Randomized Trial of Targeted Performance Feedback to Facilitate Quality Improvement in Acute Myocardial Infarction Care

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Background—Efforts to improve quality of care for patients with acute myocardial infarction (AMI) are a national priority. To date, there have been few studies that have prospectively evaluated hospital quality improvement (QI) interventions.

Methods and Results—Using hospitals in the National Cardiovascular Data Registry (NCDR) ACTION Registry–GWTG, a cluster randomized trial of the effectiveness of targeted performance feedback to facilitate process improvement for AMI care will be conducted. ACTION Registry–GWTG hospitals with a minimum of 50 AMI patients per 2 quarters are eligible for randomization. The control arm receives standard performance feedback reports, and the intervention arm receives standard performance feedback reports in addition to a supplemental report on the “top 3” centrally identified, hospital-specific performance gaps. The primary outcome will be improvement in a composite of all metrics, and the secondary outcome will be improvement in the targeted metrics. At study inception in January 2009, 149 sites were randomized: 76 to the intervention arm, and 73 to the control arm. Intervention and control sites were well balanced in terms of baseline performance, center characteristics, and AMI volume (~70 patients per quarter). The intervention phase will continue for 5 feedback cycles, each containing 2 quarters of data feedback over 18 months. A final trial outcome report will follow.

Conclusions—This randomized trial will evaluate a novel hospital-level QI intervention of targeted performance feedback for AMI, thereby demonstrating the effective use of national registries for QI and furthering our understanding of effective QI methods.


Key Words: randomized controlled trials • quality improvement • acute myocardial infarction
novel QI feedback method is currently being performed. This trial will definitively test a strategy of specific and targeted performance feedback versus standard feedback for its ability to better facilitate QI.

Methods

Data Sources

The ACTION Registry–GWTG includes detailed clinical information on >150,000 existing patients with either ST-elevation or non–ST-elevation–myocardial infarction (STEMI and NSTEMI). Participating hospitals submit data on consecutive patients with a primary diagnosis of STEMI or NSTEMI, as defined by (1) ischemic symptoms at rest, lasting ≥ 10 minutes, occurring within 24 hours before admission or up to 72 hours for STEMI; (2) ECG changes associated with STEMI (new left bundle-branch block or persistent ST-segment elevation of ≥ 1 mm in 2 or more contiguous ECG leads); or (3) positive cardiac markers associated with NSTEMI (CK-MB or troponin I/T local laboratory upper limit of normal values) within 24 hours after initial presentation. Patients are ineligible for inclusion if they were originally admitted for clinical conditions unrelated to the STEMI or NSTEMI diagnosis. At most hospitals, patients are identified retrospectively through a review of local administrative or clinical databases. All data are entered via a secure, password-protected web-based server system with programmed front-end logic and range checks to optimize data quality at the time of data entry. Data elements include patient demographics, presenting features, prehospital and in-hospital therapies, timing of care delivery, laboratory tests, procedure use, and in-hospital patient outcomes. The ACTION Registry–GWTG case report form can be found at: www.ncdr.com.

All sites receive quarterly feedback reports describing the use of guideline-indicated therapies, dosing errors, and outcomes (eg, bleeding, transfusion, MI, congestive heart failure, or death). These results are benchmarked to national averages, hospitals with similar cardiac service capabilities, and the hospitals that provide evidence-based AMI care most consistently.

Site Selection

Eligible ACTION Registry–GWTG sites had to meet the following criteria: (1) participation from January 1, 2007, through March 31, 2008; (2) a minimum of 50 records over the prior 2 quarters; (3) a minimum of 10 records each for STEMI and NSTEMI; and (4) agreement to participate in the project.

Randomization

Eligible sites were randomized to control (standard feedback) or intervention (targeted feedback). Randomization was stratified by baseline quality performance score, academic status, and cardiac services (hospitals with cardiac surgery versus other). Of the 149 eligible sites, 76 were randomized to intervention, and 73 were randomized to control (Figure 1). Institutional review board approval for this QI project was obtained centrally by the coordinating center.

Performance Measures and Quality Metrics

Performance measures undergo a rigorous process of public comment, whereas quality metrics are those of potential interest for hospital systems looking to improve their care. We chose performance measures and quality metrics based on the 2008 American College of Cardiology/American Heart Association Performance Measures for MI care as well as the newer ACTION Registry–GWTG metrics, based on the current NSTEMI and STEMI Guidelines Updates11,12 (Table 1). In evaluating metrics for inclusion in this study, we prioritized those metrics that were the most actionable and amenable to change as well as those with the largest anticipated impact on outcomes. These metrics are applied to the appropriate subpopulations (STEMI and NSTEMI) and population exclusions (eg, contraindications) and are put in place where necessary. Quality performance scores on the standard reports include a composite of acute and discharge measures. Assessments for all AMI patients include use of acute aspirin therapy, left ventricular function evaluation, discharge aspirin therapy, discharge β-blocker therapy, discharge angiotensin-converting enzyme inhibitor or angiotensin receptor blocker therapy in the setting of left ventricular dysfunction,
Table 1. Performance Measures and Quality Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Eligible Patients</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute measures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin†</td>
<td>All AMI</td>
<td>Aspirin first 24 hours among those without contraindications</td>
</tr>
<tr>
<td>ECG ≤10 min‡</td>
<td>Direct arrival</td>
<td>ECG before or within 10 minutes of ED arrival: includes prehospital ECG</td>
</tr>
<tr>
<td>Antiplatelet†</td>
<td>NSTEMI only</td>
<td>Clopidogrel or glycoprotein IIb/IIIa inhibitor first 24 hours among those without contraindications</td>
</tr>
<tr>
<td>Any antithrombin†</td>
<td>NSTEMI only</td>
<td>Heparin, LMWH, fondaparinux, or bivalirudin first 24 hours among those without contraindications</td>
</tr>
<tr>
<td><strong>Discharge measure (without contraindications, exclude transfer-out)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin†</td>
<td>All AMI</td>
<td>Aspirin at discharge</td>
</tr>
<tr>
<td>ACE/ARB for LVSD†</td>
<td>All AMI; EF &lt;40%, LV dysfunction</td>
<td>ACE/ARB at discharge for LVSD or signs of HF</td>
</tr>
<tr>
<td>Statin†</td>
<td>All AMI</td>
<td>Statin at discharge</td>
</tr>
<tr>
<td>Clopidogrel†</td>
<td>All AMI</td>
<td>Clopidogrel at discharge</td>
</tr>
<tr>
<td>In-hospital LDL†</td>
<td>All AMI</td>
<td>Assessment of LDL in-hospital</td>
</tr>
<tr>
<td>Cardiac rehabilitation†</td>
<td>All AMI</td>
<td>Referral to cardiac rehabilitation</td>
</tr>
<tr>
<td>Smoking cessation†</td>
<td>All AMI; smokers</td>
<td>Advice to quit smoking among smokers</td>
</tr>
<tr>
<td><strong>Excess dosing metrics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UFH†</td>
<td>Treated; exclude cath lab initiation</td>
<td>Initial UFH dose: bolus &gt;70 U/kg or &gt;4000 U and/or infusion &gt;15 U/kg/min or &gt;1000 U</td>
</tr>
<tr>
<td>LMWH†</td>
<td>Treated; exclude cath lab initiation</td>
<td>Initial LMWH dose 10 mg over 24-hour recommended dose (2 mg/kg/24 h if CrCl &gt;30 mL/min or 1 mg/kg/24 h if CrCl &lt;30 mL/min) or &gt;1.05 mg/dL initial dose</td>
</tr>
<tr>
<td>GP2b3a†</td>
<td>Treated; exclude cath lab initiation</td>
<td>Initial GP2b3a dose: Not reduced if CrCl &lt;50 mL/min for eptifibatide, and CrCl &lt;30 mL/min for tirofiban</td>
</tr>
<tr>
<td><strong>Reperfusion metrics (STEMI only; among those without contraindications)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any reperfusion†</td>
<td>Chest pain onset ≤12 hours</td>
<td>Any reperfusion therapy</td>
</tr>
<tr>
<td>Door-to-needle ≤30 minutes†</td>
<td>Thrombolytic patients; direct arrival only</td>
<td>Time from presentation to thrombolytic therapy</td>
</tr>
<tr>
<td>Door-to-balloon ≤90 minutes†</td>
<td>Primary PCI; direct arrival only</td>
<td>Time from presentation to balloon</td>
</tr>
<tr>
<td>Door-to-balloon ≤90 minutes transfer-in†</td>
<td>Primary PCI; transfer-in only</td>
<td>Time from presentation to balloon</td>
</tr>
</tbody>
</table>

ACE/ARB indicates angiotensin-converting enzyme/angiotensin receptor blocker; CrCl, creatinine clearance; ED, emergency department; GP2b3a, glycoprotein 2b3a; HF, heart failure; LDL, low-density lipoprotein; LMWH, low-molecular-weight heparin; LVSD, left ventricular systolic dysfunction; and UFH, unfractionated heparin. *Age and sex drill-down performed for all measures. Patients with comfort measures only are excluded. †American Heart Association/American College of Cardiology Performance Measure 2008. ‡2007 NSTEMI American Heart Association/American College of Cardiology Guidelines.

discharge statin therapy, smoking cessation counseling for smokers, and referral to cardiac rehabilitation. Assessments for STEMI patients only include door-to-needle ≤30 minutes, door-to-balloon for PCI ≤90 minutes, use of any reperfusion therapy, door-in to door-out time for transferred PCI patients, and door-to-balloon for nontransferred PCI patients. These composite performance scores summarize successes (eg, number of times eligible patients received the appropriate care process) relative to all opportunities to deliver these care processes.

QI Intervention: Targeted Performance Reports

The data coordinating center compared each hospital’s performance on quality measure or metrics to performance of other hospitals with analyzable data. Performance was expressed as the percentage of the number of successes, relative to the number of care opportunities. For each metric, all hospitals with performance percentages were then rank-ordered from highest to lowest. Ties in performance were given the same numeric rank (eg, 1, 1, 3, 4, 4, 6, etc). Hospitals were excluded from consideration for individual metrics if they lacked performance data. For example, some hospitals use no low-molecular weight heparin. Other hospitals exclusively perform direct PCI for STEMI; therefore no door-to-needle times from fibrinolysis are available. Rankings were used to identify three improvement targets for each site in the following way: 3 metrics with the worst numeric rank compared with other hospitals were identified, but any selected metric with an absolute performance ≥90% was excluded. There were compressed rankings within high levels of absolute performance for certain measures, such as aspirin on admission (eg, all percentages above 85%). Once selected, targets remained the same throughout the study period to allow time for meaningful changes to be assessed.

For the intervention arm, performance targets are presented on a report supplement (Figure 2). Care opportunities for each metric, along with ranking among all participating centers, called Centers for Education and Research on Therapeutics (CERTs) Nation, and top performers (CERTs top 10%), are shown. This is to distinguish centers participating in this trial and all ACTION Registry–GWTG centers. Intervention sites will receive these special supplement reports every other quarter summarizing their performance on 2 quarters of AMI patients. Sites will be followed for five reporting periods. Improvement will be measured using ongoing data collection with trend graphs allowing centers to track performance over
time. Supplemental data analyses provide a better understanding of performance among key subgroups (Appendix A). For example, if use of antithrombotic medications was low, then the report would provide further detailed information on antithrombotic use by clinical and process factors that might inform the gap. In addition, “outlier tables” (which list blinded identifiers for cases in the denominator but not the numerator for each metric) are provided to the site for their internal use for hospital record review. These outlier tables are intended to help sites determine patterns that might have contributed to the omission.

**QI Intervention: Report Distribution**

Each site was asked to provide multiple contacts for electronic report distribution. The average number of contacts per site was 2.4 (min =1, max =13). All sites had coordinator recipients, and 28% of sites also had physician recipients. Reports also were posted on a secured web site for future downloading via password access. Training slides encouraged sharing of reports broadly within the institution.

**QI Intervention: QI Community and Education**

Intervention sites are connected via an interactive web-based community. Available by password entry, sites are able to exchange their own QI problems and solutions. Resources offered through this community also include evidence summaries, dosing guides, and order sets. Best-practice tips also accompany the reports that describe successful strategies used in high-performing centers (Appendix B). Order set review and recommendations by CERTs clinicians were offered for hospitals with dosing identified as an improvement target. Continuing medical education and continuing nursing education modules were developed to address QI processes in general, as well as best-practice recommendations for each of the target areas (eg, acute and discharge care, reperfusion, dosing measures). These continuing medical education–certified, web-based modules reviewed the evidence and outlined actionable steps for improved performance. These modules were originally delivered to sites live, but are now archived on: www.cardiosource.org.

**Analysis**

The primary outcome of this analysis is improvement in the overall composite of all metrics. The secondary outcome is improvement in the composite of the 3 site-specific selected metrics. The level of observation is each performance opportunity, with potential for multiple observations per patient. Each care opportunity is coded as a binary indicator variable signifying success or failure. Each of these end points will be analyzed in a patient-level mixed-effects logistic regression model that includes covariates for the intervention arm, time, and the interaction between time and the intervention arm. The intervention will be considered successful if sites in the intervention arm exhibit greater improvement than sites in the control arm. We will also compare trends in patient outcomes including in-hospital bleeding and mortality. Outcomes will be assessed among all sites, and relevant performance subgroups (eg, low performers, academic centers, cardiac services capability, and between medication versus process metrics).

**Statistical power** is based on the anticipated effect of the intervention on individual metrics. We assumed that at the end of the study, the intervention would increase composite performance by at least 7%, compared with the control arm. We considered within-hospital correlation and secular linear trends in the control arm up to 5% per year with baseline adherence rates of 40%, 60%, or 80%. Despite these assumptions, there was ≥84% power for all scenarios. Metrics with a baseline performance rate greater than 80% had anticipated power close to 100%.

**Results**

The trial randomization resulted in balanced allocation between the 2 arms for hospital size, academic affiliation,
cardiac surgery facilities, and baseline performance (Table 2). One in 5 hospitals is academically affiliated, and more than 80% have full cardiac surgical services. The hospitals are moderate to large in size (median 347/254, 526 beds), and report MI care on between 50 and 70 patients per quarter. In addition, the overall performance at baseline was high across centers, with a median composite adherence on all metrics of 93.2%. The baseline composite adherence scores were also balanced between intervention and control arms, with lower overall quality adherence hospitals (90%) comprising approximately one-third of the hospitals within each arm.

The baseline distribution of the centrally selected “top 3” performance targets is shown in Figure 3. Acute and discharge measures were selected for three-quarters of the hospitals, and reperfusion and dosing measures were selected for one-third of the hospitals; again evenly balanced between arms. Newer quality measures (eg, time-to-ECG 10 minutes, in-hospital low-density lipoprotein assessment, and clopidogrel at discharge) were most common. Of note, door-to-needle times ≤30 minutes and door-to-balloon times ≤90 minutes for transfer patients were not selected for any hospital.

To date, 3 report cycles have been completed. Site contacts note the level of detail in the reports is manageable and helpful.

**Discussion**

This trial evaluated the role of targeted feedback versus standard feedback for improving AMI care. We found that hospital-level performance gaps are evenly distributed across categories of care (eg, acute and discharge metrics, reperfusion, and dosing) and vary within each center. Although overall performance was higher in top centers, 3 targets for improvement were identified for every hospital. In addition, new quality measures (eg, time-to-ECG, dosing excess) were more often selected for improvement targets, compared with those that have longer been a focus of QI efforts (eg, aspirin at discharge). This observation supports the importance of selecting site-specific targets from an evolving expanded panel of performance metrics. Building on prior experience, this intervention combines feedback with best practice tips from the community, QI discussion boards, and educational support. The trial duration was selected to enable adequate time to observe a change in response to the intervention; therefore, we will definitively test the value of hospital-specific targeted performance feedback to facilitate improvements in hospital MI care.

**Prior QI Interventions**

Early feedback for MI care using simple administrative data were successful in improving performance and mortality among participating hospitals. Since that time, large registries have been established to retrospectively collect more detailed information directly from the medical record. These data, which are provided as standard feedback to participating hospitals, have narrowed performance gaps further—even among high-risk populations. Over time, high performance in measures has enabled their retirement, whereas gaps in others still remain. Although few in
number, randomized interventions for QI strategies have furthered our understanding of effective methods for improving AMI care. One trial found that a single episode of administrative feedback was ineffective, underscoring the need for ongoing feedback.20 Another found no difference in mailed versus in-person delivery of performance reports, enabling centralized distribution to a variety of centers.21 An important trial also found that achievable benchmarks for performance clarified and motivated improvement.22 Foremost, the elements necessary for QI are reliable data feedback, coupled with physician-led efforts.13,23

Current QI Intervention

The current intervention builds on prior works in QI. First, the ACTION Registry–GWTG is the largest national registry of AMI care and provides rapid and credible feedback as a dynamic platform for QI research. In addition, target identification and ranking provides hospitals with achievable performance goals. The panel of metrics used in this study is also more comprehensive than in prior works, including performance measures and quality metrics. This comprehensive panel revealed that performance within each hospital is variable across this broader group of measures, with high performance coexisting with low performance. This underscores the idea that performance on QI measures should be independently assessed, and also bypasses a pitfall that centers may be reassured by performance on some metrics, undervaluing efforts to improve others.24

Only 3 targets were selected for the supplemental reports, but they are supported by additional data analysis and outlier reports. We hope that target selection will focus efforts at the hospital level, thereby activating QI processes (with the use of feedback being left up to the center’s discretion). Nevertheless, feedback in the absence of administrative support or leadership may be ineffective.5 Therefore, the ability of targeted feedback to motivate hospital-level QI will be tested. If no differences are found between the intervention and control groups, further work on understanding the role of the local environment may be necessary. However, if the intervention is successful, this strategy can be promptly implemented in the ACTION Registry–GWTG.

There are limitations to the generalizability of this trial. The ACTION Registry–GWTG sites are high-performing centers with sufficient infrastructure to participate in a national registry. They are also likely to prioritize QI more than nonparticipating centers. From among these, we further selected centers with high-volume, consistent reporting. Therefore, these hospitals are mature in their QI process and infrastructure and may not represent the average center. In addition, how the feedback is used at each center is not proscribed or evaluated. Accordingly, local environmental factors may impact the results, yet randomization should balance unmeasured factors between intervention and control sites. Finally, these measures, although new and expanded, remain granular in their ability to identify highest AMI quality of care.

The gap between ideal and actual performance requires identification of gaps, as well as the tools, to fix them. Research in QI is necessary to optimize the final translation of knowledge to the bedside. This randomized QI feedback trial within the ACTION Registry–GWTG will test the ability of selected targets to rapidly facilitate hospital improvement in MI care. This effort is also evidence to the ACTION Registry–GWTG’s ability to serve as a data platform and dynamic community for such studies. Future trials that build on the results of this study will surely be needed.

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References


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