



Quality Improvement. Quantified.™

ACTION Registry®-GWTG™

Program Overview *December 2009*

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1. Background

Coronary artery disease (CAD) is a condition that leads to serious health complications, including myocardial infarction (MI) and cardiac death. A ruptured plaque in a coronary artery can lead to clot formation within the artery that disrupts blood flow and causes damage to the heart muscle. Because the heart muscle is not receiving a sufficient supply of blood, this can lead to acute myocardial ischemia, otherwise known as chest pain. The term “acute coronary syndrome” refers to any of the clinical conditions that arise as a result of acute myocardial ischemia, including ST-segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI), and unstable angina (UA).¹

These life-threatening disorders are a major cause of emergency medical care and hospitalization in the United States. In 2005, the National Center for Health Statistics reported 33.2 hospitalizations in 10,000 for CAD, and 23.1 hospitalizations in 10,000 for acute MI.

HEART DISEASE STATISTICS	
Estimated number of American adults with CAD in 2006 ²	16,800,000
Total number of deaths in the U.S. in 2006 ³	2,426,264
Number of deaths from heart disease in 2006 ⁴	631,636
Estimated annual incidence of new and recurrent MI attacks in 2007 ⁵	1.2 million
Estimated direct and indirect cost of CAD in the U.S. for 2008 ⁶	\$475.3 billion

Over the past 30 years, advances in cardiovascular care have resulted in a dramatic decline in mortality and morbidity associated with STEMI and NSTEMI.⁷ The ACC/AHA practice guidelines for the management of AMI patients define evidence-based diagnostic and treatment strategies that provide a framework for the use of evidence-based medications and interventions designed to improve outcomes and extend the life expectancy of these patients.⁸ However, there is strong evidence that the best treatments and strategies are not always utilized.

Recent registries that have documented patterns of care for ACS patients — NRMI (National Registry of Myocardial Infarction) and CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the ACC/AHA Guidelines) — have also demonstrated that guidelines adherence is sub-optimal for a large proportion of these patients. Despite targeted quality improvement (QI) efforts within these registries, treatment patterns for many high-risk sub-groups of patients remain sub-optimal, and treatment disparities persist. Thus, there is a unique opportunity for a comprehensive, nationwide assessment of AMI care to guide future quality improvement efforts designed to facilitate equitable and comprehensive delivery of care for these patients.

2. ACTION Registry®–GWTG™ Description

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) recently merged the NCDR® ACTION Registry® with the Get With The GuidelinesSM-Coronary Artery Disease registry. The resulting risk-adjusted, outcomes-based quality improvement program is called ACTION Registry–GWTG. By combining the data collection and quality reporting features of the former NRMI and CRUSADE registries along with the strengths of the GWTG-CAD program, the new ACTION Registry–GWTG is now the largest national quality improvement initiative focusing on high-risk AMI patients with STEMI and NSTEMI,

The purpose, objectives, audience, and scope of ACTION Registry–GWTG are far-reaching.

3. Purpose of ACTION Registry–GWTG

- Create a national surveillance system to assess the characteristics, treatments, and outcomes of patients hospitalized with AMI – focusing on high-risk patients with STEMI and NSTEMI

- Optimize the outcomes and management of AMI patients through implementation of evidence-based guideline recommendations in clinical practice
- Facilitate efforts to improve the quality and safety of AMI patient care; and to investigate novel quality improvement methods

4. Objectives of the ACTION Registry–GWTG

- Monitor the characteristics, treatments, and outcomes of patients hospitalized with AMI (STEMI/NSTEMI)
- Improve adherence to the ACC/AHA STEMI and NSTEMI guideline recommendations through monitoring of process of care measures, development of quality indicators based upon guideline recommendations, and benchmarked quality-of-care feedback reports
- Explore the association between evidence-based acute treatment strategies and risk-adjusted clinical outcomes
- Assess utilization of diagnostic imaging, laboratory tests and invasive procedures; and track hospital/coronary care unit length-of-stay data
- Assess utilization of evidence-based discharge medications; and risk-factor modification interventions
- Assess trends in medication dosing patterns, and improve drug safety through targeted quality feedback related to medication overdosing
- Identify barriers to implementing guideline recommendations for patients with AMI, and develop effective strategies to overcome these barriers
- Provide a valuable resource for research designed to improve the treatment and outcomes of patients with AMI
- Facilitate data collection for use in Joint Commission Core Measures reporting requirements, and for other performance measures

Sample questions that ACTION Registry–GWTG can answer:

- What are the characteristics of, and treatments used for, AMI patients?
- Are certain patient groups (e.g. women, elderly) being under-treated?
- What procedures are used, and how do they relate to outcomes?
- What are the in-hospital, procedure-related complications?
- How do measures of quality of care (i.e. use of proven therapies) relate to clinical outcomes?

5. ACTION Registry–GWTG Audience

Clinicians (cardiologists, emergency medicine physicians, hospitalists, primary care physicians, nurses, physician assistants, nurse practitioners), pharmacists, case managers, allied health care personnel, hospital quality improvement personnel and administrators, professional organizations, accrediting organizations, regulatory agencies, payers, pharmaceutical and device industries, and clinical research organizations.

6. How to Participate in ACTION Registry–GWTG

First steps include registering at the NCDR ACTION Registry–GWTG Website, www.ncdr.com. An ACTION Registry–GWTG Support Specialist will contact you after registration with the forms you will need to complete your enrollment, including the Business Associate Agreement.

7. ACTION Registry–GWTG Case Inclusion/Exclusion Criteria

Eligible patients must be admitted within 24 hours of acute ischemic symptoms, typically reflected by a primary diagnosis of STEMI or NSTEMI. Patients admitted for any other clinical condition are not eligible.

8. ACTION Registry–GWTG Data Collection

NCDR registry products, including ACTION Registry–GWTG, are created under the leadership of clinical experts with critical input from NCDR participants regarding the feasibility of implementation and the burden of data collection. ACTION Registry–GWTG Premier collects data on 270 variables, including patient demographics, transfer facility therapies, and reperfusion strategies. ACTION Registry–GWTG Limited collects data on 180 variables. Data are collected, validated, and submitted under the responsibility of a designated Registry Site Manager at each participating institution. The Duke Clinical Research Institute (DCRI) coordinates data collection efforts for ACTION Registry–GWTG.

8.1 Web-Based Data Capture

Information collected on Data Collection Forms (DCFs) may be entered by participating facilities via one of two secure, password-protected Web-based data entry systems. Through an Electronic Data Collection (EDC) tool managed by the NCDR; or a second Web-based data collection system managed by DCRI Participation in ACTION Registry–GWTG is required to be able to enter and access data from either collection system.

8.2 Vendor-Based Data Capture

The NCDR provides ACTION Registry–GWTG software specifications to interested vendors who wish to develop a registry software package product. With this data collection method, data are submitted via a secure Website in an encrypted, password-protected file. A list of certified software vendors is available on the ACTION Registry–GWTG Web page at www.ncdr.com under “Software Vendors.”

9. Collection of Existing Recorded Data, Privacy, and Ethical Considerations

The American College of Cardiology Foundation (ACCF) does not require Institution Review Board review and approval as a condition of participation in NCDR. The ACCF does, however, require that all participating facilities abide by policies and procedures of their facility. Please consult with your facility for guidance in participation in quality improvement activities. This program summary for ACTION Registry–GWTG may be used for presentation to your IRB if required by your facility policies.

ACTION Registry–GWTG is designed as a quality improvement registry that collects and reports observational data relating to patients presenting with STEMI and NSTEMI. Data collected in the registry are collected using existing medical record data. ACTION Registry–GWTG does not require that participating facilities contact individual patients.

The ACCF takes reasonable safeguards to protect the data collected through the registry including physical, technical and administration safeguards required of a Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All facilities participating in the registry are required to sign a Business Associate Agreement with the ACCF which stipulates permitted and restricted data uses.

The registry requires collection of direct identifiers allowing data captured in multiple registries to be interoperable, hence reducing the data collection burden of participating facilities. The Business Associate Agreement also stipulates permitted disclosures and secondary uses of registry data. Please note that the ACCF is only permitted to disclose a Limited Data Set to third parties for very restrictive purposes. The only permitted disclosure of direct identifiers is to entities who actively act as sub-contractors of the ACCF. Such sub-contractors are bound by contract under the same requirements stipulated in the Business Associate Agreement as required by HIPAA.

10. ACTION Registry–GWTG Data Quality

The NCDR Data Quality Program (DQP) is designed to meet the requirements needed for a comprehensive health information management system. The Onsite Data Audit Program is a component of this effort. The overall purpose of the DQP is to ensure that data submitted to the NCDR are complete, consistent, and accurate – ultimately improving the overall quality of ACTION Registry–GWTG.

10.1 Data Completeness

In keeping with established NCDR data quality procedures, participant data submissions are reviewed to establish overall completeness prior to analyzing and developing reports for any given quarter. NCDR assesses the overall completeness of a participant’s data submission and provides feedback to the participating hospitals via a Data Quality Report (DQR). The DQR provides the participating hospitals with a confidential analysis of their data completeness, and is used by the participant to help prioritize data “cleaning” efforts.

10.2 Data Consistency and Accuracy

Each year participating sites will be randomly selected to be audited. Trained nurse abstractors will conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Overall accuracy of the audited information will be determined by comparing audit findings against data originally submitted from each site. Each participant will receive a confidential audit report which will display their audit score and individual accuracy for each data element.

11. ACTION Registry–GWTG Call for Data, Reporting, and Data Analysis

The quarterly Call for Data (CFD) occurs during the two calendar months following the end of each quarter throughout a calendar year. For example: Q1 CFD is during the months of April and May. Registered participants will receive the CFD reminder via email, reminding participants of the data submission deadline. Participants have until 11:59 p.m. on the last day of the CFD period following the end of each quarter. A DQR that identifies invalid data to be corrected and resubmitted is available to participants to minimize revision volumes, and to provide rapid cycle feedback on the data submission process. The DQR is available for download on the DCRI Data Collection Tool website. After submission/resubmission, the data are compiled and analyzed for the ACTION Registry–GWTG quarterly benchmark report.

ACTION Registry–GWTG participants receive access to comprehensive, timely information about measuring quality of care for their AMI patients in the form of reports that are comprised of evidence-based elements that correspond to the ACTION Registry–GWTG data elements. Participants can use this information for improving patient care, supporting local quality-improvement programs, and communicating with regulatory and contracting organizations.

We recommend that data submission occur at regular, frequent intervals to minimize the volume of data to be reviewed for completeness and accuracy, as well as to provide more timely feedback to participating facilities. It is recommended that data submission to the DQR occur on a weekly basis.

Data are available to participating hospitals in two formats:

- Real-time, continuously updated online reports: These user-friendly, real-time reports are available on demand at the NCDR and DCRI Website, and allow hospitals to view their non-risk-adjusted data by condition type, specific procedures, guideline recommendations, and patient outcomes.
- Risk-adjusted, institution-specific quarterly and annual reports: These reports provide detailed and comprehensive representations of reported data. Risk adjusted values are reported providing data about performance measures.

Both types of reports facilitate continuous monitoring of quality improvement efforts and enable facilities to compare, on a blinded basis, their institution's practice patterns to national averages and volume-based peer comparison groups.

As a result, participation in ACTION Registry–GWTG provides a potent research tool that permits focused analysis of clinical treatment, procedures, and outcomes of AMI patients. Data collected through ACTION Registry–GWTG can be analyzed to assess determinants of practice guideline implementation, to assist in medical decision-making, and to assess the appropriateness of medical care provided for patients with STEMI or NSTEMI.

12. Ongoing ACTION Registry–GWTG Participant Support

ACTION Registry–GWTG provides “help desk” support to all participants from 9:00 a.m. to 5:00 p.m. (ET) on regular business weekdays. This includes telephone and email support for participants who have questions or need assistance with any facet of the registry operations.

12.1 Participant Training and Orientation

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the “help desk” functions described above, training and orientation take the following forms:

- **Introductory Calls and Webcasts**

ACTION Registry–GWTG participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the ACTION Registry–GWTG program and answer questions.

- **Electronic Data Capture Training**

Participants who submit data via the web-based platform will need to complete training for the system, either via Webcast or online module. This training educates users regarding platform functionality, data entry and review, and user account management.

- **Third-Party Vendor Data Capture Systems**

Participants who submit data through certified third-party vendor systems will receive training regarding the use of these systems from the originating organization. A list of certified software vendors is available on the ACTION Registry–GWTG web page at www.ncdr.com under “Software Vendors.”

12.2 Regional Group Meetings

NCDR registry participants, in many cases, have organized themselves into regional training and networking groups. ACTION Registry–GWTG staff support these groups and also organize additional groups as needed. Educational meetings and/or teleconferences may include presentations regarding recent findings from ACTION Registry–GWTG data analyses, strategies for ensuring successful collaboration between various hospital specialties and departments in support of the quality improvement process, question and answer sessions or case studies, and other topics of interest. Members of the ACTION Registry–GWTG Clinical Support Team and staff conduct these sessions.

13. ACTION Registry–GWTG Governance

The mission of NCDR is to improve the quality of cardiovascular patient care by providing information, knowledge, and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes. Oversight of NCDR is provided by the NCDR Management Board.

13.1 ACTION Registry–GWTG Steering Committee

The ACTION Registry–GWTG Steering Committee reports to the NCDR Management Board. It provides strategic direction for ACTION Registry–GWTG, and monitors research and clinical activities that include the following:

- Sets a high level agenda for the strategic direction of ACTION Registry–GWTG
- Advocates, promotes, and influences key groups regarding ACTION Registry–GWTG activities
- Ensures that activities conducted by the ACTION Registry–GWTG Research and Publications Committee and Clinical Support Team are congruent with NCDR methodologies and policies
- Identifies new opportunities and strategies to further promote utilization of ACTION Registry–GWTG
- Establishes working groups as needed to support specific projects

13.2 ACTION Registry–GWTG Research and Publications Subcommittee

This subcommittee oversees all activities related to research and publications for ACTION Registry–GWTG including:

- Oversees all research activities, including the evaluation and approval of industry and government research proposals
- Oversees the production of analytical and/or descriptive abstracts, poster presentations, and manuscripts
- Selects secondary reviewers for abstract and manuscript development
- Participates in open sessions of the Data Monitoring Board and reviews reports from closed sessions

13.3 ACTION Registry–GWTG Quality Improvement (QI) Subcommittee

This subcommittee oversees all activities related to quality improvement for ACTION Registry–GWTG including:

- Oversees all QI activities, including the development of QI toolkits, site-specific feedback, and clinic educational initiatives such as:
 - Quarterly benchmarked outcomes reports, D2B reports, utilization reports, other canned reports
 - Discharge tools, standing orders, treatment algorithms, etc.
 - Speaker PowerPoint slide sets, Webinars, Webcasts, discussion boards
 - Descriptive quarterly performance reports
- Participates and coordinates with other NCDR committees, specifically the Science and Oversight Committee (SOC), and subcommittees to provide optimal quality improvement initiatives

13.4 ACTION Registry–GWTG Clinical Support Team

The ACTION Registry–GWTG Clinical Support Team provides ad hoc clinical expertise as needed to respond to questions from participating hospitals regarding data elements and data collection. The team consists of a small group of members, all of whom are clinical experts on the ACTION Registry–GWTG patient population.

14. ACTION Registry–GWTG Operations Oversight

NCDR oversees all activities associated with ACTION Registry–GWTG. DCRI provides a Web-based EDC, report generation, and statistical functions for ACTION Registry–GWTG.

15. ACTION Registry–GWTG Sponsorship

ACTION Registry–GWTG is sponsored by Bristol-Myers Squibb/Sanofi Aventis Pharmaceuticals Partnership and Schering-Plough Corporation who provide material support for the operation of the data collection infrastructure, marketing, and organizational activities. As a result, there is no cost to hospitals to participate in ACTION Registry–GWTG.

Sponsoring organizations participate in the ACTION Registry–GWTG Sponsor Liaison Group, which provides input to the ACTION Registry–GWTG Steering Committee for their consideration. They have no role in the operations, governance, or oversight of ACTION Registry–GWTG, including the collection of data, designation of quality indicators, or development of feedback reports. Similarly, sponsors may independently support registry research subject to NCDR policies and processes. Such sponsoring organizations will have no undue influence on the registry’s research pipeline, including the selection of topics, approval of proposals, or approval of manuscripts prior to publication.

16. ACTION Registry-GWTG Partners

NCDR and AHA are joined in support of ACTION Registry–GWTG by the Society of Chest Pain Centers and the American College of Emergency Physicians.

17. Other NCDR Quality Improvement Initiatives

NCDR QI initiatives are designed to increase the use of, and encourage adherence to, evidence-based clinical guidelines. Examples of ongoing QI efforts include the following:

17.1 **D2B: An Alliance for Quality**

The D2B (Door to Balloon) Alliance is a network of hospitals, physician champions, and strategic partners who have come together as a nationwide community of committed organizations and individuals to address the challenge of lowering D2B times. This program is designed to provide hospitals with the key evidence-based strategies and supporting tools that they need to begin reducing their door to balloon times to 90 minutes or less. A Web-based networking component creates a learning community that hospitals can use to share their findings and experiences with others. More information can be found at www.d2balliance.com.

ACTION Registry–GWTG encourages its participants to continue with this nationwide effort and supports them by providing detailed feedback reports and graphical depictions of critical measures related to reducing door to balloon/needle time.

17.2 **PINNACLE Registry™ formerly the IC³ Program®**

The PINNACLE Registry is the first *office-based* NCDR initiative designed to assess physician adherence to the ACC/AHA clinical practice guidelines for patients with chronic stable coronary artery disease (CAD). CAD is the leading cause of death in the U.S The PINNACLE Registry addresses the need to better understand current adherence with established, evidence-based, best practices, as codified by nationally accepted performance measures. The PINNACLE Registry will help develop strategies that can assist practitioners in treating these patients in the outpatient setting. To that end, the Registry includes customized quality improvement resources designed to assist the entire clinical care team in addressing and minimizing barriers to clinical guideline compliance, and to improve the quality of care for patients at risk for repeat AMI events. More information can be found at www.ncdr.com/PINNACLERegistry

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