Synthesizing Lessons Learned From
Get With The Guidelines
The Value of Disease-Based Registries in Improving Quality and Outcomes

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The American Heart Association/American Stroke Association (AHA/ASA) is a trusted source of scientific information in cardiovascular medicine. The AHA/ASA has a longstanding commitment to support state-of-the-art scientific research in cardiovascular disease and stroke. The AHA/ASA has also developed a leadership role in translating cardiovascular science into internationally respected guidelines. In 2000, however, the AHA/ASA concluded that, to provide maximal benefit for patients with cardiovascular disease and those at risk, it needed to develop a rigorous approach to translating its guidelines into clinical practice. The result was a comprehensive suite of programs collectively called Get With The Guidelines (GWTG). Modeled in part on the University of California, Los Angeles Cardiovascular Hospitalization Atherosclerosis Management Program (CHAMP),1,2 GWTG was successfully piloted by the AHA in Massachusetts.3 Based on the success of the Massachusetts pilot, the AHA committed significant human and financial resources to extend the program across the United States. This commitment included the development of a national steering committee composed of AHA/ASA volunteers, and the addition of multiple modules including hospital-based management of coronary artery disease, heart failure, stroke, and resuscitation after in-hospital cardiac arrest. The scientific foundation of the program is the best evidence from the latest American College of Cardiology/AHA/ASA guidelines. GWTG staff work with participating hospitals to implement these guidelines by using AHA/ASA quality improvement professional consultation, workshops, and Webinars. In addition, the AHA developed sophisticated clinical databases (registries) through which hospitals and physicians collect information in real time for the assessment of quality, regional, and national benchmarking, national recognition, and the generation of new science. The AHA underwrites a portion of the costs associated with the technology platform and data collection tools to reduce the financial burden on participating sites.

From the 4 GWTG disease-specific registries, >200 articles have been published in peer-reviewed journals. This statement will distill the information from those articles into a concise review of particular use to policy makers throughout the country and world. The scope and impact of GWTG program is profound. Of the 6280 hospitals registered with the American Hospital Association, 1956 US hospitals participate in at least 1 GWTG program (31%).4 Many institutions use ≥2 modules (Figure 1). These hospitals have submitted almost 5 million patient records since the inception of GWTG, with >2 million patients in the Stroke registry alone (Figure 2). In certain diseases, such as stroke, GWTG now enrolls >40% of all index hospitalizations in the United States annually (Figure 2).
This statement will also highlight lessons learned from GWTG and elucidate their policy implications in 4 distinct sections. The first section presents an overview of the GWTG program and evidence that the GWTG performance improvement system can be implemented nationally and is associated with a substantial improvement in quality of care over a broad range of cardiovascular conditions in multiple settings. The second section addresses the power of assembling GWTG data to (a) generate new knowledge, (b) identify areas for future quality improvement efforts and measures, (c) drive measure prioritization and construct, (d) improve the development of measures, guidelines, and implementation strategies to reduce racial and sex disparities, and (e) determine the safety and effectiveness of therapies applied in routine practice. The third section presents evidence that GWTG has made a contribution to increasing the value of health care for our hospitals, payers, and our patients. We specifically explore reductions in length of stay and readmission rates and improvements in patient safety. In the fourth section, we address how the linkage of the GWTG clinical database with administrative data (eg, Medicare fee-for-service claims data) fosters real-world clinical effectiveness research (CER) and can be used to assess current practice, identify focused areas of health disparities, and develop successful implementation strategies to address opportunities to improve care. The final 2 sections address the limitations of GWTG and summarize policy recommendations.

**National Implementation and Impact on Quality of Care**

There are substantial gaps in quality of care for cardiovascular disease, including disparities by sex, race/ethnicity, and geographic region. The GWTG program was launched to improve in-hospital quality of care and reduce disparities by providing a platform for hospitals to review their own data with hospital-selected regional and national benchmarks. The program provides clinical decision support tools, Webinars, conferences focused on quality improvement, and other educational materials. In addition, the program provides expert AHA field staff to assist providers in developing sophisticated quality improvement programs. For more detail on the scope of activities in the GWTG program readers are referred to references 3, 6, and 7. In addition to the significant commitment of resources by the AHA/ASA, hospitals must commit quality improvement professionals and data abstraction capabilities to be successful. By also facilitating real-time hospital and individual physician access to benchmarked performance data, providers can compare their performance against other hospitals based on a large selection of variables. These include benchmarking against all GWTG hospitals, hospital systems,
geographic regions, hospital teaching status, bed size, and a variety of other hospital characteristics.

GWTG uses chart abstraction of clinical data elements into a Web-based platform provided by Outcome: A Quintiles Company (Cambridge, MA). Case ascertainment is either concurrent with the use of clinical criteria or retrospective based on coding. Process measures are divided into achievement (performance) measures and quality measures. Achievement measures have the strongest supporting evidence and strongest link between the process and health outcomes. Most of these measures are endorsed by the National Quality Forum (NQF). These measures drive the GWTG Performance Achievement Award program and are shown in Tables 1, 2, and 3. Quality measures are supported by strong evidence, but not as robust as that supporting achievement measures. These quality measures are important future candidates for achievement measures, and extend the scope of interventions available to already high-performing hospitals. Finally, these quality measures can support recent changes to the NQF endorsement process requiring previous field testing of candidate performance measures.

Table 1. Time Trends in GWTG-ACS Quality-of-Care Measures, 2006–2011

<table>
<thead>
<tr>
<th>Quality of Care Measure</th>
<th>2006*</th>
<th>2007*</th>
<th>2008*</th>
<th>2009</th>
<th>2010*</th>
<th>2011*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin within 24 h of admission</td>
<td>94.7</td>
<td>92.8</td>
<td>91.2</td>
<td>90.9</td>
<td>97</td>
<td>97.6</td>
</tr>
<tr>
<td>Aspirin at discharge</td>
<td>94.4</td>
<td>95.8</td>
<td>94.9</td>
<td>95.5</td>
<td>98</td>
<td>98.3</td>
</tr>
<tr>
<td>β-Blockers at discharge</td>
<td>92.8</td>
<td>94.6</td>
<td>94.5</td>
<td>94.9</td>
<td>96</td>
<td>96.7</td>
</tr>
<tr>
<td>Lipid-lowering medication at discharge</td>
<td>84.5</td>
<td>85.6</td>
<td>81.6</td>
<td>86.8</td>
<td>92†</td>
<td>98.4†</td>
</tr>
<tr>
<td>Lipid therapy at discharge if LDL cholesterol &gt;100 mg/dL</td>
<td>89.1</td>
<td>90.7</td>
<td>91.9</td>
<td>92.5</td>
<td>NM</td>
<td>NM</td>
</tr>
<tr>
<td>ARB/ACEI at discharge for patients with LVEF &lt;40%</td>
<td>87.3</td>
<td>91.1</td>
<td>91.9</td>
<td>91.9</td>
<td>86</td>
<td>87.8</td>
</tr>
<tr>
<td>Adult smoking cessation advice/counseling</td>
<td>94.3</td>
<td>97.4</td>
<td>98.4</td>
<td>98.4</td>
<td>98</td>
<td>98.4</td>
</tr>
<tr>
<td>Cardiac rehabilitation referral for AMI patients</td>
<td>71.1</td>
<td>63.6</td>
<td>52.0</td>
<td>49.1</td>
<td>75</td>
<td>76.5</td>
</tr>
</tbody>
</table>

Values are percentages. AMI indicates acute myocardial infarction; ARB/ACEI, angiotensin receptor blocker/angiotensin-converting enzyme inhibitor; GWTG-ACS, Get With The Guidelines–Acute Coronary Syndrome; LDL, low-density lipoprotein; LVEF, left ventricular ejection fraction; and NM, not measured.

*The American Heart Association (AHA) GWTG-Coronary Artery Disease (CAD) registry was merged into the Acute Coronary Treatment and Intervention Outcomes Registry (ACTION) registry. Therefore, measures from 2006–2009 are from the AHA’s GWTG-CAD registry. 2010/2011 measures are from the ACTION registry.
†Represents statin use.
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Measures are developed by physician volunteers and AHA staff and are harmonized with measures developed by the American College of Cardiology/AHA, US Department of Health and Human Services, and The Joint Commission and those already endorsed by the NQF.

Although GWTG is a voluntary program, participation has grown remarkably in each disease module since program inception (Figures 1 and 2). The high uptake of GWTG within the stroke community is likely driven by recommendations from the Brain Attack Coalition and ASA that primary stroke centers should engage in ongoing continuous quality improvement, and by the proliferation of state regulations or state-based requirements.
legislation requiring designation of centers that receive acute stroke patients. In addition, many hospitals use GWTG-Stroke as the platform for data collection for submission to The Joint Commission, to the Centers for Disease Control and Prevention Paul Coverdell Registry, or to public health authorities as part of state-based regulatory or quality improvement initiatives. In 2012, the AHA/ASA and The Joint Commission developed and launched the Comprehensive Stroke Center program based on consensus guidelines and performance measures supported by AHA scientific statements and the Brain Attack Coalition, parallel to the process used to design the primary stroke center process. The data collection specifications for the Comprehensive Stroke Center program are in addition to the basic primary stroke center requirements and are in pilot phase in 2013, after which they will be finalized.

Outcome: A Quintiles Company serves as the data collection (through their Patient Management Tool) and coordination center for GWTG. The Duke Clinical Research Institute serves as the data analysis center and has an agreement to analyze the aggregate deidentified data for research purposes.

Examples of the rapid and sustained year-over-year improvement in evidence-based care for stroke, heart failure, and coronary artery disease are shown in Tables 1, 2, and 3. In some instances, quality of care was poor at program inception with a substantial potential for improvement.

An audit using central reabstraction of GWTG-Stroke data suggests that hospitals of all types and sizes are accurately reporting their data without a bias toward overestimating their own performance. Hospital-reported improvement in care is driven by real changes rather than by changed documentation or judgments of eligibility. The GWTG Steering Committee plans ongoing audits to ensure the validity and reliability of the GWTG databases. In addition, the databases contain optional data fields to drive hospital internal performance which have varying degrees of completeness. These fields do not, however, include the variables needed for quality measure calculation or recognition.

GWTG includes large numbers of academic and community hospitals in urban and rural settings in all 50 states, the District of Columbia, and Puerto Rico. In the 1956 hospitals participating in GWTG, median bed size is 243, 13% have bed size <100, 34% are academic, 46% are nonteaching, and 78% are urban and 20% are rural. In the United States, 54% of hospitals have <100 beds, 24% are teaching, and 65% are urban. This diversity demonstrates the feasibility of implementing GWTG in all types of hospitals, but the different distribution raises questions about blanket applicability at the hospital level. The patient population, however, appears to be representative of the overall US population for stroke patients.

Hospital retention to date has been excellent (mean of 90% over the past 3 years), but important challenges in sustaining GWTG and promoting additional program growth exist. Manual chart abstraction yields high-quality, reliable clinical data, but is time consuming and must be self-funded by the participating hospitals. In response to this challenge, GWTG has developed tools to facilitate data abstraction and has partnered with electronic health record vendors to support batch uploading and data integration. Central program coordination and database maintenance and analysis, although very efficient, are still costly. Policies that provide incentives for hospital quality improvement (eg, through accreditation programs and pay-for-performance incentives with financial support for participating hospitals) could further enhance the growth and sustainability of GWTG.

Hospital participation in GWTG is strongly associated with rapid and sustained improvement in evidence-based care in participating hospitals. All the GWTG modules have been associated

### Table 3. Time Trends in GWTG-Stroke Quality-of-Care Measures, 2006–2011

<table>
<thead>
<tr>
<th>Quality of Care Measure (%)</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV tPA in patients who arrived ≤2 h after symptom onset, treated ≤ 3 h†</td>
<td>55.8</td>
<td>60.2</td>
<td>63.9</td>
<td>73.1</td>
<td>76.2</td>
<td>78.3</td>
</tr>
<tr>
<td>IV tPA in patients who arrived &lt;3.5 h after symptom onset, treated ≤4.5 h†</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>42.5</td>
<td>57.9</td>
</tr>
<tr>
<td>IV tPA Door-to-Needle Time ≤60 min</td>
<td>22.5</td>
<td>24.9</td>
<td>25.9</td>
<td>28.0</td>
<td>29.5</td>
<td>33.8</td>
</tr>
<tr>
<td>Thrombolytic complications: IV tPA and life-threatening, serious systemic hemorrhage</td>
<td>20.8</td>
<td>17.3</td>
<td>16.1</td>
<td>15.1</td>
<td>13.1</td>
<td>15.7</td>
</tr>
<tr>
<td>Antithrombotics ≤48 h after admission*</td>
<td>94.8</td>
<td>95.8</td>
<td>96.0</td>
<td>96.2</td>
<td>96.3</td>
<td>96.7</td>
</tr>
<tr>
<td>DVT prophylaxis by second hospital day*</td>
<td>85.3</td>
<td>88.9</td>
<td>92.2</td>
<td>92.7</td>
<td>92.2</td>
<td>93.5</td>
</tr>
<tr>
<td>Antithrombotics at discharge*</td>
<td>94.1</td>
<td>95.1</td>
<td>97.0</td>
<td>97.8</td>
<td>97.8</td>
<td>98.1</td>
</tr>
<tr>
<td>Anticoagulation for atrial fibrillation at discharge*</td>
<td>88.2</td>
<td>89.5</td>
<td>93.1</td>
<td>93.5</td>
<td>93.5</td>
<td>93.1</td>
</tr>
<tr>
<td>Therapy at discharge if LDL cholesterol &gt;100 mg/dL or LDL cholesterol not measured or on therapy at admitt</td>
<td>70.3</td>
<td>76.3</td>
<td>82.1</td>
<td>86.2</td>
<td>88.1</td>
<td>89.8</td>
</tr>
<tr>
<td>Counseling for smoking cessation*</td>
<td>86.1</td>
<td>92.2</td>
<td>94.3</td>
<td>96.2</td>
<td>96.7</td>
<td>97.0</td>
</tr>
<tr>
<td>Lifestyle changes recommended for BMI &gt;25 kg/m²</td>
<td>42.5</td>
<td>45.7</td>
<td>51.7</td>
<td>57.3</td>
<td>57.8</td>
<td>57.8</td>
</tr>
<tr>
<td>Composite quality of care measure</td>
<td>85.9</td>
<td>88.9</td>
<td>91.7</td>
<td>93.3</td>
<td>93.7</td>
<td>94.4</td>
</tr>
</tbody>
</table>

Values are percentages.

BMI indicates body mass index; DVT, deep venous thrombosis; GWTG-Stroke, Get With The Guidelines–Stroke; IV, intravenous; LDL, low-density lipoprotein; and tPA, tissue-type plasminogen activator.

*Indicates the 7 key achievement measures targeted in GWTG-Stroke.

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with significant improvements in multiple processes of care strongly linked to improved outcomes. These improvements are summarized in Tables 1, 2, and 3. These changes have been rapid and sustained over many years. In addition, GWTG has produced multiple specific improvements in guideline adherence documented in the specific sections that follow.

**Facilitate Synthesis of Data to Better Understand Practice Patterns and Disease States**

**Generate New Knowledge and Understanding**

Information about healthcare trends and outcomes are critical to our understanding of and improvement in the treatment and prevention of acute and chronic diseases. The GWTG program is designed to improve the care of individual patients and to facilitate the rapid evaluation of current practices at the provider, clinic, hospital, and regional level.

Through its ongoing real-world surveillance function, GWTG can serve as a data source for agencies that track and report disease incidence and burden. Many recognize that research and its synthesis into guidelines do not have the same results or outcomes in real-world practice. This may be because research results are not applied in the same way as in a trial, diffuse slowly through the medical community, or are not applied at all. Surveillance of practice allows the characterization of these changes over time, the opportunity to accelerate improvement and demonstrate differences between practitioners and geographically diffuse healthcare institutions.

Disparities in cardiovascular health and health care in the United States are well documented in the 2003 Institute of Medicine report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. These inequalities continue and include differences by sex, education level, income, insurance, and geographic location. For example, a recent review found that blacks were less likely to be admitted to a coronary care unit, spent less time in the unit, and were likely to be discharged after a shorter hospital stay.

GWTG studies have shown both reductions in and elimination of disparities in the delivery of hospital-based cardiovascular and stroke care. In each case, new knowledge emerged from the GWTG analyses, and valuable lessons learned paved the way for new GWTG strategies to reduce health disparities elsewhere. For example, GWTG researchers reported substantial underuse of implantable cardiac defibrillators (ICDs) in eligible women and black patients in comparison with white male patients with systolic heart failure. The program then focused educational efforts in workshops and Webinars on the importance of ICD placement in eligible patients. From 2005 to 2009 in GWTG-Heart Failure–participating hospitals, the authors observed a significant increase in ICD therapy use in all sex and race groups, eliminating the observed disparities. In hospitals participating in GWTG-Stroke there were substantial improvements in acute ischemic stroke care demonstrated over time in all race/ethnic groups (Figure 3).

The GWTG platform is also a valuable tool in tracking the rate of diffusion of new knowledge and the adoption of new guideline recommendations. GWTG researchers demonstrated that the proportion of eligible patients with acute ischemic stroke treated with intravenous tissue-type plasminogen activator (tPA) within 4.5 hours of onset increased rapidly and substantially after publication of study results and an ASA advisory. GWTG was able to facilitate rapid adoption, track the rate of adoption, and identify areas for further improvement.

Finally, the GWTG program has engaged young investigators in the examination of registry information, generation of new ideas, and publication of articles that have not only contributed to new knowledge and understanding, but also have helped launch young investigator careers. To date, the program has awarded 41 young investigator awards.

**Essential for Identifying Areas for Future Quality Improvement Efforts/Measures**

Data generated by the GWTG program are essential for identifying areas for future quality improvement efforts and

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**Figure 3.** Equitable improvement in quality of care among race/ethnic groups with stroke: defect-free measure adherence for Get With the Guidelines Hospitals. Defect-free care means the percentage of patients in whom all interventions for which the patient is eligible are provided. This is also called perfect care %. Reproduced with permission from Schwamm et al. Copyright © 2010, American Heart Association, Inc.
quality measurement. Analyses of GWTG data have identified gaps in evidence-based care. With awareness of such gaps, quality measures can be highlighted and adherence subsequently tracked over time. This iterative process makes the GWTG registries dynamic—they not only report data, but they facilitate quality improvement by providing feedback to sites about their individual performance in comparison with aggregate data.

As noted, registry data provide real-world information about how patients are actually being treated in a way that randomized clinical trials cannot. For example, GWTG-Heart Failure demonstrated dramatic underuse of aldosterone antagonists despite randomized clinical trial data supporting their use. Only one third of eligible patients without any documented contraindications were prescribed aldosterone antagonists on discharge. By incorporating aldosterone antagonist prescription in appropriate patients into Target: Heart Failure, an extension of GWTG, this and other clinical opportunities can be addressed and performance improved.

Despite compelling evidence and national guidelines, a pivotal GWTG report identified immense hospital variation in the percentage of ischemic stroke patients who received their thrombolytic dose within 60 minutes of hospital arrival. Based on these data, GWTG-Stroke has implemented Target: Stroke, a national quality improvement initiative to reduce door-to-needle time in intravenous tPA use through the use of 10 key evidence-based strategies. The Target: Stroke program is now assessing the ability of the 1200 participating hospitals to achieve the 60-minute door-to–tPA target in 50% of patients.

Drive Prioritization of Measures, Identify/Test New Measures, and Determine Measure Construct

The AHA/ASA and GWTG have helped convene key stakeholders to promote harmonization and definition of evidence-based measures with strong process outcome links. Data from GWTG have been invaluable in updating American College of Cardiology Foundation/AHA performance measure sets for acute myocardial infarction and for heart failure. In addition, the AHA/ASA helped convene stakeholders to identify and prioritize measures forming the basis of stroke quality improvement over the next decade. Over the past decade, various healthcare accreditation and quality improvement organizations in the United States have become actively involved in improving the quality of care for stroke patients. These early efforts centered on the development and standardization of achievement measures designed to measure specific aspects of the structure, process, and outcomes of acute stroke care. Most of these measures were developed based on the recommendations of evidence-based clinical guidelines, and the benchmarks proposed by the Brain Attack Coalition for the establishment of primary stroke centers, as well. In 2003, the Stroke Performance Measure Consensus Group—a collaboration between the AHA/ASA, The Joint Commission, and Centers for Disease Control and Prevention—began the essential process of harmonizing definitions and abstraction rules for stroke performance measures. The consensus process resulted in 10 harmonized acute hospital care stroke performance measures. Eight of the 10 measures were subsequently endorsed by the NQF, which acts as an independent authority and clearinghouse for the establishment of quality-related measures. Centers for Medicare & Medicaid Services (CMS) will likely include the 8 NQF-endorsed stroke measures as part of its core measure pay-for-reporting initiative beginning with inpatient discharges in fiscal year 2015. These publicly reported performance measures will be available to consumers on the CMS Hospital Compare Web site. Additionally, physician-level stroke performance measures have been endorsed by the NQF for use in the CMS Physician Quality Reporting Initiative program, an incentive pay-for-reporting program.

The GWTG-Stroke Program has played an essential role in the development and tracking of these stroke performance measures; data from the GWTG-Stroke registry, as well as other stroke quality improvement initiatives, have served to illustrate the importance of ongoing and systematic data collection. For example, analysis of >320,000 ischemic stroke patients treated at 800 GWTG-Stroke hospitals between 2003 and 2008 found clinically meaningful improvements in all 7 measures examined with absolute increases ranging from 3.2% to 30.7%. Based on the strength of the GWTG program, and its reputation for reliable data collection, several states now use GWTG as a required component for state stroke center designation, and the vast majority of the states participating in the Centers for Disease Control and Prevention’s Paul Coverdell National Acute Stroke Registry also use GWTG as their data entry and quality improvement vehicle. These public–private partnerships are another critical example of how collaboration helps to identify and refine appropriate measures and ensure effective and broad implementation.

Improve Development of Process of Care Measures, Guidelines, and Their Implementation

The GWTG program and database include processes of care measures that inform clinicians about practice patterns, the level of equitable care, and adherence to clinical practice guidelines, and facilitate clinical quality improvement. In 1 report of Medicare patients, hospitals enrolled in the GWTG-Heart Failure registry demonstrated better processes of care than other hospitals and had lower 30-day readmission rates. In specific patient populations, including women, Hispanics, and Asian Americans, a decrease or elimination of sex and race/ethnic disparities was observed. GWTG researchers found that lower-risk patients were referred more often to disease management programs and that quality and performance measures were higher in those referred. Such data could be used to optimize the selection of patients for referral. In patients with acute coronary syndromes, learning that intensive lipid-lowering therapy was not prescribed at hospital discharge for most eligible patients provides evidence that greater attention is needed in the implementation of guideline-recommended intensive statin therapy.

Determine the Safety and Effectiveness of Therapies as Applied in Routine Practice Rather Than the Highly Monitored Setting of Controlled Trials

Randomized controlled trials are highly monitored for safety and for delivery of therapy, are typically conducted in
specialized practice settings, and include patient populations that may not be representative of the entire population with the disease.

A recent GWTG study showed that intravenous tPA for ischemic stroke is safe, without increased risk of intracranial hemorrhage, in patients taking warfarin with a subtherapeutic international normalized ratio of $\leq 1.7$. This study of 23,437 patients treated with tPA, of whom 1802 were taking warfarin, provides compelling evidence that patients on subtherapeutic warfarin should indeed be treated with tPA, as has been recommended by AHA guidelines and US Food and Drug Administration package labeling for years, despite no controlled trial evidence that this strategy is safe.

**GWTG’s Contribution to Increasing the Value of Health Care**

Achieving high value is an overarching goal of healthcare delivery. The simple equation, Value = Quality (Outcomes)/Cost, can guide discussion, prioritization, and program development. GWTG has improved value by identification of critical gaps in care, fostering targeted quality improvement interventions to close those gaps, measuring the rate and degree of change and facilitating development of new quality measures.

The GWTG program is associated with improved efficiency of care and thus lower costs through decreases in hospital length of stay. In addition, GWTG hospitals demonstrate decreases in 30-day readmission rate in comparison with non-GWTG hospitals. Finally, linkage to CMS cost data, as discussed below, has significant potential to demonstrate improved efficiency and effectiveness across the continuum. This may be driven in part by the increased use of evidence-based secondary preventive measures.

GWTG also helps to facilitate safe medical care. The GWTG program not only helps to ensure that eligible patients receive effective therapies, but also helps identify patients who do not qualify or are inappropriate for certain therapies. For example, aldosterone antagonists can improve clinical outcomes among patients with heart failure, but they have a definite risk of adverse effects, particularly in certain patient populations. Although some studies have demonstrated a high rate of inappropriate use of these aldosterone antagonists, the rate of inappropriate use among GWTG participants has been very low.

**Linkage to Administrative Data Fosters Real-World Clinical Effectiveness Research**

To improve cardiovascular quality of care and outcomes, evidence regarding the clinical and comparative effectiveness of therapies, especially in patient populations underrepresented in clinical trials, is needed. It is often difficult to extrapolate clinical trial results to populations that have not been evaluated. In addition, there is often a lack of information regarding the relative risks and benefits of alternative therapies. To address these important gaps, several initiatives have been developed to prioritize and accelerate CER. For example, the American Recovery and Reinvestment Act of 2009 allocated $1.1 billion for CER, and the Patient Protection and Affordable Care Act of 2010 created the Patient-Centered Outcomes Research Institute.

Unfortunately, a robust infrastructure is lacking for conducting multiple comparative trials efficiently and economically. Clinical trials are resource intensive. Although observational clinical data can be used for CER, there is often limited detailed clinical information beyond the in-hospital setting, and the United States lacks a national, integrated healthcare record to facilitate CER across the continuum.

GWTG has led an ambitious effort to link registry data with administrative claims to conduct CER and outcomes research. GWTG registries contain rich clinical details on patient characteristics, inpatient care, discharge therapies, and eligibility criteria for guideline-recommended therapies. Unfortunately, clinical follow-up is beyond the available resources for a voluntary registry and would require patient identifiers and informed consent that would likely limit enrollment.

Administrative data have traditionally been used to understand temporal changes or national patterns of outcomes such as readmission or mortality. Medicare claims are available for all Medicare fee-for-service patients and contain patient identifiers to link patient records across time to provide a continuous record of hospitalizations, outpatient care, outcomes, and now drug therapy, with the use of Part D pharmacy benefits. These databases do have important information on mortality and subsequent healthcare resource use, but they do not have detailed clinical data and therefore have limits for addressing priorities identified for CER. By linking hospitalization records from Medicare claims with GWTG clinical registries, an inpatient episode with longitudinal follow-up can be used to conduct CER.

The main methods used for linking GWTG registry data to Medicare claims take advantage of the uniqueness of combining several indirect identifiers. The GWTG registries do not have unique patient identifiers such as patient names or social security numbers. However, with the use of nonunique fields such as admission date, discharge date, site, and patient age, the combination of these indirect identifiers yields a set of unique patient records that can be matched to Medicare claims from a hospitalization without risk of personal reidentification in the aggregated data set. The high level of uniqueness facilitates linking without knowing any patient identifiers and has been externally validated. The regulatory and ethical considerations have been examined thoroughly to ensure that these linked data sets are used without risk to patient privacy.

GWTG already has substantial experience linking to Medicare claims. The predecessor to GWTG-Heart Failure was the first cardiovascular registry linked to Medicare claims. A subsequent study examined the clinical effectiveness of β-blocker therapy in Medicare beneficiaries to demonstrate lower mortality and readmission rates among older patients previously underrepresented in clinical trials. The use of ICDs in older patients has been controversial because of the low numbers of patients in the pivotal trials. The GWTG-Heart Failure registry linked with Medicare claims was among the first to address this important question by studying 4685 patients who were eligible for an ICD at discharge. In contrast to the clinical trials, the mean age was 75.2 years, and 60% of the patients were women with a mean ejection fraction.
of 25%. Among the 376 (8.0%) patients who received an ICD before discharge, mortality was significantly lower in comparison with those who did not (19.8% versus 27.6% at 1 year, 30.9% versus 41.9% at 2 years, and 38.1% versus 52.3% at 3 years; \(P<0.001\) for all comparisons).

In a study with important policy and comparative effectiveness implications, investigators used the GWTG-Heart Failure registry to examine early follow-up after discharge. In this study, patients discharged from hospitals with the lowest early follow-up rate had the highest 30-day readmission rate.\(^5\) These data have subsequently been used to promote efforts to have heart failure patients follow-up shortly after discharge.

In a GWTG-Stroke study, use of the National Institutes of Health Stroke Scale was shown to substantially improve prognostic information regarding 30-day mortality risk in Medicare beneficiaries with acute ischemic stroke.\(^5\) Because stroke severity information such as the National Institutes of Health Stroke Scale is currently available only by chart review and is not coded in administrative data, the implication of this research is that ischemic stroke mortality risk adjustment models based on Medicare administrative data alone will not adequately adjust for variation in stroke severity across hospitals. Therefore, this study has important implications for internal use in hospitals and profiling hospitals nationally, as well as risk adjustment for comparative effectiveness research.

With this extensive experience, the GWTG programs are well positioned for serving as a national surveillance network to evaluate the effectiveness of cardiovascular therapies in the real world. Several important studies are in progress, including evaluation of the effectiveness of aldosterone antagonist therapy and cardiac resynchronization therapy in heart failure patients with reduced ejection fraction. The effectiveness of warfarin therapy will be examined in patients with atrial fibrillation and heart failure.\(^5\) In stroke care, the time to reperfusion and the effectiveness of secondary prevention may also be examined. As new therapies emerge, such as the novel anticoagulants and new reperfusion therapies for stroke and myocardial infarction, effectiveness and safety in the real world can be established by using GWTG registries linked to Medicare claims.

In addition, linking GWTG registries to other claims data may provide a more comprehensive picture of care. There is significant complementary potential of linkage of GWTG clinical registries to commercial insurance claims data with information on younger patients. Finally, linkage to The Guideline Advantage Program, which focuses on outpatient care, may prove very useful in promoting CER.\(^5\)

**Limitations of GWTG**

Although there are many contributions GWTG can make to inform policy, there are a several limitations that deserve mention. GWTG is not a randomized trial and has no matched control group, and thus, as all observational studies, has limitations. The program is voluntary, and although sites are instructed to enter all patients consecutively whether identified by concurrent review or at coding, it is possible that not all patients are included. Nevertheless, the observation that the GWTG Medicare stroke population was highly representative of the CMS population when those 2 databases were linked suggests that a representative sample is included.\(^4\) It is also possible that data are incomplete and adjudication has not been formalized in the program. Data accuracy has been formally assessed in a sample of stroke patients\(^11\) but not in the other modules, and thus, inaccuracies including diagnosis and interventions may be present. In addition, the observation that GWTG hospitals are larger, more often teaching, and urban raises the issue of broad applicability to small rural communities, particularly the large number of critical access hospitals in the United States. Critical access hospitals make up 7.1% of GWTG hospitals. However, because most patients are cared for in larger urban settings, a significant percentage of the acute cardiovascular admissions are included in GWTG. It is also possible that poor-performing hospitals have not joined GWTG, and, therefore, the overall performance of the program overestimates actual US performance.

The program does not directly collect cost information, but linking to CMS data as discussed in the “GWTG’s Contribution to Increasing the Value of Health Care” section above may help. Although some information on comorbidities is available, more in-depth collection might ultimately be helpful. In addition, limited pre-event data are collected, but this may also be partially addressed by linking to administrative databases. Finally, we have limited data on functional status postdischarge at this time, although other programs, such as The Guideline Advantage, may be helpful in capturing outpatient quality of care and health status.\(^6\)

**Summary and Policy Recommendations**

Table 4 summarizes the key findings of GWTG and evidence from >200 peer-reviewed articles. Summary and policy recommendations are organized by section to highlight the links to the GWTG evidence base. Many of our recommendations, although specific for the GWTG program, are broadly applicable to other conditions. For example, general and vascular surgery, cardiovascular surgery, and critical care medicine all already have or have the potential to develop and leverage comprehensive programs with sophisticated clinical databases.

**Discussion and Conclusions**

The AHA GWTG Program is a national voluntary, sustainable model linking state-of-the-art quality improvement tools with a sophisticated and flexible database documenting the care of almost 3 million cardiovascular disease patients in almost 2000 US hospitals. Experience with previously published guidelines suggests that traditional educational interventions such as lectures and other simple dissemination strategies do not significantly impact practice in secondary stroke and coronary artery disease prevention.\(^61-65\) To change healthcare provider practice, implementation strategies must be coupled with novel guideline dissemination and systematic physician engagement strategies. The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults identified the need for enabling strategies (eg, reminders), reinforcing strategies (eg, feedback), and predisposing strategies (eg, practice guidelines) to improve the quality of practice.\(^66\) All these evidence-based approaches to performance improvement are used by the GWTG program.
Table 4. Key Findings of GWTG and Evidence From Peer-Reviewed Articles

National implementation and impact of GWTG on quality of care

Summary
- The GWTG platform of clinical decision support tools, Webinars, educational resources, data collection tools, real-time feedback and benchmarking information is effective in improving cardiovascular quality and outcomes. Participating hospitals have demonstrated rapid and sustained improvement in evidence-based process measures in coronary artery disease, heart failure, and stroke.3,4,5
- Almost 3 million patients with heart failure, CAD, and stroke treated at >3000 (Figure 2) hospitals across the country have participated in GWTG (Figures 1 and 3).
- All types of hospitals across the United States (eg, large and small, academic and community, rural and urban hospitals) have participated and all have demonstrated significant improvement in care quality. GWTG patients are representative of patients treated for the same diseases across all hospitals in the United States.6
- GWTG-participating hospitals have improved care of patients with cardiovascular disease well beyond secular trends (that is, the improvements expected over time regardless of the intervention).7,8
- Unfortunately, many hospitals face financial challenges in supporting the trained staff required to optimally use GWTG tools despite the program’s low participation cost.

Policy recommendations
- State and national policy makers should explore approaches to improving the uptake of the GWTG model. Possible approaches include general legislation, support of accreditation initiatives, and financial incentives for participation, particularly in financially challenged organizations or for those who serve a disproportionate number of disadvantaged patients.
- Because greater participation translates to better delivery of care and better patient outcomes, policy makers should consider general or regional support for the GWTG program and other registries through creative partnerships and alliances. This would leverage the significant commitment of the AHA.
- Policy makers should provide incentives, such as the Electronic Health Record Incentive program, to standardize clinical information systems, health information exchange, and interoperability to reduce the major cost of manual chart abstraction for GWTG and other clinical performance improvement registries. This would better support electronic health record integration with quality improvement.

Promote assembly of data to better understand practice patterns and disease states

Summary
- The GWTG program provides a unique assessment of how clinicians and health systems translate best evidence (efficacy) into real-world practice and care (effectiveness).9
- These comparative effectiveness data facilitate evaluation of practice at the local, regional, and national level, informing providers and policy makers of variation (gaps) and opportunities to improve selected evidence-based interventions in specific settings. These data can facilitate novel interventions to overcome barriers in the equitable delivery of safe, reliable, and patient-centered care.
- Using this timely gap information, policy makers, the AHA, or local systems can then develop focused clinical initiatives. For example, the GWTG program developed additional complementary programs (Target: Stroke and Target: Heart Failure) when assessments from the GWTG registries revealed significant opportunity to safely decrease the door-to-needle time for stroke patients10,11 and increase the use of aldosterone antagonists in patients with HF12.
- Assessment of adherence and usability of GWTG measures can have a significant impact on the selection and prioritization of existing and new measures used by other organizations such as CMS, CDC, and The Joint Commission. Such harmonization is important for any national initiative and helps healthcare providers make data abstraction more efficient by consistently collecting the same data for all stakeholders.
- The GWTG registry facilitates assessment of new guidelines, their rate of uptake and potential unintended consequences. For example, GWTG-Stroke rapidly and accurately assessed the real-world impact of the expanded time window from 3 to 4.5 hours for the administration of tPA.13

Policy recommendations
- Policy makers should strongly consider partnering with performance improvement registries, such as GWTG, that concurrently measure and report performance. Such partnerships can potentially decrease the lag between the publication of evidence and the real-world uptake of life-saving interventions.
- Policy makers should facilitate the adoption of clinical registries such as GWTGs by all health systems to promote consistent and excellent care throughout a state or region.
- Policy makers should encourage the use of registries such as GWTG to promote equitable care for all patients.
- Leaders should facilitate the adoption of a few, valid, and reliable registries, rather than multiple databases from multiple governmental organizations, insurers, and other interested parties. Where possible, links to existing respected outpatient registries such as The Guideline Advantage program should be facilitated. This would help reduce the data abstraction burden of hospitals and health systems while ensuring the integration of data across the healthcare continuum.
- Before setting national guidelines, policy makers should use registry information to rigorously assess the potential benefits and unintended consequences of new guidelines and their associated measures.

Contribution to the value of health care

Summary
- The concept of value (quality/cost) is now driving US health care and is central to our approach to improving the performance of the US healthcare system. VBP is already an important driver of Medicare reimbursement.
- Many of the GWTG interventions focus on evidence-based secondary prevention. The GWTG-associated improvements in quality thus have the potential to decrease costs through reduction in readmissions,14 complications, and recurrent events.
- Substantial reductions in LOS were associated with the implementation of GWTG-Stroke among patients with stroke and transient ischemic attack admissions, suggesting that the acute-care intervention may have decreased in hospital complications and made care more efficient.15
- GWTG has improved care for all patient groups and has substantially reduced or, in some cases, eliminated, inequities in care between men and women, older and younger patients, and different race/ethnic groups.16,17

Policy recommendations
- Policy makers should encourage the use of registries such as GWTG as a way to potentially improve the value of care. The GWTG program is associated with significant increases in the quality of care and certain measures of efficiency such as the reduction in 30-day readmission rates.

(Continued)
Table 4. Continued

Linkages with administrative data foster real-world clinical-effectiveness research

Summary
- CER is now a national priority with $1.1 billion allocated by the American Recovery and Reinvestment Act. This research depends on assessing clinical effectiveness in the real world in a broad range of patient populations.
- Linking GWTG to administrative databases presents a unique, cost-effective approach to CER, and the quality of the GWTG data has been validated in a national audit.
- GWTG researchers have demonstrated the feasibility and value of such integration without compromising patient privacy through the use of unique fields and probabilistic algorithms.
- GWTG researchers have demonstrated the value of these linkages in a variety of clinical interventions including the impact of β-blocker therapy in Medicare patients in reducing readmissions and the mortality benefit in HF patients of ICD implantation before discharge in older men and women who were underrepresented in clinical trials. In addition, GWTG researchers have demonstrated the value of the NIH Stroke Scale for stroke prognosis after hospital discharge.
- Multiple additional studies using GWTG data integrated with national databases such as CMS are underway and have tremendous potential to assess the benefits of various interventions on prognosis and mortality.

Policy recommendations
- Policy makers should facilitate the integration of clinical and administrative databases at the national and state level to identify opportunities to improve care and provide a cost-effective strategy for CER across the healthcare continuum. This includes careful examination of privacy regulations and, where appropriate, clarification of standards to ensure that linkages are accurate and reliable, and can take full advantage of claims data sources to collect outcomes and the use of healthcare resources.
- Policy makers should consider facilitating registries including GWTG and QIO partnerships, not only to further leverage of administrative data, but also to drive regional hospital and health system participation in GWTG and other quality improvement efforts, overall.

AHA indicates American Heart Association; CAD, coronary artery disease; CDC, Centers for Disease Control and Prevention; CER, clinical effectiveness research; CMS, Centers for Medicare & Medicaid Services; GWTG, Get With The Guidelines; HF, heart failure; ICD, implantable cardiac defibrillator; LOS, length of stay; NIH, National Institutes of Health; QIO, quality improvement organization; tPA, tissue-type plasminogen activator; and VBP, value-based purchasing.

The GWTG program facilitates the dissemination of new knowledge and is associated with improved care across a broad representative range of patients, institutions, and domains of care. Participating hospitals improve care more rapidly than nonparticipating hospitals and that improvement is sustained over many years.

The data reflecting interventions and outcomes for these patients can be used to document current care, identify areas for improvement, test new measures, and benchmark performance. The GWTG program can then be used to rapidly drive change to close identified treatment gaps.

GWTG may improve the value of care (quality/cost) through rapid and sustained improvements in quality. GWTG is associated with improved care and the narrowing or elimination of treatment gaps for women, younger and older patients, and those of ethnic or racial minorities. GWTG can improve care quality while potentially contributing to decreases in the costs of care through associated decreases in length of stay, readmissions, and preventable complications.

Linking the granular clinical information in GWTG with administrative data can help drive CER, meaningful use, and multiple national and state initiatives to improve quality and decrease costs. For policy makers, the opportunities presented by GWTG to drive improved value in our health system are profound and exciting.
## Disclosures

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<th>Employment</th>
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Synthesizing Lessons Learned From Get With The Guidelines: The Value of Disease-Based Registries in Improving Quality and Outcomes

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Get With The Guidelines® Publications - Stroke, Heart Failure, Coronary Artery Disease
(As of 5/28/13)

2013:

Selim Krim: Do BNP Levels and Prognostic Value Vary by Race/Ethnicity in Patients Hospitalized with Heart Failure? JACC HF (in press) * AHA Young Investigator Runner Up


Feng Qian: Racial and Ethnic Differences in Outcomes in Older Patients with Acute Ischemic Stroke. CIRC CVQO (in press)

Michael L. James: Insurance Status and Outcome after Intracerebral Hemorrhage: Findings from Get With The Guidelines-Stroke. Journal of Stroke and Cerebrovascular Diseases (online)

Kociol: Are We Targeting the Right Metric for Heart Failure? Comparison of Hospital 30-Day Readmission Rates and Total Episode of Care Inpatient Days. AHJ (in press)


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**Hospital Performance in Acute Ischemic Stroke With versus Without Adjustment for Stroke Severity.** JAMA. 2012;308(3):257-264. Epub 7/17/12


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Allen N. Regional Variation in Recommended Treatments for Ischemic Stroke and TIA: Get With the Guidelines- Stroke 2003-2010. Stroke. Epub 5/15/12


Mountantonakis S. Presence of Atrial Fibrillation is Independently Associated with Adverse Outcomes in Patients Hospitalized with Heart Failure: An Analysis of GWTG-Heart Failure. [Epub 2/23/12] CircHF

El Husseini, N. Depression and Antidepressant use after Stroke and Transient Ischemic Attack. Stroke (in press) *AVAIL


Al-Khatib S. Trends in Use of Implantable Cardioverter Defibrillator Therapy Among Patients Hospitalized for Heart Failure: Have the Previously Observed Sex and Racial Disparities Improved Over Time? [Epub 1/27/12] Circ

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Xian, Ying. Data Quality in the American Heart Association Get With the Guidelines Stroke: Results from a National Data Validation Audit. [Epub 3/13/12] AHJ


Bangalore, Sripal. Quality of Care and Outcomes of Young Patients with ST-Segment Elevation Myocardial Infarction. AJM (in press) *YI Winner*

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