During the past decade, payers, providers, and health systems have increasingly focused on closing the quality chasm for health care in the United States. Heart failure (HF) is a classic depiction of the challenges involved in delivering high-quality care within our current healthcare environment. More than 5 million Americans have HF, and treatment for HF costs are $31 billion annually.1 Despite the prevalence of this common and costly condition, delivery of evidence-based HF care varies significantly across hospitals, as do HF patient outcomes.2–4

Editorial see p 335

Improving adherence to evidence-based recommendations has been the focus of large quality improvement initiatives, such as the Get With The Guidelines-Heart Failure (GWTG-HF) program. GWTG-HF began in 2005 and provides clinical decision support tools, educational materials oriented to patients and providers, and the ability for hospitals to compare performance against local, regional, and national benchmarks. Recent data suggest that hospitals participating in GWTG-HF have better processes of care compared with hospitals that are not participating in the program.6

We sought to evaluate whether quality of care could be further improved by providing sites with personalized performance feedback. To test the effect of our intervention, we performed a cluster-randomized trial. We hypothesized that sites receiving the intervention would have improved performance on achievement measures and quality metrics compared with sites that did not.

Methods

Get With The Guidelines-Heart Failure

Details of the GWTG programs have been previously published.5,7 Briefly, GWTG is a voluntary in-hospital quality improvement program sponsored by the American Heart Association and the American Stroke Association, with 1900 participating hospitals in the United States. The goal of GWTG is to improve care for patients with HF, and the prevalence of this common and costly condition, delivery of evidence-based HF care varies significantly across hospitals, as do HF patient outcomes.2–4

Background—There is significant variation in the delivery of evidence-based care for patients with heart failure (HF), but there is limited evidence defining the best methods to improve the quality of care.

Methods and Results—We performed a cluster-randomized trial of personalized site performance feedback at 147 hospitals participating in the Get With The Guidelines-Heart Failure quality improvement program from October 2009 to March 2011. The intervention provided sites with specific data on their heart failure achievement and quality measures in addition to the usual Get With The Guidelines-Heart Failure tools. The primary outcome for our trial was improvement in site composite quality of care score. Overall, 73 hospitals (n=33 886 patients) received the intervention, whereas 74 hospitals (n=37 943 patients) did not. One year after the intervention, both the intervention and control arms had a similar mean change in percentage points in their composite quality score (absolute change, +0.31 [SE, 1.51] versus +3.18 [SE, 1.68] in control; P=0.21). Similarly, none of the individual achievement measures or quality measures improved more at intervention versus control hospitals.

Conclusions—Our site-based intervention, which included personalized site feedback on adherence to quality metrics, was not able to elicit more quality improvement beyond that already associated with participation in the Get With The Guidelines-Heart Failure program.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00979264.

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Key Words: heart failure ■ hospitals ■ quality of health care ■ quality improvement ■ randomized controlled trial

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421
WHAT IS KNOWN
- The delivery of evidence-based heart failure care varies significantly across hospitals, as do patient outcomes.
- There is limited evidence defining the best methods to improve adherence to evidence-based recommendations.

WHAT THE STUDY ADDS
- We performed a cluster-randomized trial of personalized site feedback on adherence to quality metrics at hospitals participating in the Get With The Guidelines-Heart Failure quality improvement program.
- Our intervention provided sites with specific data on their heart failure achievement and quality measures in addition to the usual Get With The Guidelines-Heart Failure tools but was not able to elicit more quality improvement beyond that already associated with participation in the Get With The Guidelines-Heart Failure program.
- Our study demonstrates the feasibility and importance of a rigorous evaluation of quality improvement interventions and highlights the low adherence rates to many discharge quality measures including the use of aldosterone antagonists, cardiac resynchronization therapy, and implantable cardioverter defibrillators.

coronary artery disease, HF, and stroke. GWTG-HF specifically assists hospitals in improving the care of patients with HF. GWTG-HF collects data on 188 variables, including patient demographics, medical history, in-hospital treatments, and discharge treatments. Institutions submit information either on consecutive patients or by random sample (a sample is permitted if the institution has a large volume of patients [i.e., >75 cases per year]) using an online interactive case report form and Patient Management Tool (Quintiles, Cambridge, MA). From the submitted data, GWTG-HF provides hospitals with real-time, quality improvement, and guideline adherence reports that are easily available online by site request.

Institutions participating in GWTG-HF are required to comply with local regulatory and privacy guidelines and to obtain institutional review board approval, when necessary. Because the data are used primarily at the local site for quality improvement, sites are granted a waiver of informed consent under the common rule for usual GWTG-HF practices and for this intervention. Quintiles (Cambridge, MA) serves as the registry coordinating center, and the Duke Clinical Research Institute (Durham, NC) serves as the data analysis center. Institutional review board approval was granted to analyze aggregate deidentified data for research purposes.

Participating Hospitals
All 434 hospitals participating in the GWTG-HF program were invited to participate in the study via email and were provided with the ability to opt out of participation. Of the 434 hospitals, 75 (17%) declined participation or did not have available contact information to receive an invitation. Of the remaining 359 hospitals, 165 (46%) had at least 30 patient records for the preceding 12 months and at least 1 admission per quarter. These hospitals were randomized on a 1:1 basis to the control or intervention arm. The study design is displayed in Figure 1.

Study Intervention
For this study, the control hospitals continued to receive access to the usual on-demand reports, GWTG-HF quality improvement tools, and publicly available GWTG-HF webinars. These reports continued to be available on request but were not actively pushed to the sites on a routine basis. These reports also focused on composite and specific metrics based on recommendations from the 2006 American College of Cardiology/American Heart Association Clinical Performance Measures (evaluation of left ventricular systolic function, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker use, anticoagulants use for patients with atrial fibrillation, discharge instructions, and smoking cessation). Our intervention added to the current baseline reports with personalized quality improvement reports pushed directly to the site by email each quarter, as well as tailored teleconferences, webinars, and specialized tool kits. The personalized reports were designed to describe the site’s HF patient population compared with other GWTG-HF hospitals, highlight performance on both GWTG-HF achievement measures and 9 GWTG-HF quality metrics (Outcomes section),

Figure 1. Flow diagram of the study design. This figure displays the initial study population, through exclusions, to the final study population. *Get With The Guidelines-Heart Failure (GWTG-HF) hospitals with >30 patient records over the preceding 12 months and >1 admission per quarter were eligible for the study. †Hospitals in the intervention arm also continued to receive access to GWTG-HF quality improvement reports, tools, and webinars.
and to suggest process improvement targets based on site adherence trends during the past year compared with other GWTG-HF hospitals in the region and nation-wide (Figure 2). GWTG-HF project coordinators and quality improvement leaders at each site were then invited to webinars. The webinars were conducted by a study coordinator and clinician and were designed to provide education on the personalized reports and the newer process measures. The webinar presentations also stressed the importance of accurate data collection, offered general suggestions for quality improvement, and provided a forum for quality improvement leaders to network and share experiences on successful improvement strategies. The lowest performers (bottom 25% of intervention sites for the opportunity-based composite score) were also targeted with additional phone calls and webinars to develop solutions for improvement. The specialized tool kits were administered to all intervention sites and provided resources, such as patient instructions and order set templates.

Outcomes

The prespecified primary outcome of the study was improvement in an opportunity-based composite score for adherence to 5 achievement measures and 9 quality measures that were based on published quality performance measures.8,9 The opportunity-based composite score counted the number of times a quality metric was performed and divided by the total number of instances in which care processes were required. This is in contrast to the defect-free composite score that counted the number of patients that received all achievement and quality measures divided by the total number of patients eligible for these measures.10

For both composite scores, we specifically assessed 5 GWTG-HF achievement measures: (1) angiotensin-converting enzyme inhibitor/angiotensin receptor blocker prescription at discharge in patients with a left ventricular ejection fraction (LVEF) <40%; (2) β-blocker prescription at discharge in patients with an LVEF of <40%; (3) discharge instructions addressing activity level, diet, discharge medications, follow-up appointment, weight monitoring, and how to respond to a change in symptoms; (4) LVEF assessment performed or planned for after discharge; and (5) current or recent smokers who received smoking cessation advice or counseling during a hospital stay. We also specifically assessed 9 GWTG-HF quality metrics: (1) aldosterone antagonist prescription at discharge in patients with an LVEF of <40%; (2) anticoagulation prescription at discharge for patients with atrial fibrillation; (3) cardiac resynchronization therapy placed or prescribed at discharge in patients with an LVEF of <35% and a QRS of >120 ms without reason for exclusion; (4) use of deep vein thrombosis prophylaxis by the end of hospital day 2 in patients with HF who were nonambulatory; (5) evidence-based specific β-blockers (ie, bisoprolol, carvedilol, and metoprolol) at discharge; (6) hydralazine and nitrate combination use in black patients with an LVEF of <40% and no contraindications; (7) implantable cardioverter defibrillator placed or prescribed at discharge in patients with an LVEF of <35% without reason for exclusion; (8) influenza vaccine administration before discharge during flu season; and (9) pneumococcal vaccine before discharge. Secondary outcomes for the study included improvements in a defect-free composite score and in-hospital mortality.

Statistical Methods

All statistical analyses of the aggregate deidentified data were performed by the Duke Clinical Research Institute using SAS software.
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β-blocker prescription at}
on achievement measures, such as
thrombosis prophylaxis, hydralazine and nitrate medications,
use was lower in the control group, but the use of deep vein
thrombosis prophylaxis, hydralazine and nitrate medications,
In contrast, the baseline performance on quality metrics was
different in the 2 groups. Cardiac resynchronization therapy
was missing completely at random and excluded these sites. Therefore, 147 sites
were available for our analysis (Figure 1).

Baseline patient and hospital characteristics were summarized for
the control and treatment groups. Continuous variables were reported
as medians and 25th and 75th percentiles and categorical variables
as counts and percentages. Hospital-level aggregated percentages
were calculated for each measure and reported as means with SEs.
Some sites did not have patients eligible for each measure in every
quarter. For these sites, we imputed missing data using multiple im-
putation involving treatment group and all measures in all 6 study
period quarters. We imputed all measures, including the composite, at
once. Twenty imputations were performed with a maximum number
of iterations set at 25,000. We assumed that the missing data pattern
was missing completely at random, and Markov chain Monte Carlo
methods with ridge priors were used.

At the conclusion of the study, we noted small imbalances in the
baseline quality metrics and opportunity-based composite scores. We
also noted that patient opportunities varied by site. Our final analy-
sis assessed for differences in the absolute change from the baseline
quarter (Q4 2009) to the follow-up quarter (Q4 2011) between control
and treatment groups using linear regression weighted by the total
site size during the study period.

In a sensitivity analysis for the 6 sites not contributing patients in
the follow-up quarter, we used multiple imputation of the outcome
with fully conditional specification methods given baseline patient
and hospital characteristics. Results reflect the summary of 25 im-
putations accounting for uncertainty because of nonresponse.

Results

The study was conducted from October 1, 2009 to March 31,
2011 and included data from 71,829 patients hospitalized for
HF at a total of 147 hospitals (74 controls and 73 interven-
tions) across the United States. Patient characteristics are
shown in Table 1. There were no major differences between
patients at hospitals randomized to the control or the inter-
vention, although small differences were noted in the medical
history. Patients in the control group were more likely to have
a history of HF, ischemia, diabetes mellitus, hyperlipidemia,
hypertension, and chronic kidney disease. Hospital character-
istics are shown in Table 2. There were more hospitals in the
Western United States in the intervention arm and more hospi-
tals in the Southern United States in the control arm.

The baseline adherence to achievement measures and qual-
ity metrics along with absolute change over the study period
are displayed in Table 3. The mean baseline performance
on achievement measures, such as β-blocker prescription at
discharge in patients with an LVEF of <40%, and discharge
instructions were similar in the control and intervention groups.
In contrast, the baseline performance on quality metrics was
different in the 2 groups. Cardiac resynchronization therapy
use was lower in the control group, but the use of deep vein
thrombosis prophylaxis, hydralazine and nitrate medications,
implantarable cardioverter defibrillators, influenza vaccines, and
pneumococcal vaccines was higher in the control group. The
baseline overall composite scores were similar in both groups,
but the mean opportunity-based score across hospitals was
higher in the control group (61.1% versus 56.6%). The base-
line inpatient mortality rates were similar in both groups.

The primary outcome for the trial was the change in the
overall opportunity-based composite score. The absolute
change in the opportunity-based score was slightly larger in
the control group than the intervention group (+4.18 compared
with +0.31 percentage points), although there was no statisti-
cal difference (P=0.21) between the 2 groups. The estimated
treatment effect in our model was −2.87 favoring the control
although the 95% confidence interval (−7.32 to 1.58) included
zero. Similarly, for the defect-free score, the improvement was
slightly larger in the control group than the intervention group
(+4.50 compared with +1.14 percentage points; P<0.31), and the
estimated treatment effect favored the control, −3.36,
although the 95% confidence interval (−9.88 and 3.17) again
included zero. For the achievement measures, the absolute
scores had small increases over time in both groups for most
measures, but there were no statistical differences between the
groups. For the quality metrics, the absolute changes over the
study period favored the control group for 8 of the 9 metrics,
but there were no statistical differences between the groups.
The inpatient mortality rates remained stable over time with
no significant changes in either group. Given that the lowest
performers at baseline (bottom 25%) received a slightly dif-
ferent intervention, we also looked for improvement in that
subgroup. There was no statistical difference in improvement
between these groups for the overall opportunity-based score
(absolute change, +8.66 versus +5.86 percentage points in
the control group; P=0.62). In a sensitivity analysis with multiple
imputation of the outcomes for the 6 sites with no patients in
the follow-up quarters, we noted no qualitative changes in the
composite score or individual achievement or quality
measures.

Discussion

Several hospital-based quality improvement programs, includ-
ing GWTG-HF, have helped improve HF quality of care, yet
significant gaps and variations in HF care persist.24612 Our
study evaluated whether a novel intervention of personal-
ized performance feedback could improve performance of
HF achievement measures and quality metrics above current
levels at hospitals participating in GWTG-HF. The interven-
tion specifically focused on pushing detailed reports on a
quarterly basis to quality leaders at sites that provided detailed
information on both standard HF achievement measures and
newer quality metrics. In an environment with existing quality
improvement efforts, we did not find that a more tailored inter-
vention improved the overall composite quality score nor did
we find that it significantly changed any of the achievement
or quality measures. However, our study demonstrates the
feasibility and importance of a rigorous evaluation of quality
improvement interventions and highlights the low adherence
rates to many discharge quality measures, including the use
of aldosterone antagonists, cardiac resynchronization therapy,
and implantable cardioverter defibrillators.

Circ Cardiovasc Qual Outcomes
July 2015
Our study adds to the literature on hospital-based interventions to improve the quality of care for patients with HF. The Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) was one of the first large-scale national quality improvement registries for patients with HF, which was associated with increased use of evidence-based therapy and adherence to quality measures.\textsuperscript{13} Similar to the current GWTG-HF program, this program provided feedback on specific HF quality measures and provided general quality improvement tools and education. In contrast, our intervention added to this by providing personalized and tailored feedback on specific quality measures with poor performance. The Enhanced Feedback for Effective Cardiac Treatment (EFFECT) study assessed whether publicly released hospital report cards could improve hospital quality of care for patients hospitalized with acute myocardial infarction or congestive HF in Ontario, Canada. The investigators found no improvement in a composite score of 6 HF performance measures.\textsuperscript{14} Nevertheless, the EFFECT study (like ours) highlights the importance of conducting a rigorous evaluation to assess the effect of quality improvement interventions before widespread dissemination of these interventions.

The reasons our intervention was not successful are not entirely clear. One possibility is that hospitals participating in GWTG-HF have previously been shown to have higher compliance with quality of care measures than those not participating in the program.\textsuperscript{6} Our intervention may have had a larger and more discernible effect if tested in hospitals that are not already participating in GWTG-HF. In addition, even control GWTG-HF hospitals may have already implemented programs to improve the targeted measures before randomization. A thorough assessment of ongoing quality improvement efforts before implementation of the intervention may have been helpful. Another possibility is that the study follow-up was not long enough to detect a change in performance. Our intervention provided information and did not mandate behaviors, allowing for local experimentation with innovations most useful to the local healthcare environment. This process may take months of planning, implementation, and improvement through different iterations before noting a change, although this is speculative. Future interventions that provide performance feedback should consider eliciting organizational readiness to act on this data at the onset of the study. Our study was designed to improve local HF care delivery, yet the reports were designed at a national level. Finally, it is possible that our intervention did not provide actionable information at a local level and that soliciting feedback from local quality improvement leaders during initial study planning or the initial rollout phase may have improved the quality of the feedback and the success of the intervention.

Improving the quality of care for patients with HF is an essential goal, but the results of our study raise questions about best practices for hospital-based quality improvement interventions. Our study highlights that providing additional

### Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Control, n=37,943</th>
<th>Intervention, n=33,886</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, median (IQR)</td>
<td>74 (62–83)</td>
<td>75 (63–84)</td>
</tr>
<tr>
<td>Female, sex, %</td>
<td>48.8</td>
<td>48.3</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>66.5</td>
<td>66.1</td>
</tr>
<tr>
<td>Black</td>
<td>23.2</td>
<td>18.2</td>
</tr>
<tr>
<td>Other</td>
<td>10.3</td>
<td>15.7</td>
</tr>
<tr>
<td>Insurance, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>56.1</td>
<td>53.1</td>
</tr>
<tr>
<td>Medicaid</td>
<td>11.5</td>
<td>10.9</td>
</tr>
<tr>
<td>Medical history, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous history of HF</td>
<td>64.4</td>
<td>61.7</td>
</tr>
<tr>
<td>History of ischemia*</td>
<td>50.5</td>
<td>47.4</td>
</tr>
<tr>
<td>CRT use</td>
<td>6.8</td>
<td>6.5</td>
</tr>
<tr>
<td>ICD use</td>
<td>15.4</td>
<td>12.9</td>
</tr>
<tr>
<td>Valvular disease</td>
<td>16.9</td>
<td>18.4</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>42.2</td>
<td>39.0</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>45.5</td>
<td>43.1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>73.6</td>
<td>71.0</td>
</tr>
<tr>
<td>Chronic kidney disease, %</td>
<td>21.8</td>
<td>20.8</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>16.9</td>
<td>16.1</td>
</tr>
<tr>
<td>Atrial fibrillation/flutter</td>
<td>36.0</td>
<td>34.1</td>
</tr>
<tr>
<td>Previous stroke or TIA</td>
<td>13.7</td>
<td>13.6</td>
</tr>
<tr>
<td>Anemia</td>
<td>17.3</td>
<td>17.3</td>
</tr>
<tr>
<td>COPD or asthma</td>
<td>28.5</td>
<td>27.2</td>
</tr>
<tr>
<td>LVEF, %, median (IQR)</td>
<td>40 (25–55)</td>
<td>40 (25–55)</td>
</tr>
<tr>
<td>LVEF &lt;40%</td>
<td>49.1%</td>
<td>47.3%</td>
</tr>
<tr>
<td>LOS, d, median (IQR)\†</td>
<td>4 (3–7)</td>
<td>4 (2–6)</td>
</tr>
<tr>
<td>LOS &gt;4 d, % \†</td>
<td>47.4</td>
<td>42.9</td>
</tr>
</tbody>
</table>

\*History of ischemia includes the following: coronary artery disease, previous myocardial infarction, or previous revascularization (percutaneous coronary intervention or bypass surgery).

\†Transfers in and out of the hospital were excluded.

### Table 2. Hospital Characteristics

<table>
<thead>
<tr>
<th>Hospital Characteristics</th>
<th>Control, n=74</th>
<th>Intervention, n=73</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital no. of beds, median (IQR)</td>
<td>296 (210–491)</td>
<td>294 (162–406)</td>
</tr>
<tr>
<td>US geographic region, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>10.8</td>
<td>22.5</td>
</tr>
<tr>
<td>South</td>
<td>44.6</td>
<td>28.2</td>
</tr>
<tr>
<td>Midwest</td>
<td>20.3</td>
<td>21.1</td>
</tr>
<tr>
<td>Northeast</td>
<td>24.3</td>
<td>28.2</td>
</tr>
<tr>
<td>Hospital setting, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>19.7</td>
<td>12.7</td>
</tr>
<tr>
<td>Urban</td>
<td>80.3</td>
<td>87.3</td>
</tr>
<tr>
<td>Teaching hospital, %</td>
<td>57.8</td>
<td>50.8</td>
</tr>
<tr>
<td>Cardiac surgery, %</td>
<td>65.6</td>
<td>60.9</td>
</tr>
<tr>
<td>Heart transplantation, %</td>
<td>8.7</td>
<td>6.1</td>
</tr>
</tbody>
</table>

IQR indicates interquartile range.
information on quality performance alone may not necessarily translate to better performance, an important lesson for quality improvement efforts. Unfortunately, we did not collect data on interventions implemented as a result of our feedback and cannot comment on the efficacy of local interventions. We initially intended to analyze 160 hospitals and estimated randomization, conformity with many of the quality metrics was different at baseline. Third, the available sample size (<75 hospitals in each arm) may have been inadequate to detect small improvements in the composite quality of care scores. We initially intended to analyze 160 hospitals and estimated 98% power to detect a difference of 7.5% in the primary end point, what we determined to be a clinically meaningful difference. Given the nature and scope of the intervention though even smaller improvements could have a large public health effect. Finally, we were unable to determine why certain treatments were not used in eligible patients despite targeted feedback; this gap in understanding needs to be investigated in future research.

In conclusion, reliably incorporating evidence-based recommendations into routine clinical care in eligible patients remains an elusive but important goal. Our study demonstrates the importance of scientific evaluation of quality improvements initiatives are already active, consequently making interventions like ours less effective. Second, despite randomization, conformity with many of the quality metrics was different at baseline. Third, the available sample size (<75 hospitals in each arm) may have been inadequate to detect small improvements in the composite quality of care scores. We initially intended to analyze 160 hospitals and estimated 98% power to detect a difference of 7.5% in the primary end point, what we determined to be a clinically meaningful difference. Given the nature and scope of the intervention though even smaller improvements could have a large public health effect. Finally, we were unable to determine why certain treatments were not used in eligible patients despite targeted feedback; this gap in understanding needs to be investigated in future research.

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improvement efforts before widespread adoption through rigorously designed and well-controlled studies. Lessons from this trial can be used to better inform hospital-based quality improvement interventions in the future and for evidence development for other strategies of care that are deployed at the hospital-level.

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