Cluster-Randomized Trial of Personalized Site Performance Feedback in Get With The Guidelines-Heart Failure

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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.

Methods

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 heart failure (HF) by comparing 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.

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.
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 [ie, >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 used 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 >50 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 coordi-
nators 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 personal-
ized reports and the newer process measures. The webinar presenta-
tions 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 (bot-
tom 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 mea-
sures and 9 quality measures that were based on published quality per-
formance 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 pa-
tients 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 car-
dioverter defibrillator placed or prescribed at discharge in patients
with an LVEF of <35% and a QRS of >120 ms without reason for exclusion; (8) 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 car-
dioverter defibrillator placed or prescribed at discharge in patients
with an LVEF of <35% and a QRS of >120 ms 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 per-
formed by the Duke Clinical Research Institute using SAS software
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 imputation 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 analysis assessed 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 imputations 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 interventions) 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 intervention, 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 characteristics are shown in Table 2. There were more hospitals in the Western United States in the intervention arm and more hospitals in the Southern United States in the control arm.

The baseline adherence to achievement measures and quality 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, implantable 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 baseline 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 (+3.18 compared with +1.14 percentage points), although there was no statistical 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 different 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, −5.66 versus −5.86 percentage points in the control group; P = 0.82). 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, including GWTG-HF, have helped improve HF quality of care, yet significant gaps and variations in HF care persist. Our study evaluated whether a novel intervention of personalized performance feedback could improve performance of HF achievement measures and quality metrics above current levels at hospitals participating in GWTG-HF. The intervention 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 intervention 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.
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 (25–65)</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>

COPD indicates chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter defibrillator; IQR, interquartile range; LOS, length of stay; LVEF, left ventricular ejection fraction; and TIA, transient ischemic attack.

*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.

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. 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. 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 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...
Our study had several limitations. First, GWTG-HF demonstrates the importance of scientific evaluation of quality improvement 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.

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 performance and cannot comment on the efficacy of local interventions implemented as a result of our feedback; this gap in understanding needs to be investigated in future research.
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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Disclosures

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References


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