A Phased Cluster-randomized Trial of Rural Hospitals Testing a Quality Collaborative to Improve Heart Failure Care

Organizational Context Matters

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Background: Use of evidence-based practices for heart failure (HF) patients has the potential to improve outcomes and reduce variations in care delivery.

Objectives: To evaluate the effect of a rural hospital quality collaborative and organizational context (nurse staffing and practice environment) on 4 HF core measures.

Research Design: Phased cluster-randomized trial with delayed intervention control group. The intervention included a HF toolkit, 2 onsite meetings, and a monthly phone call.

Subjects: Twenty-three rural eastern US hospitals, registered nurses who care for HF patients (N = 591).

Measures: Seven quarters of 4 HF core measures, nurse staffing (nursing skill mix, registered nurse hours per patient day, nurse-turnover), and a survey of practice environment.

Results: Using regression models with generalized estimating equation autoregressive methods, no statistically significant changes were found during the intervention period on all 4 core measures for either group. Higher nurse-turnover was related to all 4 core measures: lower compliance with discharge instructions [$\beta = -1.042$; 95% confidence interval (CI): -1.777, -0.307], smoking cessation ($\beta = -1.148$; 95% CI: -2.180, -0.117), left ventricular ejection fraction ($\beta = -0.893$; 95% CI: -1.784, -0.002), and prescribing angiotensin converting enzyme inhibitors on discharge ($\beta = -1.044$; 95% CI: -1.820, -0.269). Better practice environment was related to higher left ventricular ejection fraction ($\beta = 0.217$; 95% CI: 0.054, 0.379).

The authors declare no conflict of interest.

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Conclusions: Significant improvements in 4 core measures were realized in stable environments (less nurse-turnover). Assuring appropriate nurse staffing and stability is essential to increase organizational preparation for quality initiatives and adoption of best practices in HF care in rural hospitals.

Key Words: rural hospital, quality, nursing, quality collaborative, core measures

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H eart failure (HF) affects over 5.8 million Americans and is the most resource intensive cardiovascular illness, with direct and indirect costs exceeding \$37 billion dollars.^{1–5} Although the overall HF hospitalization rate declined substantially from 1998 to 2008, improvements were uneven across states.³ Underutilization of effective therapies continues to contribute to length and frequency of HF hospitalizations.^{6,7}

Guidelines for HF management⁸ are widely promulgated and accepted by clinicians. Joint Commission requires the reporting of HF performance measures [ie, HF core measures including left ventricular ejection fraction (LVEF) assessment, angiotensin converting enzyme inhibitor/angiotensin receptor blocker (ACEi/ARB) use, discharge instruction, and smoking cessation counseling] in efforts to improve care processes. Despite these efforts, HF care remains suboptimal, even among hospitals participating in quality improvement initiatives.⁹

Examples of suboptimal HF care in large samples of observational data reporting core measures include: 95% LVEF assessment, 87% ACEi/ARB use, 82% discharge instruction, and 91% of eligible patients receive smoking cessation.⁹ Older patients and those with evidence of renal failure were less likely to receive each care measure except for discharge instructions. Small hospitals (<200 beds) and rural hospitals were less likely to provide recommended care compared with larger hospitals.⁹ This is particularly troublesome as rural hospitals discharge almost 1 quarter of HF patients.⁵ This indicates that rural residents are at risk for not receiving care known to work for them because of where they live.

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Rural settings in the US are not located in urbanized (highly developed) areas.¹⁰ By nature, rural hospitals serve populations that are farther away from other health care resources (providers, services), have less beds (so smaller), and care for lower volumes of patients. Nursing care is directly related to quality, and is central to improving problem-prone processes.

There is strong and consistent evidence supporting the relationship of registered nurse (RN or nurse) staffing and patient outcomes.¹¹ Rural settings present unique challenges for nursing,^{12,13} including physical and professional isolation. A quality collaborative is a cost-effective approach to link remote settings, connecting professionals to focus on improvement efforts.

A quality collaborative brings practitioners together from different health care organizations in a series of meetings to improve quality focused on a specific aspect of care using a structured approach.¹⁴ Improvements in HF performance measures have been achieved using evidencebased HF practices in a rapid cycle quality improvement¹⁵ and HF collaborative initiatives.¹⁶ Quality collaborative approaches have also been effective in decreasing adverse events, nosocomial infection, and cost.^{17,18} Others have found that teams embrace the collaborative method, but there is variance in their success.¹⁹ Quality collaborative efforts can be enhanced by addressing factors that enhance the uptake of evidence in practice.

We evaluated the effect of a rural hospital quality collaborative and organizational context (nurse staffing and practice environment) on HF patient care (4 HF core measures) in 23 rural hospitals. This study was approved by the University of Maryland Institutional Review Board.

METHODS

Study Design

A phased cluster randomized trial with preintervention, baseline, and postintervention measures was used. Hospitals were randomly assigned to an experimental (group 1) or control group with delayed intervention (group 2). Group 1 received the intervention for the first 6 months of the study. After 6 months in the control condition, group 2 received the intervention and became a secondary experimental group.

Sample

Rural hospitals from the eastern US were recruited to participate through a phone call or personal contact with their nurse executives. Hospital inclusion criteria were: (1) designated as rural by federal or state reimbursement or program definitions; (2) located in the eastern US (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and North Carolina); and (3) reports HF measures, discharging at least 25 HF patients per year (considered adequate for public reporting).²⁰

Figure 1 describes hospital recruitment, randomization, enrollment, and sites that completed the study. Of 51 hospitals invited, 29 responded to the invitation to participate. The 29 rural hospitals were randomly assigned to one of the 2 groups using computer-generated randomization. There were 2 samples nested in each hospital: (1) hospital's performance on quarterly HF core measures and (2) medical surgical RN who care for HF patients.

HF Quality Collaborative Intervention

The quality collaborative intervention included a 2-day in-person meeting, an evidence-based HF tool kit, and monthly group teleconference calls with the site coordinators and study team. The agenda for each call was driven by the sites (eg, study progress, interim results, issues experience or new HF guidelines or research reports). Site coordinators attended an in-person meeting at the beginning of the intervention phase (by group for training) and at the end of the study (both groups to present their results). The HF toolkit included resources that could be tailored for implementation in each organization (eg, fact sheet, education modules, discharge checklist, patient education).

Context and Outcomes Measurement

Table 1 includes the operational definitions of the organizational context and process measures. Four National Quality Forum²¹ endorsed context measures were used including nursing skill mix, nursing care hours per patient day (HPPD), nurse-turnover, and the Practice Environment Scale (PES).²² The HF core measures include compliance with LVEF assessment, ACEi/ARB use, discharge instructions, and delivery of smoking cessation counseling.

Data Collection

Secondary and survey data were collected using written Teleform survey (Autonomy Cardiff, Vista, CA). Secondary data for HF core measures, and contextual factors (nursing skill mix, nurse-turnover, HPPD) for 7 quarters (quarter ending September 2007 through March 2009) were abstracted from hospital data systems (the same data submitted by hospitals for public reporting). Seven quarters of data were collected to capture precollaborative baseline measures and both groups' intervention periods. The PES²² was administered to medical surgical RNs and licensed practical nurses that care for HF patients preintervention at baseline with a 37% response rate (N=683/1852). Only the RN responses (N=591) were used for this analysis as the PES has only been tested in the RN population.

Statistical Analysis

Exploratory data analyses and regression models with generalized estimating equation autoregressive methods (GEE AR) were performed using Predictive Analytics Software (Version 19.0; SPSS/IBM Inc., Somers, NY). Without the ability to match specific HF core measures to specific members/nurses from each hospital, the nurse and outcome measures were aggregated at the hospital level by quarter (beginning in September 2007 and ending in March 2009). All the aggregated values for the nurse context and core measure variables were standardized using *z*-score statistics. Data quality and completeness were examined through outliers' identification and missing data analysis. Multiple imputation method was applied to impute the missing data (ranging between 1.3% for ACEi/ARB and 8.9% for nurse-turnover) and outliers (*z*-scores >3 or <-3) were treated as



FIGURE 1. Cluster randomization of rural hospitals.

missing. An unconditional random effects model was used to estimate hospital cluster effects and an intraclass correlation coefficient (ICC) calculated. Regression models with GEE AR were applied to test and estimate the following: (1) the intervention effect with prepost comparison (within groups differences and time effects); (2) cohort effects for between groups/cohorts comparison; and (3) the organizational context (nurse staffing and practice environment) effects on HF core measures. Using GEE AR allowed us to account for the clustering effects among hospitals (between hospital difference) and also within hospital variations (with repeated quarterly measures differences). Subgroup analysis of low core measure performer was conducted using dependent t test. Using 2005 Maryland core measure data, we conservatively estimated that the change (6 mo postintervention) in the proportion of HF cases reporting overall compliance with HF patient care would be 20%, and that a sample size of 30 hospitals would yield a power of 0.73 to detect a significant improvement.

RESULTS

Table 2 summarizes the means of organizational context variables and HF core measures for each group separately and combined at the intervention baseline (quarter 3: March 2008). Before the intervention (baseline), there were no significant differences between groups on the organizational context variables or HF core measures. There was a small hospital site effect (ICC=0.07), which indicates that 7% of the variance is attributed to between hospital differences.

Quality Collaborative Effects

To test intervention (quality collaborative) effects between preintervention and postintervention periods from each group, GEE AR modeling was used. There were no statistically significant changes during the intervention period for any core measures for either group 1 or 2. There was no group difference for the cohort effect during the intervention period for any of the 4 core measures. Figure 2 demonstrates the descriptive changes across quarters/time by core measure and group among all hospitals. Change patterns vary preintervention, by cohort and over time.

In a subgroup analysis of these data, 13 low-performing hospitals (<90%) on the discharge instruction core measure at study baseline attained significantly greater improvements (71% to 81%) than the 10 high performers at baseline who demonstrated no improvements (98% unchanged; t=2.17, df=21, P<0.05). Group 2 (N=6) had 8% greater descriptive improvement than group 1 (N=7; 14% vs. 6%).

We then examined if core measures improved over the 7 quarters controlled by their baseline difference. Significant improvements were observed on discharge instructions (P=0.005), LVEF (P=0.026), and ACEi/ARB (P=0.011), but not smoking cessation counseling (P=0.149).

TABLE 1. Context and Process Measures

Context	Main Measurement
Nursing skill mix*	Numerator: number of productive hours worked by each type of nursing staff [registered nurse (RN), licensed vocational/practical nurse (LVN/LPN), unlicensed assistive personnel (UAP), and contract]
	Denominator: total number of productive hours worked by nursing staff with direct care responsibility
Nursing care hours per patient day (HPPD)*	Numerator: number of productive hours worked by each nursing staff (RN, LPN, and UAP0) with direct care responsibilities. Nursing care HPPD
Voluntary nursing turnover*	Numerator: imparent days Numerator: number of voluntary uncontrolled separations for each category of nurses (RNs, advanced practice nurses, LVN/LPN, UAP) Denominator: number of employees in each category (RNs, advanced practice nurses, LVN/LPN, UAP) on the last day of the month
Practice Environment Scale* ²²	Nurse participation in hospital affairs, nursing foundations of quality care, nurse manager ability, leadership and support of nurses and staffing, and resource adequacy and collegial nurse- physician relationships
Processes	r ,
Compliance with heart failure (HF) core measures	Numerator: number of HF inpatients who receive care interventions during hospitalization Denominator: number of total HF inpatients

Organizational Context Effects

To test organizational context effects on HF core measures, GEE AR modeling approaches were then applied. Table 3 reports the results from regression with GEE AR method for nurse staffing and practice environment on HF measures across the study period. Higher nurse-turnover was related to all 4 core measures: lower compliance with discharge instructions [$\beta = -1.042$; 95% confidence interval (CI): -1.777, -0.307]; smoking cessation ($\beta = -1.148$;

DISCUSSION

There are 3 major implications of the results of this study: (1) HF care improved over time during the study period; (2) the quality collaborative intervention resulted in descriptive (but not statistically significant) improvements in HF care; and (3) organizational context (nurse-turnover and PES) are associated with core measure performance. Each will be discussed further.

Quality Collaborative Effect on HF Care

95% CI: 0.054, 0.379).

HF core measures improved during the study period, but there were no statistically significant effects of the quality collaborative intervention. These improvements mirror the trend in HF care core measures over time as a result of the continuous improvement efforts nationwide.⁹ There are a number of possible explanations for the absence of a quality collaborative intervention effect, including the quality collaborative design, the use of process measures, and the sample.

First, quality collaboratives differ in design, methods, and sample with varied success. In a cluster randomized trial comparing a formal quality improvement education program to a control group, no differences were observed in HF measures.²³ Investigators also found low adherence to the completion of the educational program.²³ An interdisciplinary workgroup was effective for improving coordination and standardization of HF care.²⁴ Hospitals involved in "Get with the Guidelines" longer had best performance in HF processes and also had lower rates of mortality.²⁵ Others realized improvements in HF care by engaging interdisciplinary teams and the hospital Board, and using rapid feedback common in quality improvement activities.^{26,27} It is important to note that compared with the literature cited from other settings, this study was conducted in rural hospitals.

Barriers present in rural hospitals (such as culture or system barriers) may be different than those encountered in other settings. Furthermore, this quality collaborative focused on the nurse's role (with a physician partner) in

Measures	Group 1 (n = 11)	Group 2 $(n = 12)$	Total ($N = 23$)	Р
Organizational context				
Nursing skill mix	0.59 (0.11)	0.64 (0.14)	0.61 (0.12)	0.33
RN hour per patient day	16.83 (31.75)	8.24 (4.08)	12.74 (23.04)	0.41
RN turnover	0.04 (0.05)	0.02 (0.02)	0.03 (0.03)	0.45
Practice Environment Scale	86.94 (10.22)	85.01 (6.72)	85.94 (8.43)	0.60
Heart failure core measures		× ,		
Compliance discharge instructions	0.84 (0.23)	0.80 (0.24)	0.82 (0.23)	0.69
Compliance smoking cessation	0.98 (0.60)	0.94 (0.15)	0.96 (0.11)	0.35
Compliance LVEF	0.94 (0.11)	0.95 (0.07)	0.95 (0.09)	0.75
Compliance with angiotensin converting enzyme inhibitors	0.91 (0.15)	0.91 (0.14)	0.91 (0.14)	0.99

LVEF indicates left ventricular ejection fraction; RN, registered nurse.



FIGURE 2. Core measure means across 7 quarters. ACE indicates angiotensin converting enzyme; LVEF, left ventricular ejection fraction.

improving HF. Many different types of clinicians treat HF patients and they may not have been sufficiently engaged. Future research should focus on identifying the active components of interdisciplinary quality collaboratives in the rural setting.

Second, core measures may not be the right metric to capture improvements in HF care that occurred as a result of the quality collaborative. Core measures reflect processes of care, not patient outcomes. At the final quality collaborative, site coordinators advised the study team that there were many changes within organizations that were not captured by core measures, and that the next study should test evidencebased tools to improve HF processes and improve patient outcomes. Establishing effective care processes in acute care is essential, but needs to be extended into the outpatient and home settings.²⁸ Long-term patient outcomes such as functional status, self-management, or physiological measures (eg, B-type natriuretic peptide) may better represent improvements benefiting the target population.

Core measures are intended to be accountability measures that lead to better outcomes.²⁹ In a study of the 6 required Joint Commission processes, discharge instructions

TABLE 3.	Effects of Nurse Staffing a	nd Environment on Hea	rt Failure Core Measures	Across the Study	Periods With	Both Cohorts
(From Sep	otember 7 to March 9; N=	591 nurses; n = 23 hos	pitals) With GEE AR			

	Compliance Discharge Instructions		Compliance Smoking Cessation		Compliance Left Ventricular Function		Compliance With ACE Inhibitors	
	Standardized β	95% CI	Standardized β	95% CI	Standardized β	95% CI	Standardized β	95% CI
RN skill mix RN HPPD								
RN turnover	-1.042*	-1.777, -0.307	-1.148^{\dagger}	-2.180, -0.117	-0.893^{\dagger}	-1.784, -0.002	-1.044^{\dagger}	-1.820, -0.269
Practice environment					0.217*	0.054, 0.379		

*P < 0.01.

[†]P < 0.05. Only significant effects (P < 0.01) with β estimates and 95% CI were reported.

ACE indicates angiotensin converting enzyme; CI, confidence interval; GEE AR, generalized estimating equation autoregressive methods; HPPD, hours per patient day; RN, registered nurse.

compliance was low (68%). However, if patients received all discharge instructions (compared with those who did not receive at least one) they were less likely to be readmitted for any cause (P=0.003) and for HF (P=0.035). No effect on mortality was found.³⁰ Measurement of the discharge instruction elements goes far beyond the core measure "discharge instructions," which only captures if discharge instructions were completed (yes or no). A dichotomous process measure falls short in capturing the effectiveness or appropriates of content delivered.

Third, the quality collaborative had greater benefit to organizations with lower baseline performance. Many of the hospitals included in this study had core measure compliance rates above 90%, creating a ceiling effect in which the sites had little opportunity to improve. Type II error was possible, as the number of total hospitals that completed the study (N=23) was lower than the sample needed according to a priori power estimates (N=30). Twenty-nine hospitals were recruited, but 6 did not attend the quality collaborative making them ineligible to complete the study. Data used in power estimates described lower core measure means than encountered at study baseline (so many hospitals could not achieve the estimated improvements). Future research should target rural hospitals with lower baseline compliance, so that resources are allocated to those settings with the greatest need and propensity for improvement. A focus on quality initiatives in rural setting is a priority, as rural hospitals have reported lower levels of resources and worse patient outcomes (with lower performance for critical access hospitals) and higher HF patient mortality.³¹

Previous studies have found that factors associated with quality collaborative success include obtaining a written commitment from hospital leadership for staffing the implementation, involving high level oversight, providing progress reports at each meeting to the Board, commitment to standardize measurement, submission of data to the quality collaborative monthly signed by the high level administrator, and commitment to use the model for improvement to implement the practices.¹⁹ In this study, the nurse executive committed to participation, sites used their internal quality processes, progress reports were submitted at the end of the intervention, and sites reported interaction and frequency of reporting to leaders in

their monthly reports. There was no long-term follow-up or quarterly reporting past the intervention period.

Organizational Context Effect on HF Care

Organizational context (nurse-turnover and PES) makes a difference in core measure performance. Nursing processes are intrinsic to performance of discharge instructions and smoking cessation counseling. The effectiveness of discharge instructions relates to patient's knowledge of medication, including rationale, dose, schedule, and side effects.²⁹ Nurses screen for smoking on patient admission, and either provide or refer patients to other internal resources for cessation counseling.

A consistent result is that higher nurse-turnover is related to lower compliance for all core measures (discharge instructions, smoking cessation, LVEF, and ACE inhibitors). A stable nursing staff will affect the quality of HF care processes. Although multiple studies have linked predictors of nurse-turnover, there is a paucity of studies to evaluate the relationship of the effect of nurse-turnover on patient care. Prior studies have linked nurse-turnover to patient satisfaction^{32,33} and quality of care³⁴ but no studies have linked nurse-turnover to quality of care delivered.

Unexpectedly, RN HPPD or skill mix was not related to core measure performance. As nurses are actively involved in discharge education and smoking cessation assessment, counseling, and referral, it was expected that better staffing should result in better performance at least in these 2 measures. Rural nurses report higher levels of assessment and referral than advanced smoking cessation counseling activities.^{35,36} The smoking cessation core measure however, only indicates that education was accomplished (or not). High compliance was present at baseline (96%), providing little opportunity to observe variances.

Practice environment was only related to LVEF performance in this study. As better practice environments are associated with lower risks of death and failure to rescue,³⁷ it was expected that better environments would have greater effects on HF core measure processes. Documentation of LVEF is usually not within the nurse's control, but nurses do actively engage in system quality improvement and embed system prompts that would act as reminders for compliance. It is also important to note, that there was little unique hospital effect (ICC = 7%). Because there was small between hospital variance, no additional control variables or statistical control were required. Using GEE AR as an analytic approach controlled for these small effects.

Implications

There are a number of clinical and research implications of this study for future work. First, quality collaborative efforts for rural hospitals should include processes and outcomes beyond core measures, and the longitudinal design should extend the duration of the collaborative intervention. Core measures are important but not sufficient to capture the specific activities and relationships that lead to better care for HF patients (eg, multidisciplinary team membership, roles, and responsibilities). Study planning may also necessitate longer or multisite studies as the small sample size within rural hospitals may increase random error when using outcome measures. Second, instruments should be developed and tested for use in complex interventions (such as a quality collaborative). These instruments should capture the context in each practice setting, allowing for better identification of the active required components of the intervention so that reliable effective processes can be replicated, disseminated, and spread. Third, more research is needed to understand what characteristics of the health system and practice environment enhance and restrain positive change.

Limitations

When interpreting the results of this study limitations include the representativeness of the nurse sample, limited collection of contextual data to capture changes, and the short 6-month intervention period. First, there was a low response rate for nurse survey data collected to describe the practice environment, which may result in biased estimates. Second, the quality collaborative was a complex intervention. Organizational or process changes that were important may not have been captured. Third, an intervention period of 6 months may not have been long enough to realize expected improvements.

In conclusion, organizational context (nurse staffing) is associated with core measure improvements. Significant improvements in HF core measures were realized in stable environments (less nurse-turnover). Assuring appropriate nurse staffing and stability is essential to increase organizational preparation for quality initiatives and adoption of best practices in HF care in rural hospitals.

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