The NCDR ACTION Registry–GWTG: transforming contemporary acute myocardial infarction clinical care

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The NCDR ACTION Registry–GWTG: transforming contemporary acute myocardial infarction clinical care

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ABSTRACT

Aims The NCDR ACTION Registry-GWTG collects detailed in-hospital clinical, process-of-care and outcomes data for patients admitted with acute myocardial infarction (AMI) in the USA. The registry is a national AMI surveillance system that contributes to the scientific enquiry process of AMI care through the facilitation of local and national quality improvement efforts.

Interventions No treatments are mandated, participating centres receive routine quality-of-care and outcomes performance feedback reports and access to quality of care tools, such as dosing algorithms and standing orders.

Population AMI patients are retrospectively identified. No informed consent is required, as data are anonymised. From January 2007 to date, 147 165 records have been submitted from 383 participating US hospitals. Patients with a primary diagnosis of ST-segment elevation myocardial infarction or non-ST-segment elevation myocardial infarction are eligible for enrolment in the registry. These patients must have ischemic symptoms and electrocardiogram changes, and/or positive cardiac markers within 24 hours of initial presentation.

Baseline data Approximately 350 fields encompassing patient demographics, medical history and risk factors, hospital presentation, initial cardiac status, medications and associated doses, reperfusion strategy, procedures, laboratory values, and outcomes. Data are manually entered by study personnel; there are non-financial incentives at the hospital level. Completeness within the registry is noteworthy with most fields at less than 5% missing.

Endpoints Main outcome measures include American College of Cardiology/American Heart Association myocardial infarction performance indicators, as well as in-hospital patient outcomes. Data are available for research by application to: http://www.ncdr.com.

Cardiovascular disease (CVD) remains the leading cause of death in the USA, yet mortality rates have declined substantially in the past two decades.[1] These improved outcomes are partly a consequence of the more consistent use of evidenced-based treatments for patients with acute myocardial infarction (AMI).[2] Yet despite these incremental improvements, many patients still fail to receive effective, safe and timely AMI treatments, particularly among certain vulnerable patient populations.[3–9] National clinical registries offer a unique opportunity both to understand how care is being delivered in practice in the USA and to promote improved quality of care.

In the past decade, several voluntary, free-standing, AMI registry programmes were introduced in the USA including the National Registry of Myocardial Infarction, the 'Can Rapid risk stratification of Unstable angina patients Suppress ADverse outcomes with Early implementation of the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines' (CRUSADE), and the AHA's Get With the Guidelines (GWTG) Coronary Artery Disease Programme. These unique registries had success in stimulating science and quality improvement (QI), but they did result in participant and resource competition.

OVERVIEW OF DATA

Background, reason for existence of database and when it began

Launched in January 2007, the ACC's Acute Coronary Treatment and Intervention Outcomes Network (ACTION) Registry was established through a merger of the National Registry of Myocardial Infarction and CRUSADE (http://www.ncdr.com). One year later, the AHA's GWTG–Coronary Artery Disease Programme joined ACTION to create a landmark AMI registry, entitled the NCDR ACTION Registry–GWTG (hereafter ACTION Registry-GWTG).[10] The ACTION Registry-GWTG was created to serve as a national AMI surveillance system, to contribute to the scientific enquiry process of AMI care, and to facilitate local and national QI efforts. This paper briefly describes the methodology of the ACTION Registry-GWTG and summarises the results of this registry's data, to date.

THE DATA

Who is in the database?

Consecutive patients with a primary diagnosis of ST-segment elevation myocardial infarction (STEMI) or non-ST-segment elevation myocardial infarction (NSTEMI) are eligible for enrolment into the ACTION Registry-GWTG. These patients must have: (1) ischaemic symptoms at rest, lasting 10 min or more, occurring within 24 h before admission or up to 72 h for STEMI; and (2) ECG changes associated with STEMI (new left bundle–branch block or persistent ST-segment elevation ≥1 mm in two or more contiguous ECG leads); or (3) positive cardiac markers associated with NSTEMI (creatine kinase myocardial type or troponin I/T greater than local laboratory upper limit of normal values) within 24 h after initial

presentation. Therefore, only confirmed AMI are entered into the database. All data are anonymised at the level of analysis.

What is measured?

Data elements

The data elements that are central to the ACTION Registry-GWTG include the ACC/AHA performance measures[11] and class I recommendations of the ACC/AHA clinical practice guidelines.[12] These two sets of professional practice standards are used to define the performance and quality metrics presented in the quarterly benchmarked reports. Other data elements include patient demographics, presenting features, pre, acute and discharge medications, timing of care delivery, laboratory tests, procedure use and inhospital patient outcomes. Data are limited to only the inhospital admission.

Performance feedback and QI

The ACTION Registry-GWTG is designed to assist US hospitals in their QI efforts. Quarterly performance feedback reports and tailored QI tools are carefully designed to help achieve this objective.[13] The structure and content of these reports aid hospital QI personnel in the identification of evidence-based care gaps, delays in care delivery and potential medication safety concerns.

External and internal benchmarks are integral components of these reports and include local performance over time, national benchmarks and an achievable benchmark of care[14] that describes the treatment provided at top performing hospitals (eg, 'top 10%'). This top 10% benchmark encapsulates patients submitted by those select hospitals that most frequently provide evidence-based care. Innovative quality metrics presented in these reports include the use of anticoagulants, dosing of antithrombotics and procedural use.

Patient subgroups are presented to assist in evaluating potential inequities in treatment—not just by age, sex and race—but among patients with specific comorbid illnesses. The ACTION Registry-GWTG not only provides feedback to participating hospitals about their performance, but allows hospitals access to practical tools that assist in the improvement of local adherence to guidelines. These tools include: standing order templates; risk stratification algorithms; dosing pocket cards; drug dosing nomograms; internet discussion forums and clinician educational materials presented through webinars and slidesets. The ACTION Registry-GWTG is also a platform for participation in national QI initiatives, such as the AHA's Mission: Lifeline.[15 16]

How are individual patients identified?

Patients are primarily identified retrospectively through a screening of local administrative or clinical databases. Each patient's medical record serves as the main data source. After these records are abstracted by chart review, ACTION Registry-GWTG data are entered either through a software vendor or a secure, password-protected, web-based, data-entry system.

DATA QUALITY

Accuracy, validation and completeness

In accordance with NCDR data quality standards, each site's data submissions are measured for overall completeness before analysing and generating quarterly outcomes reports. Hospital-specific data quality information is also provided to participating sites throughout each quarterly data submission period. These reports provide details about records failing to meet inclusion criteria, duplicate patient entries, missing data elements and out of range values. Sites are encouraged and expected to reconcile these data problems, because poor data quality can adversely impact performance feedback. Current rates of missing data in the registry are remarkably low, averaging less than 5% across all collected data elements. Notably, variables such age, sex and race are missing in less than 0.5% of all cases.

RESULTS

Statistics

For descriptive purposes, we displayed results based on a hospital's aggregate composite performance score. Composite performance included five acute (eg, within 24 h) guideline metrics and six discharge guideline metrics, derived from the ACC/AHA clinical performance measures.[11] In particular, these acute therapies and care were as follows: (1) aspirin; (2) evaluation of left ventricular dysfunction; (3) STEMI time to fibrinolytic 30 min or less; (4) STEMI time to primary percutaneous coronary intervention 90 min or less; and (5) STEMI any reperfusion therapy. Similarly, discharge therapies included: (1) aspirin; (2) β-blocker; (3) ACE inhibitor or angiotensin receptor blocker (prescribed for patients with ejection fraction <40%); (4) statin; (5) smoking cessation advice; and (6) cardiac rehabilitation referral. Patient eligibility for each individual measure was determined according to predefined performance measure indications and recorded contraindications. Deaths within 24 h of hospital arrival were excluded from the acute measures and deaths at any time were excluded from the discharge measures. Calculated hospital composite performance scores are equal to the ratio of total received therapies for all patients at a single site out of the total number of opportunities for all patients at that site. Next, results were summated at the hospital level. Then, hospitals were divided into deciles of patients, based on their composite performance scores. We describe results for the 'top' and 'bottom' 10%, as well as the 'middle' 80%, of hospitals. Median values were used to describe continuous variables and percentages were reported for categorical variables.

Results summary

From 1 January 2007 to 30 September 2009, 383 sites submitted a total of 147 165 records into the ACTION Registry-GWTG database. The largest proportion of sites were non-academic (83%), cardiothoracic surgical centres (70%) and located in the south (37%). Notably, 12% of the ACTION Registry-GWTG hospitals did not have a cardiac catheterisation laboratory. Thirty hospitals (n=14 749 patient records) represented the top 10% of performers, whereas 95 hospitals (n=14 762 patient records) represented the bottom 10%. Top performing hospitals had a higher volume of data submission than poorer performing hospitals, thereby accounting for the discrepancy in numbers of hospitals in the top and bottom deciles. Hospitals were divided into these deciles irrespective of size. Of note, larger hospitals tended to have a better performance than small hospitals.

Patient demographics

Overall, ACTION Registry-GWTG patients had a median age of 64 years (54, 76) (25th, 75th interquartile range) with 28% of the patients being 75 years or older. Women comprised 35% of ACTION Registry-GWTG patients and 16% were non-white minorities (table 1). Patients were classified as having a STEMI in 39% of cases. The reported comorbid illness and previous cardiac history were characteristic of a higher-risk AMI population, particularly when compared with those enrolled in randomised clinical trials. Notably, 30% had a revascularisation procedure before admission, 12% had a previous episode of congestive heart failure and 8% had a history of stroke.

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Table 1 Baseline characteristics of patients by hospital overall composite performance

	Overall (n=147 165)	Top 10% (n=14 762)	Middle 80% (n=117 654)	Bottom 10% (n=14 749)
Demographics				
Age, median (Q1, Q3)	64 (54, 76)	64 (54, 76)	64 (54, 76)	65 (55, 78)
Age ≥75 years	28	27	28	32
Female gender	35	35	35	37
Minority race	16	11	16	21
Government or self-insured	44	43	43	48
Previous cardiac history				
Previous MI	25	24	25	25
Previous revascularisation	30	32	30	29
Previous CHF	12	11	12	13
Previous stroke	8	7	8	8
Comorbid illness				
Hypertension	69	69	69	70
Diabetes	30	29	30	31
Peripheral arterial disease	10	10	10	9
Dyslipidaemia	56	58	56	51
Current smoker	35	36	35	32
Presentation				
STEMI	39	39	39	38
Acute transfers in	31	40	31	19
Acute transfers out	7	2	5	21

CHF, congestive heart failure; MI, myocardial infarction; STEMI, ST-segment elevation myocardial infarction.

Processes of care

Overall rates of certain therapies among eligible patients were high, as illustrated in figures 1 and 2. The greatest disparities were observed in the use of acute clopidogrel, acute glycoprotein IIb–IIIa inhibitor, and discharge ACE inhibitor or angiotensin receptor blocker among patients with left ventricular dysfunction (left ventricular ejection fraction <40% or if qualitative moderate to severe left ventricular dysfunction). Hospitals in the bottom 10% also routinely had lower rates of invasive cardiac procedures, compared with their top 10% counterparts.

Ninety-six per cent of eligible STEMI patients received primary reperfusion therapy at the top performing hospitals

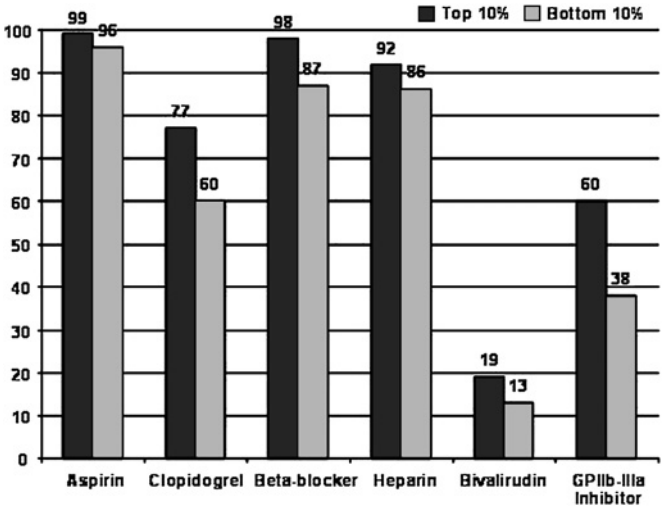

Figure 1 Acute therapies* by hospital overall composite performance. *All medication contraindications excluded. The top and bottom 10% hospitals are displayed for each type of acute therapy.

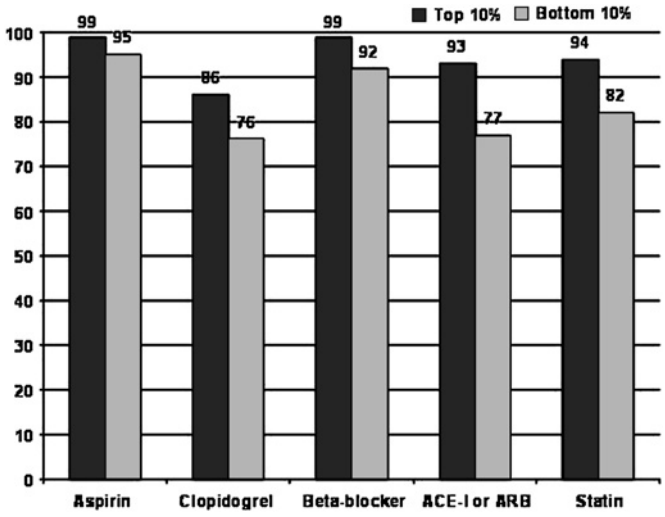

Figure 2 Discharge therapies* by hospital overall composite performance.** *All medication contraindications excluded. **Among ideal patients—ST-segment elevation myocardial infarction: ejection fraction less than 40%; non-ST-segment elevation myocardial infarction: ejection fraction less than 40%; any heart failure, diabetes mellitus, or hypertension. The top and bottom 10% hospitals are displayed for each type of discharge therapy. ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

(table 2), although 12% of patients received primary percutaneous coronary intervention outside of the recommended 90-min time window. This figure was over 30% in the bottom performing hospitals.

Unadjusted inhospital outcomes

The inhospital outcomes of ACTION Registry-GWTG patients are presented in table 3. Overall unadjusted inhospital mortality was 4.8%. Inhospital deaths occurred in 4.0% of the population at the top centres, compared with 5.6% at the bottom centres. Major bleeding rates during AMI hospitalisation remained relatively high; the top and bottom hospitals reported bleeding among 12.7% and 10.4% of patients, respectively.

Table 2 STEMI reperfusion strategies and NSTEMI invasive cardiac procedures by hospital overall composite performance

	Overall (n=147 165)	Top 10% (n=14 762)	Middle 80% (n=117 654)	Bottom 10% (n=14 749)
STEMI				
Overall reperfusion use*	93	96	94	83
Among all patients	78	84	80	61
Thrombolytic therapy	15	15	14	14
Primary PCI only	81	82	82	73
Timing of reperfusion†				
Door-to-balloon ≤90 min	79	88	79	69
Door-to-needle ≤30 min	58	67	61	49
NSTEMI				
Cath	82	98	91	66
Cath ≤48 h	67	82	75	51
PCI	55	62	55	46
PCI ≤48 h	45	52	47	37
CABG	12	13	14	10

*Among eligible.
†Excludes transfer-in patients.
CABG, coronary artery bypass grafting; Cath, catheterisation; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Table 3 Inhospital outcomes by hospital overall composite performance

	Overall (n=147 165)	Top 10% (n=14 762)	Middle 80% (n=117 654)	Bottom 10% (n=14 749)
Death	4.8	4.0	4.9	5.6
Death within 48 h	2.0	1.7	1.9	2.6
Cardiogenic shock	4.1	4.8	4.0	3.6
Congestive heart failure	6.9	7.4	6.9	6.9
Stroke	0.7	0.8	0.7	0.6
Major bleeding*	10.4	12.7	10.1	10.4

*Major bleeding defined as including any of the following: absolute drop from baseline to nadir haemoglobin values of 4 g/dl, intracranial haemorrhage, retroperitoneal haemorrhage, red blood cell transfusion (if baseline haemoglobin 9 g/dl), or witnessed bleeding event and red blood cell transfusion (if baseline haemoglobin <9 g/dl). Patients undergoing coronary artery bypass grafting (CABG) were censored from the major bleeding calculations starting at the time of CABG (eg, pre-CABG bleeding events were captured in the major bleeding calculations).

DISCUSSION

The ACTION Registry-GWTG is less than 3 years old, yet the registry has already spread to 383 US hospital sites and enrolled over 147 000 patients. The ACTION Registry-GWTG represents a national unification effort among leading organisations. The registry has demonstrated that the abstraction of high quality, reliable data, reflective of community practice, is possible. Furthermore, the ACTION Registry-GWTG can serve as a valuable resource for research and clinical care improvement in the following ways.

First, analysis of the ACTION Registry-GWTG data can provide important insights into the safety and effectiveness of AMI treatments when used in the 'real world'. In particular, the ACTION Registry-GWTG registry can serve as a platform for tracking new drugs or devices as they become utilised in routine clinical practice. This type of post-market information is vital to ensure that the safety and effectiveness of therapeutic agents is maintained throughout the transition from selected trial populations to the general CVD population. Roe *et al*[17] have already used the ACTION Registry-GWTG registry to track the use of drug-eluting stents in the USA.

Second, our assessment of the care provided by the top and bottom 10% of performers highlights the dual functionality of the ACTION Registry-GWTG—both as a national surveillance system of myocardial infarction (MI) and as a mechanism to promote local QI at participating sites. In general, opportunities for improvement tend to be newer therapies and procedures that involve multiple systems of care. Such cases are well positioned for QI efforts, such as revising admission and discharge order sets. Through the feedback reports, the ACTION Registry-GWTG sites can monitor their improvement over time through trended internal benchmarks. As sites (particularly those in the bottom 10%) work to improve care locally, the ACTION Registry-GWTG can be used to monitor improvements in patterns and predictors of overall care in the USA. Finally, as we look to the future, the ACTION Registry-GWTG registry can be used to assess the effectiveness of its recently launched Mission: Lifeline programme, a national campaign to improve STEMI systems of care.[15 16]

Third, with regard to research, the ACTION Registry-GWTG registry provides a unique opportunity to assess and describe the characteristics, care and outcomes of patients with MI in the USA. Interested authors can submit a publication proposal for consideration by the NCDR ACTION Registry-GWTG Research and Publications Committee (http://www.ncdr.com). Approved analyses are then conducted free of charge by the NCDR Analytic Center; the primary analytic centre for the ACTION Registry-GWTG is located at the Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina, USA.

In summary, ACTION Registry-GWTG data demonstrate the ongoing need for local improvement of adherence to clinical practice guidelines and other performance measures. The ACTION Registry-GWTG registry enables sites not only to identify opportunities to improve patient care across a broad range of process measures, but facilitates specific solutions to address these gaps, through both performance feedback reports and QI tools.

Limitations

The ACTION Registry-GWTG registry has several limitations. First, it is a voluntary registry. As a result, the current participating hospital profile trends to larger, tertiary centres (which may have better baseline performance) compared with smaller centres (which may possess fewer resources). There remains a large opportunity to increase site participation, given that there are approximately 4000 acute care hospitals that treat MI in the USA. Cited barriers to participation include patient privacy restrictions, personnel resource constraints and a presumed data collection burden. Educational efforts should highlight feasible solutions to these operational challenges as part of ongoing site recruitment efforts. Furthermore, the sponsoring organisations should pursue alignment of incentives for participating hospitals, such as reporting of quality of care data to payers by the registry to meet reporting requirements.

Second, data are limited to acute/subacute care and inhospital clinical outcomes documented in the medical record. As a result, the ACTION Registry-GWTG is reliant upon the quality and accuracy of the chart abstraction. The ability to track patients over time is necessary to develop a more thorough understanding of downstream resource utilisation, as well as long-term outcomes associated with use-specific therapies and procedures. Currently, there are efforts underway to expand the ACTION Registry-GWTG from its inhospital focus to one that could provide a longitudinal evaluation of MI patients. In particular, the ACTION Registry-GWTG can be linked with other administrative data sources (such as Medicare and private payers), to provide information on downstream clinical events and resource use (including deaths and rehospitalisations). Future intentions are to include patient identifier information that would permit direct linking of patients across multiple clinical registries (such as other procedure or ambulatory registries). Each of these possibilities present incremental patient privacy and sampling bias challenges, yet with a robust methodology, many efficiencies and beneficial cross-collaborations can be gained by adopting such an approach.

CONCLUSIONS

The ACTION Registry-GWTG is a prototype clinical registry that serves multiple purposes including disease surveillance, quality measurement and improvement and scientific discovery. Registries like the ACTION Registry-GWTG have the advantage of being able to provide dynamic performance feedback and being adaptable to the rapidly changing CVD therapeutic landscape. Furthermore, such registries have secured a valuable position in the scientific community by providing a dependable mechanism that allows the investigative process to be continued with regard to care delivery, patient safety and patient outcomes in clinical practice.

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