

China Quality Improvement Program Proposal

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Table of Contents

Overall Goal & Objectives	3
Gaps in Care and Educational Needs	5
Performance Gaps.....	6
Educational Needs.....	6
Technical Approach.....	6
Current Assessment of Need.....	6
Intervention Design and Methods	7
Evaluation Design	10
Detailed Work Plan and Deliverables Schedule	12

Overall Goal & Objectives

The overarching vision and purpose of the American Heart Association's (AHA) suite of cardiovascular quality improvement programs, Get With The Guidelines® is to use data collection, analysis, feedback, and process improvement to extend the use of evidence-based guidelines throughout the healthcare system and improve patient care.

Previous support provided by Pfizer allowed the AHA to expand its Get With The Guidelines® (GWTG) program into stroke with CME-based beta pilot and outpatient programs. The success and key learning from those initiatives resulted in additional expansion with GWTG- HF (heart failure), GWTG-Resuscitation (focused on cardiopulmonary arrest events in hospital), and GWTG- AFIB (atrial fibrillation).

Based on the overall success of the Get With The Guidelines suite of programs and the current public health landscape of cardiovascular disease within China, the Chinese Ministry of Health (MOH) and the Chinese Society of Cardiology (CSC) expressed strong interest in adapting the GWTG program for China. In June 2013, the AHA and the CSC entered into a formal Memorandum of Understanding for the two organizations to jointly develop and implement quality improvement programs in China.

This grant outlines the proposed program and its goals.

Get With The Guidelines Background

Get With the Guidelines was created in 2001 to reduce the gap in the use of secondary prevention guidelines for patients hospitalized with cardiovascular disease (CVD). The program was modeled on the Cardiac Hospital Atherosclerosis Management Program (CHAMP), which used treatment algorithms to improve guideline utilization.{Fonarow, 2001 #60}

In the more than 10 years since the launch of the first GWTG module, GWTG-CAD (coronary artery disease), the suite of programs has grown. Today, the AHA has GWTG modules for stroke, heart failure, cardiopulmonary resuscitation, and atrial fibrillation, several developed with support from Pfizer.

These in-hospital programs include a registry component that uses a web-based platform with embedded clinical decision support and real-time benchmarked reports, access to a quality consultant to assist participants with program implementation, and participation in regional collaborative learning sessions.

A recently released publication synthesizing the lessons learned from the past decade of GWTG notes that the program helped facilitate rapid adoption of guideline recommendations while identifying areas for further improvements.{Ellrodt, 2013 #3826} Specifically:

- The percentage of patients with CAD who were discharged on lipid-lowering therapy prior increased from 84.5% in 2006 to 98.4% in 2011.

- The percentage of patients with heart failure who were discharged on anticoagulation for AF or atrial flutter increased from 62.9% in 2006 to 75.4% in 2011.
- The percentage of patients with stroke who arrived within 2 hours of symptom onset and who received intravenous tissue plasminogen activator (tPA) within 3 hours increased from 55.8% in 2006 to 78.3% in 2011.
- The percentage of patients with AF who were discharged on anticoagulation increased from 88.4% in 2003 to 95.2% in 2010. {Lewis, 2011 #3835}

Other research finds that GWTG programs demonstrate remarkable reduction of disparities in care related to gender, race, and ethnicity. {Ellrodt, 2013 #3826} For instance, in sites that implemented GWTG, racial and ethnic disparities in care for patients with acute myocardial infarction (AMI) and disparities in the use of implantable cardiac defibrillators in women and African-American patients with heart failure disappeared. {Cohen, 2010 #3834}{Al-Khatib, 2012 #3828}

There are currently more than 2,000 hospitals in the GWTG registry and more than 4 million patient records. More than 250 peer-reviewed publications on the program have been published, clearly demonstrating that it leads to improved compliance with evidenced-based guidelines, generalizable knowledge regarding successful process improvement strategies, and superior quality of care in participating versus non-participating hospitals. Of particular importance to this grant is data showing improvements regardless of the type of hospital (academic or community-based), or its geographic setting (urban or rural). {Ellrodt, 2013 #3826} The AHA is certain that the success of the GWTG program can be repeated in other countries.

The AHA has considerable experience in China developing and implementing the following programs:

AHA Professional Resource Centers

The AHA, in collaboration with EMD China, a medical education company, launched a scientific educational initiative in major Chinese cities in 2012. The program involves 91 leading academic cardiology hospitals that are designated as AHA Professional Resource Centers.

These centers are the key locations where the AHA broadcasts ongoing professional education developed and presented by key volunteers around topics that meet the needs of the Chinese population. The program is managed under an advisory committee headed by the President of the CSC and co-chaired by Sidney C. Smith, Jr., MD, of the AHA's International Committee.

AHA International Training Centers

The AHA is continuing to develop International Training Centers to advance Emergency Cardiovascular Care and advanced cardiac life support. The AHA currently manages the vast majority of this type of training in China with 72 training centers. To date, 8,782



providers and 470 instructors have been trained. The resuscitation training and establishment of training centers is done in collaboration and with endorsement of the Chinese Medical Doctors Association (CMDA).

Bridging the Gap on CVD Secondary Prevention in China (BRIG)

The BRIG project is being carried out with the World Heart Foundation; Beijing Institute of Heart, Lung and Blood Vessel Diseases; Anzhen Hospital, Beijing; the CSC; and the China National Health Heart Programme.

Its goal is to bridge the gap between guidelines for the secondary prevention of coronary heart disease and clinical practice in China, and to improve the quality of care in patients with acute coronary syndrome (ACS). The principal investigators are Dong Zhou, MD, PhD and Sidney C. Smith, Jr., MD, Professor of Medicine and Director of the Center for Cardiovascular Science and Medicine at University of North Carolina and past President of the American Heart Association.

These programs provide the AHA with in-country experience in delivering educational programs. It has also allowed the organization to build connections to government agencies, clinical institutions, and key organizations.

Through its experience in China, the AHA understands the effort required to understand a new market, including cultural and economic differences, the type of healthcare system already in place, legal and political issues, and compliance requirements.

The AHA will work closely with the CSC to ensure that these factors are considered in all aspects of the GWTG program, and that the program itself is modified to address these issues within each region and to be culturally appropriate for Chinese clinicians and patients.

Gaps in Care and Educational Needs

The overarching aims will be:

1. Improve care and education of patients in China hospitalized with CVD and Stroke to promote heart healthy lifestyle.
2. Accelerate initiation of the evidence-based, guideline-recommended therapies in appropriate patients in China to reduce death and disability related to CVD and Stroke.
3. Enhance management of co-morbidities and related risks during hospitalizations and post-discharge patient to reduce hospital readmissions.
4. Facilitate coordination of care, transition of care and outpatient follow-up for the Chinese patient with known cardiovascular disease and stroke to accelerate recovery and return to pre-hospital functionality as appropriate.

Specific metrics will be defined in collaboration between the Ministry of Health, the Chinese Society of Cardiology, and the Senior Management Group.

Performance Gaps

- Clinicians demonstrate low use of clinical guidelines in the prevention, diagnosis, and management of patients with, or at risk for, CVD.
- Clinicians demonstrate low use of evidence-based guidelines for the secondary prevention of CVD.
- Clinicians demonstrate low use of evidence-based guidelines in the care of patients with AF and in the secondary prevention of stroke in these patients.
- The quality of care provided to patients with CVD following discharge is poor.

Educational Needs

- Educate clinicians regarding the application of evidence-based guidelines for primary and secondary prevention of CVD.
- Educate clinicians regarding clinical guidelines for managing CVD patients following hospital discharge.
- Educate clinicians on clinical guidelines demonstrated to improve outcomes following an acute coronary event.
- Educate clinicians on clinical guidelines demonstrated to improve outcomes in patients with AF.

A full needs assessment was conducted to identify performance gaps, educational needs and the learning objectives for this program (attachment).

Technical Approach

Current Assessment of need in target area

Cardiovascular disease (CVD) is responsible for more than 17 million deaths each year, accounting for 30% of annual deaths worldwide.¹ The global burden of CVD is expected to increase, with an estimated 23.4 million annual deaths from CVD expected by 2030. In China, CVD is the leading cause of death, responsible for over 3.1 million deaths in 2010, a substantial increase from 2.2 million in 1990.² These deaths were most commonly attributed to coronary artery disease (CAD) or stroke. Additionally, CVD related disability-adjusted life years, a measure of overall disease burden, totaled more than 58.2 million in China in 2010, an increase from 45.2 million in 1990.

Continuing economic growth has led to dramatic lifestyle changes for the people of China over the past 30 years. Dietary changes, such as increased consumption of meat and other fatty foods, paired with reduced physical activity, has significantly increased the risk of CVD.^{3,4} For example, obesity in China has quadrupled in the past 20 years. This has been accompanied by increased rates of hypertension and dyslipidemia.³ These increased risk factors, along with an aging population, is behind the increased rates of CVD morbidity and mortality that are expected to continue to rise.⁴

Secondary prevention for CVD, including the use of antiplatelet, blood pressure lowering, and lipid-lowering medications, reduces mortality rates when used in accordance to clinical practice guidelines.³ However, a sizeable gap exists between guideline recommendations and the care provided for CVD care in China.⁵ Research indicates that less than 50% of patients with CAD receive secondary prevention treatment in line with clinical practice guidelines, and that up to 80% of patients hospitalized for stroke may receive medications that are not part of clinical guideline recommendations.⁵

Several recently published Chinese studies demonstrate the low utilization rates of guideline-recommended therapies for patients hospitalized with CVD (including acute coronary syndrome, heart failure, and atrial fibrillation) in China.⁵⁻⁸ These gaps exist in the management of CVD, treatment of these CVD-related conditions after acute events, and disease management following hospital discharge.

Practice gaps and educational needs were determined with an in-depth review of the medical literature, government databases, current treatment guidelines, and Internet searches. Full needs assessment conducted for this program attached.

Describe the primary audience(s) targeted for this intervention. Also describe who will directly benefit from the project outcomes.

The primary audience is healthcare providers (cardiologists, internists, nurses, hospital administrators and others) who care for cardiac patients in 200 Chinese secondary and tertiary hospitals, and primary care physicians who provide outpatient care for these patients after discharge. Increasing adherence to evidence-based guidelines through the GWTG program will benefit approximately 1,530,000 ischemic heart disease and heart failure, 183,000 in need of arrhythmia management, and 2, 056,277 with cerebrovascular disease patients who pass through these hospitals each year. The increased use of life saving therapies can have an impact on reducing the 11.4% mortality rate related to ischemic heart disease and the 21% mortality rate related to stroke in China. {Chinese Ministry of Health 2011}

Intervention Design and Methods

This educational program will be driven by the Continuous Quality Improvement framework, which uses the Plan, Do, Study, Act (PDSA) cycle as its core component to drive process improvements designed to change provider practice. The PDSA cycle allows for small tests of change to be applied and evaluated for effectiveness, leading to iterative tests of change and, finally to revised processes with demonstrated improvement.

The cycle of process improvement begins with applying peer-reviewed research in the form of evidence-based guidelines to current practice. Participants receive baseline feedback on key indicators, which provide a benchmark against which to evaluate any changes in behavior and outcomes post-education. This benchmark is extrapolated to non-participating hospitals to provide a control group.

The educational intervention is designed based on the individual benchmarks, and outcomes tracked at regular intervals to assess progress and modify the educational content and delivery as necessary. Participants receive regular feedback on their progress.

All data is collected in a registry and used for evaluation and further research with a goal of shifting the public health paradigm in the community.

Pre-test, post-test, prospective, and retrospective research is conducted to determine how a specific facility and aggregate population improve over time.

This cycle is illustrated below:

2 *Circulation* August 5, 2008

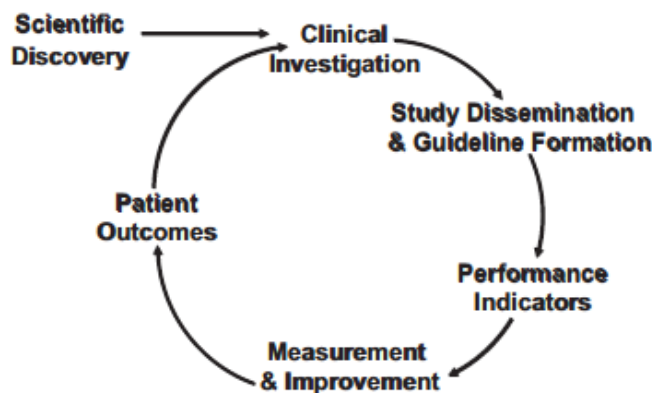


Figure. Improving evidence-based medicine. Adapted from Calif et al,¹¹ with permission from Elsevier. Copyright 2002, American College of Cardiology.

All participating sites will receive feedback reports that will include site specific and aggregate benchmark reports at regular intervals. A summary report will be provided to the Program Coordinator and the Senior Management Group at the same intervals.

Program Details

The expansion of GWTG to China will be a multi-phase approach at the hospital and outpatient level.

Phase 1. Seventy-five hospitals will be enrolled in the quality initiative focused on ACS/AMI. Over the next 6 to 9 months, they will participate in collaborative workshops, receive consultations from a quality improvement specialist, and get monthly reports highlighting performance trends.

Phase 2. Six to 12 months after the ACS/AMI program begins, the sites will add a focus on atrial fibrillation. Again, they will participate in collaborative workshops, receive consultations from a quality improvement specialist, and get monthly reports highlighting performance trends.

Nine to 12 months after the first group of hospitals are enrolled, another 75 sites will enroll, followed by a third group of 50 hospitals 9 to 12 months later. They will follow the same processes described above.

Phase 3. The final phase extends the program to the primary care level to facilitate patient compliance with prescribed therapies, as well as increase number of patients being treated to goal. During this phase, approximately 50 primary care physicians associated with hospital-managed outpatient clinics will be enrolled from among the 200 hospitals enrolled in the initiative.

The quality improvement activities in this phase of the project include communication among and education for healthcare providers. The providers will also be required to complete data forms to track patient compliance with prescribed medications and their progress in reaching treatment goals.

The educational intervention for each site will be based on the initial assessment of gaps in performance metrics identified in the baseline data. The interventions will build upon each other, with the initial component of knowledge transfer from KOLs to provide scientific evidence to support the performance metrics, delivered through collaborative learning workshops.

That will be followed by site consultations to identify and plan the specific QI activity for each facility. Finally, each site will report its goal targets, which will be correlated into aggregate results.

Hospitals will participate in virtual user forums to review feedback reports from the central database repository.

Data based on the metrics described below will be gathered for each hospital at baseline, at 3, 6- and 12-month intervals, and then annually to determine improvements in practice gaps associated with the intervention.

The CSC will manage the central data repository for all participating sites. The registry will establish a common data set aligned with Chinese guidelines, global cardiovascular metrics, and AHA quality improvement programs for ACS/AMI and AF.

Sites will use the monthly feedback reports to monitor their progress towards meeting the initiative's goals. In addition, the principal investigator and QI consultant will review the reports and topics for ongoing professional education collaborative workshops.

All faculty and monitors in the Chinese GWTG programs will be based in the region in which the hospital is based. This is important to ensure cultural appropriateness in terms of practice patterns and the ability to tailor the program for a Chinese population.

All sites will be required to:

1. Identify a physician champion to lead the hospital-level implementation
2. Create a multidisciplinary team of physicians, nurses, a data abstractor, and other appropriate health professionals to direct and execute the process improvement activity within the hospital
3. Commit to pursuing goals related to improving compliance with ACS/AMI metrics, secondary prevention metrics, and AF metrics as defined by the project leadership.
4. Establish and implement a data collection strategy to ensure accurate and timely data completion
5. Participate in collaborative workshops and regional user forums to discuss best practices and review data to monitor the progress toward goals

Evaluation Design

The following evidence-based metrics will be used to evaluate the success of the program and its goal of closing the identified gaps. These measures are based upon recommendations from the American College of Cardiology/American Heart Association (ACCF/AHA) performance metrics for acute coronary syndrome and acute myocardial infarction, the ACCF, AHA, and HRS (Heart Rhythm Society) guidelines for atrial fibrillation, and TJC (The Joint Commission)/CMS (Centers for Medicare and Medicaid Services)/ASA (American Stroke Association) harmonized measures for stroke. The measures included apply to acute care and secondary prevention as appropriate for the patient.

Acute Myocardial Infarction

1. Early aspirin (within 24 hours of hospital arrival)
2. Aspirin prescribed at time of hospital discharge
3. Beta blocker prescribed at time of hospital discharge
4. ACEI/ARB prescribed at time of discharge for patients with left ventricular systolic dysfunction $\leq 40\%$
5. Statin or other lipid-lowering prescription at time of discharge for patients with LDL ≥ 100 .
6. Blood pressure control (% of patients who had blood pressure , 140 systolic /,90 diastolic at time of discharge)
7. Cardiac rehabilitation education provided at time of discharge (use of educational materials and coaching related to appropriate physical activity and nutrition)
8. Smoking cessation counseling provided prior to discharge from hospital
9. Door-to-needle time for tPA and percentage of eligible patients receiving tPA within 30 minutes
10. Door-to-balloon time for primary percutaneous coronary intervention and percentage of eligible patients receiving it within 90 minutes

Atrial Fibrillation

1. ACEI/ARB prescribed at discharge for patients with left ventricular systolic dysfunction of $\leq 40\%$
2. Assessment of thromboembolic risk factors during hospitalization
3. Beta blocker prescribed at discharge for patients who require rate control
4. Patient discharged on anticoagulation therapy
5. International normalized ratio follow up appointment for patients discharged on warfarin
6. Statin prescribed at discharge for patients with coronary artery disease, stroke or transient ischemic attack, or peripheral vascular disease

Outpatient Care

The metrics for application in the Outpatient setting will be focus on the secondary prevention therapies for individuals with documented ischemic heart disease; appropriate rate, rhythm, and anticoagulation/antithrombotic therapy for the patient with atrial fibrillation; and monitoring of several of the World Heart Federation Non-communicable disease risk factors.

NCD (Non Communicable Disease) Risk Factors

1. Tobacco Use in adults aged 18 +
2. Blood Pressure to be maintained <140 systolic/ <90 diastolic
3. Physical Activity
4. Lipid therapy in patients with LDL ≥ 130

Describe how you expect to collect and analyze the data.

The data will be collected at each hospital using electronic technology and centralized under the direction of Professor Zhao Dong at the Data Coordinating Center AnZhen Hospital.

Hospitals will be able to enter patient-level data into the registry through electronic health record pre-population of data points; downloading available data points from hospital specific databases, or manually entering the data.

Identify the method used to control for other factors outside this intervention (e.g., use of a control group)

Baseline data for non-participating hospitals will serve as the control for the intervention.

Quantify the amount of change expected from this intervention in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%).

Given preliminary data from other GWTG registries, we anticipate a $>20\%$ increase over baseline for most, if not all, metrics.

Indicate how you will determine if the target audience was fully engaged in the intervention.

Involvement of the target audience will be reflected by the changes in implementation metrics for quality improvement.

Describe how you plan to broadly disseminate project outcomes.

The results will be disseminated through presentations at major meetings such as the Great Wall International Congress of Cardiology and AHA Scientific Sessions, as well as publication in journals such as Circulation.

Detailed Work Plan and Deliverables Schedule

The quality improvement initiative will begin with development of a database that will serve as the central repository for all data. Site recruitment begins with hospitals that have participated in similar registry activities, educational programs, or have an identified physician champion.

The goal is to recruit 200 hospitals over three years. Once sites have undergone database training, data entry will begin and continue throughout the project. Sites should capture their baseline data within the first 6 months.

The aggregate benchmark data will then be assessed and areas for improvement defined. This information will determine the professional education topics and scheduling of presentations to begin within 90 days of assessment.

Following the educational program, all sites will be asked to review their inpatient processes to identify areas for improvement in the consistent delivery of evidenced-based therapies. The sites will apply quality improvement methods to drive system improvements that will be measured and reported on a regular basis.

During the first 6 to 12 months, hospitals will focus on ACS/AMI. After 6 months but before 12 months, all participating sites will add AF as a new focus, following the same steps highlighted above.

The collaborative workshops will expand to offer both ACS/AMI and AF components. User Forums may be offered for focus on each of the clinical conditions.

The focus on transitions of care is the final phase of the project. The key component of this phase is to develop and execute appropriate communication protocols at the time of discharge between the tertiary/secondary hospital and the patient's primary care provider.

To ensure the appropriate communication occurs, during the first post-discharge visit? The PCP will complete a form listing all medications and their dosages the patient was discharged with, and any changes the PCP makes. Review of the discharge plan of care to the current patient reported information allows for determination of patient compliance post discharge. The goal is to determine how well the patient adheres to the secondary prevention plan, and how closely the physician's practice patterns follow current evidence-based guidelines

The accumulated data will be analyzed for insights regarding the impact of the interventions in increasing the use of evidence-based therapies, insights regarding patient adherence with



prescribed therapies, and general comparative analysis of impact of QI on compliance in China versus the US.



Implementation_Plan
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