available at the project web site.<sup>29</sup>

### Patient Recruitment

All sites identified patients with CHF who had received care between July 1998 and August 2000. Consent procedures varied between the sites, with 2 participating/control site pairs requiring written consent and 2 requiring passive consent only. All 907 CHF patients were identified (430 from the participating sites and 477 from the control sites). Of these, 665 consented to medical record review. Two records could not be located; therefore, we abstracted data from 663 medical records (73% of the target sample), including 330 records from the participating sites (77%) and 333 from the control sites (70%). We only included patients who had received care at least once during the baseline period (July 1998 to May 1999) and at least once during the postintervention period (September 1999 to August 2000), as indicated in the medical record. A total of 74% of those with medical records, or 489 patients (261 from the participating and 228 from the control sites) met this criteria and formed our sample. Of these patients 301 completed a survey, and these patients form the sample for the sensitivity analyses on documentation of counseling and education. We allowed for a 3-month delay between the baseline and postintervention periods so that the organizations could begin to implement their reforms.

### Quality Indicator Development

We assembled a team of physicians and nurses with CHF expertise to help us determine which processes of care should be measured. After reviewing existing guidelines and lists of quality indicators,<sup>30–33</sup> the team selected indicators that were likely to be available in the medical record. In addition, we added a measure of patient activation (ie, evidence of goal setting or action plan in the medical record) since the Chronic Care Model emphasizes this aspect of care. A final list of 23 indicators (Table 1) was compiled a priori, and differences of opinion were resolved through group discussion. We categorized the indicators by function, including diagnosis, medication use, follow-up, and counseling.

### Data Elements

We operationalized each indicator into its component data elements for chart abstraction, including exclusions for indicated care. For example, ACEI are not indicated in patients with a Cr greater than 2.0 or when patients have noted previous allergic reactions, and such patients were excluded from the denominator of the ACEI indicator. We considered patients to be newly diagnosed only if this was noted in the medical record; We also assessed each medical record for the presence of comorbid conditions that might influence indicator performance, including diabetes, hypertension, coronary artery disease (CAD), hyperlipidemia, val-

ular heart disease, thyroid disease, alcohol abuse, renal insufficiency, and atrial fibrillation. We assessed other cardiac risk factors, such as age, gender, current smoking status, and family history of CAD in a first-degree relative younger than the age of 55 years. In addition, we collected all documented measurements of several intermediate physiological outcomes related to CHF care: serum lipid levels, anticoagulation levels and blood pressure. We assessed utilization patterns by counting visits to providers and hospitalizations. We did not use change in functional status as an outcome variable since it was unreliably documented in the medical records and not available in the survey on a longitudinal basis.

### Medical Record Abstraction and Survey

We developed a computerized tool into which the data elements were entered. We trained abstractors (nurses and medical record technicians) during a 3-day session, and provided them with detailed verbal and written instructions on rules for answering each question in the abstraction instrument. Abstractors were blinded to study group and question and used file transfer protocol (FTP) to send their completed records to a central data repository. We audited all records to ensure complete data entry. We identified a lead abstractor who performed a quality review of a 10% subsample of each abstractor's work; once the abstractors had met a specified quality standard, we reduced the number of quality assurance reviews. For initial reliability testing, we chose a random subsample of 25 records. We measured reliability by calculating kappa scores at the quality indicator level (range 0.64–0.78). Of a possible 25 months of observation, the duration of observed care (time between the first and last observed visit) in the participating and control sites was very similar (24.3 versus 23.7 months).

To test whether any increases in indicated educational activities were caused by increased documentation rather than improved performance, we surveyed a subset of patients about receipt of education and counseling approximately 10 months after the initiation of the BTS. Data elements matched 5 of the counseling quality indicators addressing medication, diet, exercise, water weight management and goal setting.

### Analytic Methods

All statistical tests were considered significant at a level of  $P < 0.05$ . We calculated indicator scores for each patient during the baseline and postintervention periods. For most indicators, scores were binary, that is, the patient either passed or failed the indicator. For 2 diagnostic indicators evaluating history taking and physical examination, patients received a score between 0 and 1 representing the proportion of required data elements identified in the medical record. We calculated aggregate indicator scores by function (ie, diagnostic, medication, follow-up, and counseling) as the total

**TABLE 1.** Baseline Processes of Care for CHF in Participating and Control Groups

Indicator	No. Participating	% Participating	No. Controls	% Controls	Adjusted P Value*
<b>Diagnostic indicators</b>					
Adequate history for new CHF diagnosis	16	39	12	38	0.94
Adequate physical exam for new CHF diagnosis	18	65	14	71	0.58
LVEF measured	261	65	228	65	0.72
Cr measured if on digoxin	57	93	52	89	0.33
BP measured >50% visits	179	85	165	83	0.65
LDL measured if CAD	136	59	139	58	0.85
<b>Medication indicators</b>					
ACEI for LVEF ≤40%	96	81	92	95	0.016
Beta blockade for LVEF <40%	139	55	134	55	0.83
Anticoagulation for atrial fibrillation	76	82	58	72	0.24
Lipid-lowering therapy for CAD	154	60	158	63	0.49
<b>Follow-up indicators</b>					
Electrolyte monitoring during ACE Rx	119	87	109	89	0.73
Electrolyte monitoring during diuretic Rx	116	89	117	88	0.83
Electrolyte monitoring on ACE initiation	51	53	44	41	0.29
Electrolyte monitoring on diuretic initiation	72	52	71	47	0.46
Visit within 4 weeks after discharge	84	73	73	77	0.54
<b>Counseling indicators</b>					
Medication counseling	261	21	228	18	0.48
Diet counseling	261	13	228	14	0.93
Exercise counseling	261	18	228	14	0.23
Smoking counseling	53	30	48	31	0.72
Weight loss counseling	261	12	228	12	0.14
Disease management counseling	261	20	228	19	0.60
Water weight management plan	232	2	219	1	0.33
Goal setting	232	1	219	4	0.03
<b>Outcomes indicators</b>					
BP <130/80 mm Hg post-MI or LVEF <40%	79	62	76	62	0.77
BP <140/90 mm Hg no MI and LVEF >40%	142	57	121	48	0.02
INR 20.0- 30.0 in atrial fibrillation	62	63	42	60	0.54
LDL <100 if CAD	93	38	99	34	0.25

\*Adjusted for age, comorbidity, gender, and site using logistic regressions.

ACE indicates angiotensin-converting enzyme; ACEI, angiotensin-converting enzyme inhibitor; BP, blood pressure; CAD, coronary artery disease; CHF, congestive heart failure; INR, international normalized ratio; LDL, low-density lipoprotein; LVEF, left ventricular ejection fraction.

score of indicators in the functional category divided by the number for which the patient was eligible. For the intermediate physiologic outcomes, we determined the baseline indicator scores by averaging all available values of the intermediate outcomes during the baseline period and the postintervention score by similarly calculating all available values during the postintervention period.

For most indicators and all aggregate scores, we compared the care that patients received before and after the intervention by using individual patients as their own baselines. We aggregated these “difference scores” and, in a series

of bivariate and multivariate models, examined the difference between these difference scores for the intervention and control groups. To allow for the clustering of scores within sites (eg, patients were treated by physicians who were members of a particular health care site), we used hierarchical regression models (SAS proc MIXED<sup>34</sup> for continuous outcomes, and the GLIMMIX Macro<sup>35</sup> for binary outcomes), with patients nested within sites. A few indicators were conditional on events, such as “follow-up visit within 4 weeks after hospital discharge.” Because few patients satisfied the condition in both periods, we compared average



performance on the indicator before and after on all who satisfied the condition. We calculated the Hosmer-Lemeshow goodness of fit test for all models. For comparisons between the participating and control sites, we presented unadjusted  $\chi^2$  p-values. For comparisons of performance scores and “difference scores,” we presented performance scores as unadjusted, but calculated significance levels using multilevel multivariate logistic regressions adjusting for age, gender, and number of chronic conditions.

Because the participating and control sites differed with regard to the number of newly diagnosed CHF patients, we also performed sensitivity analyses excluding these patients. Results were very similar, so we have reported only the complete results including newly diagnosed patients. We also performed sensitivity analyses for the counseling and education indicators using self-reported data from the subset of patients who completed the survey to test for documentation effects in the medical record. These took the form of logistic regressions comparing rates of receipt of counseling for 5 indicators represented in the survey data after adjusting for age, gender, number of chronic conditions, and clustering.

## RESULTS

Table 2 compares the populations from the 4 participating and 4 control sites. The number of medical records we abstracted ranged from 27 to 88 for the participating sites and from 30 to 72 for the control sites. Participating and control

patients did not differ significantly with regard to age, gender, ejection fraction, number of comorbid chronic conditions or cardiac risk factors, or number of provider visits or hospitalizations at baseline. The participating sites had a slightly higher number of newly diagnosed CHF patients (15% versus 8%,  $P = 0.01$ ).

Table 2 compares the performance of the participating and control organizations on the quality indicators at baseline. For both groups, baseline adherence to the diagnostic indicators was only fair: two-thirds of patients had documentation **that their left** ventricular ejection fraction **had ever been measured**, and only slightly more than half of patients with CAD had their LDL measured. Overall, compliance with medications was good in both groups. The use of ACEIs among patients with left ventricular ejection fraction  $\leq 0.40$  was lower among participating patients than controls (81% versus 95%,  $P = 0.02$ ), although it was quite high for both groups. Patients with atrial fibrillation also had high rates of anticoagulation therapy in both participating and control groups (82% versus 72%,  $P = 0.24$ ). Patients with CAD in both groups had lower rates of adherence to beta blocker and lipid-lowering therapy than for other medications, with no differences between the 2 groups. Both groups were also comparable in terms of follow-up and counseling, but participatory goal setting was quite low among both groups, particularly participating patients (4% versus 1%,  $P = 0.03$ ).

Table 3 depicts the change in performance on the indicators for the 2 groups from baseline to the postintervention periods. Documentation of left ventricular ejection fraction at any point in the patient's course improved substantially in both the participating and control patients (16% versus 13%); the magnitude of this improvement was similar in both groups. Measurement of LDL cholesterol improved slightly in the participating patients and declined somewhat in the control patients (4% versus -9%), but the difference was not significant ( $P = 0.089$ ).

Among the medication indicators, use of ACEIs increased 13% among participating patients and declined 5% among control patients ( $P < 0.001$ ). In addition, participating patients with CAD showed a greater increase in the use of lipid-lowering therapy compared with controls (7% versus 1%,  $P = 0.002$ ), although 1-third of patients in both groups remained untreated at follow-up. None of the 5 follow-up indicators showed significantly greater improvement in participating groups than in the controls. Improvements in intermediate physiologic outcomes (blood pressure control, anticoagulation and lipid levels), and hospitalization rates were not significantly different between the 2 groups.

In contrast to the relatively small differences between the participating and control groups for the diagnostic, medication, and follow-up indicators, we found very large improvements among the participating patients for the counseling indicators: on 7 of the 8 indicators, participating patients

**TABLE 2.** Baseline Characteristics of Participating and Control Sites

	Participating	Control	<i>P</i> Value
No. sites	4	4	
No. CHF patients	261	228	
Range of patients/site	27–88	30–72	
Median age (years)	67	66	0.16
Male	68%	64%	0.39
New CHF diagnosis	15%	8%	0.01
Most recent LVEF <40%	47%	48%	0.74
Most recent LVEF >40%	18%	16%	0.53
No LVEF ever recorded	35%	36%	0.88
Mean no. chronic diseases	5.9	6.1	0.36
Mean no. cardiac risk factors	4.4	4.4	0.84
Diabetes	38%	36%	0.73
Hypertension	83%	89%	0.06
Mean outpatient visits/year*	9.2	9.1	0.98
Proportion hospitalized/year*	35%	36%	0.88

\*One-year period before the baseline date.

CHF indicates congestive heart failure; LVEF, left ventricular ejection fraction.

**TABLE 3.** Absolute Differences in Processes of Care for CHF in Participating and Control Groups\*

Indicator	Participating Group		Control Group		Difference in Change P Value <sup>†</sup>
	Post-BTS (%)	Change From Baseline	Post-BTS (%)	Change From Baseline	
Diagnostic indicators					
LVEF ever measured	81	16	77	13	0.49
Cr measured if on digoxin	79	−3	72	0	0.65
BP measured	90	6	89	8	0.15
LDL measured if CAD	63	4	52	−9	0.089
Medication indicators					
ACEI for LVEF ≤40	93	13	87	−5	<0.0001
Beta blockade for LVEF ≤40	61	5	87	7	0.49
Anticoagulation for atrial fibrillation	74	−8	68	−5	0.11
Lipid-lowering therapy for CAD	66	7	64	1	0.0002
Follow-up indicators					
Electrolyte monitoring during ACEI Rx	36	−17	27	−14	0.95
Electrolyte monitoring during diuretic Rx	56	3	45	−1	0.61
Electrolyte monitoring on ACEI initiation	87	0	88	−1	0.72
Electrolyte monitoring on diuretic initiation	90	+1	87	−1	0.50
Visit within 4 weeks after discharge	72	−1	67	−9	0.38
Counseling indicators					
Medication counseling	44	24	17	−1	<0.0001
Diet counseling	46	33	11	−4	<0.0001
Exercise counseling	42	24	12	−2	<0.0001
Smoking counseling	25	−6	38	6	0.16
Weight loss counseling	42	30	7	−2	<0.0001
Disease management counseling	61	41	23	4	<0.0001
Water weight management plan	42	24	4	3	<0.0001
Goal setting	5	4	4	0	<0.0001
Outcomes indicators					
BP <130/80 mm Hg post MI or LVEF <40	59	−7	65	3	0.23
BP <140/90 mm Hg no MI and LVDF >40	52	7	58	10	0.25
INR 20.0–30.0 in atrial fibrillation	62	−2	62	−3	0.86
LDL <100 if CAD	50	12	40	5	0.71

\*Changes are presented as unadjusted absolute percentage differences from baseline.

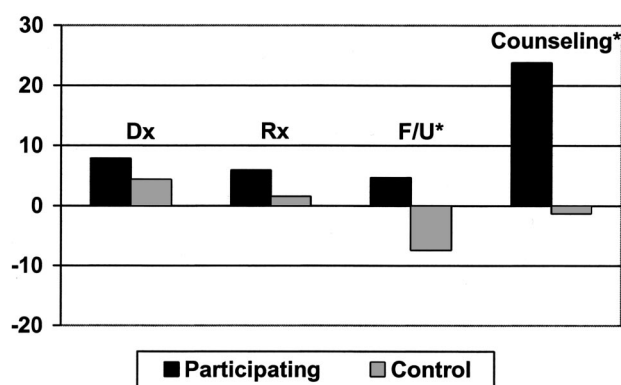
<sup>†</sup>Adjusted for age, gender, and number of chronic conditions using logistic regressions while clustering by site.

BTS indicates Breakthrough Series; BP, blood pressure; LDL, low-density lipoprotein; ACEI, angiotensin-converting enzyme; LVEF, left ventricular ejection fraction; CAD, coronary artery disease; MI, myocardial infarction.

showed significantly higher rates of improvement compared with the controls. Absolute rates of improvement for the participants ranged from 4% to 41%, although compliance for most indicators was still less than half. Smoking cessation

counseling was the only indicator for which participants did not show significant improvement over controls.

Adjusted hospitalization rates declined in both groups (35% to 28% in participating sites, as compared with 35%



\* $P < 0.05$

Dx indicates diagnostic indicators; Rx, treatment indicators; F/U, follow-up indicators.

**FIGURE 1.** Absolute % changes in participating and control sites by process indicator category.

to 30% in controls). However, the difference in this improvement was not statistically significant (7% versus 5%,  $P = 0.78$ ).

Figure 1 depicts the changes in the aggregate scores by function for the 2 groups, with significance levels adjusted for age, gender, number of chronic conditions, and clustered by site. Participating patients had insignificantly greater improvements in aggregate diagnostic scores (8% for participating versus 4% for control patients,  $P = 0.14$ ) and in aggregate treatment scores (6% for participating versus 2% for control patients,  $P = 0.08$ ). Improvement in aggregate follow-up scores was greater among participating patients compared with controls (5% versus -7%) and was even higher for aggregate counseling scores (24% versus -1%). When we combined all of the indicators into a single overall process score, participating sites showed significant improvement over controls (17% versus 1%,  $P < 0.0001$ ).

To investigate whether the observed increases in counseling performance was due to increased documentation in the medical record rather than improved performance, we compared self reported receipt of counseling in the post BTS period. Of the 7 counseling indicators for which there was a difference between participating and control sites in the medical record analyses, survey items address 5: medication, diet, exercise, and water weight counseling as well as goal setting. Adjusted results reveal that participating groups had higher performance in all.

## DISCUSSION

We found that organizations that participated in a disease-targeted collaborative provider interaction, namely, the IHI Breakthrough Series Collaborative based on the Chronic Care Model, significantly improved counseling and

education rates for CHF patients. Participation in the collaborative also improved rates for appropriate ACEI and lipid-lowering therapy, although the differences were less dramatic than for education and counseling. Baseline rates of ACE inhibitor use were quite high and education and counseling rates were very low, so there was greater opportunity for improvement in the latter set of indicators. Indeed, one possible explanation for the greater improvement in ACEI use in the participating sites was a lower baseline. The functional ceiling for ACEI and other indicators may be substantially less than 100%, and this may explain why control sites were unable to improve care dramatically from a high baseline.

The IHI BTS emphasized patient activation and education as an important method for improving CHF care. Baseline counseling and education rates in both the participating and control sites were within the low ranges previously reported in other studies, and the improvements observed at the intervention sites were dramatic: 41% for disease management counseling and 33% for dietary counseling, exceeding those achieved by most previous interventions.<sup>13</sup> Still for most educational processes, rates remained below 50%, even among the participating sites.

Despite the improvements in quality of care seen in the intervention group, there were no differences in the readmission rates of the 2 groups. There are several possible reasons for this. Previous studies designed to decrease readmission rates for patients with CHF have usually targeted very high-risk patients (ie, multiple readmissions, poor functional status). In contrast, the participants in this study were selected from all patients with a diagnosis of CHF. In 1 large study of unselected patients with CHF, only 18% of readmissions were due to CHF.<sup>9</sup> Thus, it would be very hard for an intervention focused on improving care for CHF to significantly change the overall readmission rate. It is also likely that the intervention implemented by participants in this trial was less intensive than that used in other studies. Finally, this was not a randomized study, and the 2 groups could have differed significantly in their risk factors for readmission (ie, functional class).

Similarly, it is not surprising that we did not observe improved intermediate outcomes at the intervention sites. First, there is no broad laboratory or physical examination measure of intermediate outcomes for CHF (such as the measurement of glycosolated hemoglobin in diabetes), and functional status could not serve as an outcome since it was unreliably recorded in the medical records. Our medical record-derived outcome measures were necessarily confined to more peripheral aspects of CHF management, such as lipid and blood pressure control. In randomized controlled trials, most of the processes that we measured have been shown to improve lipid and blood pressure control by 50% at best<sup>36</sup> when all patients received the process. In our study, we



observed only a 6–18% difference in improvement between the participating and the control groups in ACE inhibition or lipid-lowering therapy, so we did not have sufficient power to detect the small differences in blood pressure control or lipid levels that these process improvements would produce. Other potential explanations lie in the flexibility of focus between the participating groups, and the emphasis on educational patient activation interventions in the BTS.

The quasi-experimental design of this study is well-suited for evaluating the effectiveness of organizational interventions, but it has important limitations. First, because participating sites volunteered to improve their care, not to be in a trial, we could not randomize them to participation. Instead, we purposely selected control sites that were comparable to the participating sites, although control sites had not volunteered to participate in the intervention, potentially explaining some of the observed differences in performance. Although patients in the sites were similar on a wide range of important clinical variables, there could be unmeasured differences including functional status or severity. In addition, the intensity of participation in the collaborative program may have varied among the 4 participating groups, potentially diluting any observed effect. However, all of the participating sites achieved levels of activation that have been observed in studies of previous collaboratives. Our analyses were conducted only in patients who were present both before and after the intervention and who agreed to chart reviews, leading to potential selection bias likely in favor of the intervention. Lastly, increased documentation rather than increased quality may explain some of the observed differences, particularly for counseling and education. However, sensitivity analyses of post BTS patient reports of counseling receipt confirm most of the differences observed in the chart-based analyses, making this less likely. Future research will have to examine patient perceptions of the increased rates of education among participating sites.

Despite these limitations, this study represents one of the first controlled evaluations of the collaborative methodology of quality improvement. Although there was still room for improvement after participation in the program, several key processes of CHF care were enhanced. If confirmed with other studies and if shown to be cost-effective, our data support the use of programs like the IHI BTS for improving processes of care, particularly in education and counseling, for patients with chronic diseases.

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