# Improving the Care of Patients with Non-ST-elevation Acute Coronary Syndromes in the Emergency Department: The CRUSADE Initiative

James W. Hoekstra, MD, Charles V. Pollack Jr., MD, MA, Matthew T. Roe, MD, MHS, Eric D. Peterson, MD, MPH, Ralph Brindis, MD, MPH, Robert A. Harrington, MD, Robert H. Christenson, PhD, Sidney C. Smith, MD, E. Magnus Ohman, MD, W. Brian Gibler, MD

# Abstract

Although acute coronary syndromes (ACS) represent a well-recognized source of morbidity and mortality for patients with cardiovascular disease, evidence-based therapies shown to improve outcomes for ACS are frequently underused in appropriate patients, especially in the emergency department (ED). Despite dissemination of expert recommendations from the American College of Cardiology/American Heart Association (ACC/AHA) and ED-focused recapitulation of them in the emergency medicine literature, significant barriers continue to limit the adoption of guidelines in clinical practice and appear to hinder the use of beneficial therapies and interventions in the ED. Unique and creative approaches are therefore needed to stimulate better adherence to practice guidelines and improve the quality of care for patients with non-ST-elevation myocardial infarction (NSTE) ACS. The CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the ACC/AHA Guidelines) quality improvement and educational initiative provides an innovative and multifaceted approach to the education of emergency physicians and cardiologists in the care of patients with NSTE ACS. The CRUSADE initiative is a multidisciplinary cooperative effort involving over 400 EDs and medical centers. It includes an ACS registry designed to characterize demo-

# PRACTICE GUIDELINES AND MODIFICATION OF PHYSICIAN BEHAVIOR

Emergency physicians have for many years focused their evaluation and targeted interventions for

graphic patterns and risk stratification results in patients who meet diagnostic criteria for high-risk NSTE ACS. It also measures the use of ED treatment modalities including aspirin, heparin, beta-blockers, and platelet inhibitors as recommended in the ACC/AHA guidelines. The results of a given institution's treatment patterns will be reported back to the practitioners, with comparisons with national norms. These reports can be used as quality improvement tools to improve care at participating institutions. Beyond a static registry, these reports are coupled with educational efforts by the CRUSADE steering committee, scientific publications of risk stratification practice and success, as well as ED patterns of care, and tailored educational interventions, to reinforce compliance with the ACC/AHA guidelines. This initiative represents a truly innovative approach to improving care for ACS patients in the ED as well as on the cardiology service. This article describes the CRUSADE initiative and its implications for the practicing emergency physician. It is the intent of CRUSADE to improve patient care in the ED by tracking and encouraging compliance with evidence-based guidelines for the evaluation and management of NSTE ACS. Key words: CRUSADE; acute coronary syndromes; evidence-based guidelines; compliance; practice guidelines; quality. ACADEMIC EMERGENCY MEDICINE 2002; 9:1146-1155.

chest pain on acute ST-segment-elevation myocardial infarction (STEMI, or AMI). Recent advances both in the understanding of pathophysiology and aggressive management of non-ST-segment-elevation chest pain [encompassing non-ST-segment-elevation myocardial infarction (NSTEMI) and unstable angina (UA), or collectively non-ST-elevation acute coronary syndromes (NSTE ACS)] have provided an increased capability to approach these elements of acute cardiovascular disease as well. Large-scale clinical trials have identified numerous beneficial interventions for patients with STEMI that can and should be initiated in the emergency department (ED), such as aspirin, fibrinolytic agents, beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors, but these remain fre-

From the Ohio State University, Columbus, OH (JWH); Pennsylvania Hospital, Philadelphia, PA (CVP); Duke Clinical Research Institute, Durham, NC (MTR, EDP, RAH); Kaiser Permanente Health System, San Francisco, CA (RB); University of Maryland School of Medicine, Baltimore, MD (RHC); University of North Carolina School of Medicine, Chapel Hill, NC (SCS, EMO); and University of Cincinnati School of Medicine, Cincinnati, OH (WBG).

Received April 1, 2002; revision received May 29, 2002; accepted May 31, 2002.

Address for correspondence and reprints: James W. Hoekstra, MD, 258 Meiling Hall, 370 West Ninth Avenue, Columbus, OH 43210. e-mail: hoekstra.1@osu.edu.

quently underutilized for eligible patients with NSTE ACS.<sup>1,2</sup> Studies such as the National Registry for Myocardial Infarction (NRMI-4) indicate that ED use of evidence-based therapies for NSTE ACS, such as platelet glycoprotein IIb/IIIa receptor antagonists, are even less well utilized in the ED.<sup>3</sup>

The American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for the Management of Unstable Angina/Non-ST-Elevation Myocardial Infarction (2000, updated on the World Wide Web in 2002<sup>4</sup>) were promulgated in an effort to standardize and optimize the evaluation, diagnosis, and management of patients with NSTE ACS and to provide physicians with a framework for clinical decision making.

Practice guidelines for the treatment of STEMI<sup>5</sup> and NSTE ACS<sup>4</sup> developed by the ACC and AHA represent an effort to standardize the ED-based and inpatient care of patients with chest pain of ischemic origin based upon evidence from broad clinical experience. These guidelines were recapitulated in the ED-focused medical literature in September 2001.<sup>6,7</sup> It is recognized from past experience, however, that dissemination of guidelines has only a limited effect on clinician behaviors unless they are accompanied by other focused educational efforts and directed feedback.<sup>8-10</sup> Cabana et al.<sup>10</sup> conducted a literature review to determine the barriers to adoption of practice guidelines in clinical practice. The barriers they identified included lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy, inertia of previous practice, and external barriers. Of these barriers, lack of awareness and lack of familiarity are best remedied by educational initiatives, while lack of self-efficacy and lack of outcome expectancy are best remedied by providing continuous feedback on guideline adherence and patient outcomes data, respectively. Cabana and colleagues identified lack of awareness as the predominant barrier to implementation of guidelines, and recommended educational approaches that incorporate educational and feedback strategies to augment guideline adherence.

Multiple strategies designed to change physician behavior have been evaluated, but success rates have been highly variable. Interventions designed to enhance physician education such as continuing medical education conferences and printed materials have been shown to have little impact upon improving physician performance.<sup>11,12</sup> Reminder systems such as critical care pathways or computerized support programs, patient-oriented interventions, and the use of local opinion leaders in the education of physicians are strategies that have generally been shown to improve adherence to practice guidelines.<sup>11-14</sup> Further success has been demonstrated when feedback was provided to physicians regarding their performance according to quality indicators.<sup>15</sup> A randomized trial confirmed that improvements in patient care were greater when physicians were motivated by feedback provided according to achievable benchmarks for care (based upon top-performing practices) compared with longitudinal physician-specific feedback.<sup>16</sup> Despite the benefits of these single interventions, systematic reviews have concluded that combined or multifaceted quality improvement interventions have the greatest likelihood of successfully changing physician behavior.<sup>11,12</sup>

While a comprehensive approach to quality improvement appears to the best strategy for improving the use of evidence-based therapies, institutional and methodological obstacles must be overcome to ensure sustained improvement in patient care. A prospective study identified characteristics associated with improved use of beta-blockers for patients with STEMI, including shared goals for quality improvement, sustained administrative support for quality improvement initiatives, strong leadership from physician champions, and highquality, rapid-cycle data feedback.<sup>17</sup> Institutional characteristics appear to strongly influence the outcomes of interventions designed to improve care, so rigorous research methods are needed to identify the key determinants of success with quality improvement studies. However, quality improvement studies are often limited by inadequate statistical power, difficulties in defining baseline performance measures, uncertainty regarding the optimal duration of time needed to assess the effect of an intervention, problems applying local results to regional and national practice, and inability to determine the differential impact of the components of multifaceted quality improvement strategies. As quality improvement studies continue to evolve, these challenges must be surmounted to develop evidence-based strategies for implementing practice guidelines and defining quality standards.

In STEMI, the effectiveness of the AHA/ACC STEMI guidelines was augmented by the National Heart Attack Alert Program, which was widely publicized in the emergency medicine literature.<sup>18</sup> This national emergency medicine education program, funded by industry and the federal government, resulted in increased awareness of the guidelines, reduction of door-to-drug times, and a reduction mortality from STEMI. Results from the National Registries of Myocardial Infarction (NRMI) also demonstrated consistent improvements in the use of aspirin, beta-blockers, and ACE inhibitors and more rapid administration of fibrinolytic therapy during the last decade in associa-

tion with NRMI-published results and educational endeavors based on NRMI data.<sup>1</sup>

Although many quality improvement (QI) initiatives designed to assess physician and institutional compliance with practice guidelines and motivate health care providers to improve the use of evidence-based therapies and interventions are already in place for STEMI,<sup>19</sup> less attention has been devoted to assessing the quality of care of the much larger, and more diverse population of patients with NSTE ACS.<sup>4–7,20–22</sup> Patients with NSTE ACS are older and more heterogeneous compared with patients with STEMI, and in ED populations the proportion of patients presenting with NSTE ACS is rapidly expanding.<sup>1-3</sup> The Agency for Health Care Policy and Research (AHCPR) initially published guidelines together with the ACC and AHA for the treatment of patients with unstable angina in 1994 to help clarify treatment strategies in this diverse patient population.<sup>23</sup> However, despite educational initiatives following publication of the AHCPR guidelines, beneficial medical therapies continued to be underutilized for patients with NSTE ACS.2,24-26 Unfortunately, physician characteristics and treatment biases also appeared to impact adversely the quality of care for patients with NSTE ACS.<sup>27-30</sup>

The initial evaluation and treatment of patients with suspected ischemic chest pain in the ED has traditionally focused on the prompt identification and treatment of patients with STEMI given the time-dependent benefits of reperfusion therapy.<sup>31</sup> Whereas STEMI patients are readily identified with an initial ECG, the diagnosis of NSTE ACS is often uncertain upon initial hospital presentation. Dynamic risk stratification strategies are used in the ED to identify chest pain patients who subsequently manifest high-risk characteristics indicative of NSTE ACS.<sup>4</sup> These high-risk clinical findings (Table 1) are prognostic of morbidity and mortality but also predictive of response to aggressive treatment.<sup>4,32,33</sup> Because the treatment of NSTE ACS is invariably linked to the diagnostic strategy utilized in the ED, the AHCPR practice guidelines were recently revised to incorporate improved risk stratification tools and new treatments for the acute management of NSTE ACS.<sup>4-7</sup> Therefore, the major challenges to implementing practice guidelines for NSTE ACS are linking risk stratification strategies to early therapeutic intervention and overcoming treatment biases and institutional obstacles that hinder the use of beneficial therapies. The dynamic nature of this patient identification strategy also demands the cooperative involvement of both emergency medicine and cardiology, since either specialty may be involved in patient identification and initiation of treatment along a time continuum.

## TABLE 1. High-risk Clinical Features for Adverse Outcomes in Patients with Chest Pain and Presumed Non-ST-elevation Acute Coronary Syndromes (NSTE ACS)<sup>1</sup>

- 1. Accelerating tempo of anginal symptoms over 48 hours
- 2. Prolonged or ongoing rest pain
- 3. Pulmonary edema secondary to ischemia
- 4. New or worsening MR murmur
- 5. S3 or worsening rales
- 6. Hypotension
- 7. Bradycardia
- 8. Tachycardia
- 9. Age >75 years
- 10. ST deviation on electrocardiogram (ST depression or transient elevation)
- 11. New bundle branch block
- 12. Sustained ventricular tachycardia
- 13. Elevated serum cardiac markers (creatine kinase-MB or troponin)

The CRUSADE (Can Rapid Risk Stratification of *U*nstable Angina Patients Suppress *AD*verse Outcomes with *E*arly Implementation of the ACC/ AHA Guidelines) quality and educational initiative was designed to provide a multifaceted approach to the education of emergency physicians in the care of patients with NSTE ACS. The CRUSADE initiative is novel in that it: 1) targets patients with NSTE ACS, a previously underrepresented population; 2) incorporates a patient registry, educational sessions, and QI data feedback mechanisms as integral pieces of the multifaceted program; and 3) is multidisciplinary, including both cardiology and emergency medicine, in an effort to improve care for ACS patients in the ED and beyond.

# THE CRUSADE INITIATIVE

Given the rapidly expanding population of patients with NSTE ACS and the difficulties establishing a link between risk stratification and acute treatments in the ED, novel approaches are needed to improve implementation of diagnostic and treatment guidelines for patients presenting with NSTE ACS. The CRUSADE national quality improvement initiative utilizes a structured collaboration between emergency physicians and cardiologists to improve the care of patients with high-risk NSTE ACS. CRUSADE is a national, prospective, rapid-cycle quality improvement initiative focusing on the diagnostic evaluation of patients with ACS in the ED as well as acute and chronic treatments recommended by the ACC/AHA guidelines for NSTE ACS (Table 2).<sup>4</sup> It consists of a multidisciplinary, multicenter ACS registry and an accompanying national educational program aimed at increasing the use of ACC/AHA recommended therapies.

The CRUSADE NSTE ACS registry is a multidis-

TABLE 2. Recommendations from the ACC/AHA Guidelines for the Management of NSTE AC	TABLE 2	. Recommendations from	the ACC/AHA	Guidelines for the	Management of NSTE ACS
--	---------	------------------------	-------------	--------------------	------------------------

Medication	Acute Therapies 2000 Guidelines	Acute Therapies 2002 Update	Discharge Therapies	
Aspirin (ASA)	IA	IA	IA	
Clopidogrel in ASA-allergic patients	IB	IA	IA-B, depending on duration	
Clopidogrel, intended medical management	—	IA, ``at admission''	IA-B, depending on duration	
Clopidogrel, intended early catheterization/ percutaneous coronary intervention (cath/PCI)	_	IA, time of first dose not specified	IA-B, depending on duration	
Heparin (unfractionated heparin or low- molecular-weight heparin)	IB	IA	_	
β-blockers	IB	IB	IB	
ACE inhibitors†	IB	IB	IA	
Glycoprotein (GP) IIb/IIIa Inhibitors for in- tended early cath/PCI Eptifibatide/tirofiban Abciximab	IA IA	IA IA		
GP IIb/IIIa inhibitors for high-risk patients with- out intended early cath/PCI Eptifibatide/tirofiban Abciximab	IA	llaA IIIA	_	
Lipid-lowering agent‡	_		IA	
Smoking cessation counseling	_		IB	
Dietary modification	_		IB	

\*IA recommendations are derived from large-scale randomized trials. IB recommendations are derived from smaller randomized trials or carefully conducted observational analyses. IIaA recommendations are issued when evidence from large-scale randomized trials are in conflict, but on balance are supportive of efficacy. IIIA recommendations are issued when evidence from largescale randomized trials is clearly not supportive of efficacy and may suggest harm. ACC/AHA = American College of Cardiology/ American Heart Association; NSTE ACS = non ST-elevation acute coronary syndromes.

+For patients with persistent hypertension despite treatment, diabetes, congestive heart failure, or asymptomatic left ventricular dysfunction. ACE = angiotensin-converting enzyme.

+For patients with a low-density-lipoprotein cholesterol level >125 mg/dL.

ciplinary registry, with patient enrollment by emergency physicians, cardiologists, and their study personnel. More than 400 institutions are slated for inclusion in this registry, with a targeted registry population of more than 20,000 patients. In the first three months of the registry, more than 250 sites are actively enrolling patients, 200 more sites are planning to participate, and more than 9,000 patients have been enrolled.

The CRUSADE NSTE ACS registry includes patients who are prospectively identified in the ED as well as those who are retrospectively identified by discharge diagnosis or procedural logs. Patient inclusion criteria listed in Figure 1 include 1) chest pain or anginal equivalent at rest, at least 10 minutes in duration and occurring less than 24 hours prior to presentation; *and* 2) ischemic electrocardiogram (ECG) changes (ST depression or transient ST elevation); *or* 3) elevated levels of markers of myocardial necrosis (creatine kinase-MB or troponin) above baseline levels. Patients transferred into participating hospitals must arrive within 24 hours of their symptom onset to be eligible.

The CRUSADE ACS registry analyzes patient

Chest pain or anginal symptoms of >10 minutes' duration within 24 hours of presentation to the enrolling institution *and* ECG with >1-mV ST-segment depression or transient (<30 minute) ST-segment elevation *or* Elevated serum markers of myocardial necrosis (CK-MB or troponin above baseline) Figure 1. The CRUSADE non-ST-elevation acute coronary syn-

dromes (ACS) registry inclusion criteria. ECG = electrocardiogram; CK-MB = creatine kinase-MB. records to determine compliance with ACC/AHA guidelines for patients with NSTE ACS. The data points include those treatment elements listed in Table 2. The patient data collection form is shown in Figure 2. Risk stratification criteria such as ECG and biomarker results are documented for each patient. Exclusion criteria for each therapy (such as medication allergy) are sought to determine optimum utilization of ACC/AHA recommended therapies for eligible patients. Utilization of glycoprotein IIb/IIIa platelet inhibitors (GP IIb/IIIa) is expanded on the Crusade Data Form (Fig. 2) because early initiation of GP IIb/IIIa therapy is a relatively new treatment, of special importance to emergency physicians, which has been linked to improved outcome in patients with NSTE ACS. Timing of therapies is documented for other medications as well in order to differentiate ED utilization from downstream interventions. Patients are also followed throughout their hospitalizations to determine outcomes.

Site-specific registry data on medication utilization rates and process measurements that conform to the ACC/AHA guidelines are compiled and returned to the participating institution on a rapid turnaround quarterly basis. Utilization rates for specific therapies and procedures are compared with national benchmarks, best practice (top 10%) sites, and like hospitals (low versus high patient volume, teaching versus community, presence or absence of catheterization laboratories, geographic locations, etc.). Data are presented in graph form, with comparisons and percentile ranks with national and peer institution norms. Data presentation also includes a breakdown by patient subgroups (diabetics, elders, women, etc.) for more effective targeting of continuous quality improvement (CQI) intervention. Site and timing of medication administration are also graphed. Data are collated into acute care, discharge care, and overall care groupings based on Class I guideline indications for QI feedback to their specific physician groups (ED versus cardiology). Data are fed back to site participants, who can then disseminate the data to their colleagues in cardiology, internal medicine, or emergency medicine.

The CRUSADE initiative is more than just a patient care registry, however. Prior to participation in the CRUSADE registry, clinical site participants and their research personnel undergo a half-day educational session on the ACC/AHA guidelines, their implications in patient care, and the research behind them. These sessions, which have included up to 250 participants, are taught by nationally recognized faculty with experience in ACS research and clinical care. Participants in the CRUSADE registry also have access to the "CRUSADE Initiative Toolbox." This toolbox includes posted placards, pocket cards, order sets, discharge planning forms, and chart indicators, which serve as reminders to site participants regarding risk stratification, patient classification, specific therapies for NSTE ACS and their doses, and discharge planning programs.

In addition to the ACS registry, the CRUSADE initiative utilizes expert faculty and steering committee members to provide educational opportunities for participating institutions and physician groups. Educational symposia were included in the Society for Academic Emergency Medicine (SAEM), ACC, AHA, the American College of Emergency Physicians (ACEP), and the Society of Chest Pain Centers Providers meetings in 2002. Steering committee members were committed to providing educational lectures, utilizing CRUSADE registry data and standardized CRUSADE educational material, to increase compliance with the ACC/AHA guidelines. If regional or site-specific therapy compliance problems are identified by the registry, individual site participants may request a visiting lecturer to provide feedback to the site faculty. This feedback is intended to improve adherence to the ACC/AHA guideline recommendations. National emergency medicine and cardiology meetings and symposia have been identified for presentation of the CRUSADE registry data as an additional educational feedback mechanism. In addition, risk stratification and patient outcomes data from the CRU-SADE registry can be analyzed for publication in peer-reviewed journals, further emphasizing the importance of ACC/AHA guideline adherence.

Data analysis and registry feedback reporting for the CRUSADE initiative are coordinated by the Duke Clinical Research Institute in Durham, North Carolina. Funding for the CRUSADE initiative is provided through a grant from Millennium Pharmaceuticals, Inc., in Boston, Massachusetts, and Key ACS Pharmaceuticals in Kenilworth, New Jersey.

# TRACKING NSTE ACS RISK STRATIFICATION AND TRIGGERING THERAPY

The ACC/AHA guidelines for NSTE ACS make a number of recommendations for early and aggressive risk stratification that are pertinent to ED practice. These have been summarized previously.<sup>6,7</sup> These guidelines identify patients who are at highest risk for adverse outcomes so that appropriate therapy can be initiated. These high-risk patients are the focus of the CRUSADE initiative. Features identified as "high-risk" in the ACC/AHA guidelines, listed in Table 1, include ST-segment depression or transient ST-segment elevation, elevated biomarkers,

# CRUSADE

υπυ	SADE	Site Number: Patient Number:				
1 Histo	bry					
NO YES	Check 'No' or 'Yes' for each	Age: years				
□ <sub>0</sub> □ <sub>1</sub>	Hypertension	Gender: 🔄 Male				
	Insulin-treated diabetes mellitus	□_2 Female → If female, post-menopausal? □_0 No				
	Non-insulin-treated diabetes mellitus	Weight:				
	Currently smoking	□ 2 kg				
□ <sub>0</sub> □1	<b>Hypercholesterolemia</b> (Total Cholesterol > 200 mg/dL or 6 mmol/L or treatment with a lipid-lowering agent)	Ethnic origin: <sub>1</sub> Caucasian <sub>2</sub> Black <sub>3</sub> Asian <sub>4</sub> Hispanic				
	Prior MI	s American Indian6 Pacific Islander				
	Prior stroke	Arrival at enrolling besoital:				
□₀ □,	Prior CHF					
	Peripheral vascular disease	Date:// / IIMe: 00.00 to 23.59				
	Prior PCI	Location patient first evaluated:				
ı	Prior CABG	$\square_2$ (co) Cardiac Hool				
	Renal insufficiency {Known creatinine > 2.0 mg/dL}	Transfer from another hospital? 🔤 No 🛄 Yes				
2 Signs and Symptoms at Presentation						
2 Signs	s and Symptoms at Presentation					
2 Signs Onset date d	s and Symptoms at Presentation and time of ischemic symptoms:	Blood pressure:/ mmHg				
2 Signs Onset date c /_	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure:/ mmHg systolic / mmHg Heart rate: bpm				
2 Signs Onset date c / Check all the	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure:/ mmHg systolic / mmHg Heart rate: bpm 1 st 12-lead ECG obtained:				
2 Signs	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure:/ mmHg systolic / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Data: /				
2 Signs Onset date c / Check all the ST (> Trans	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure: / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / year				
2 Signs Onset date c / Check all the 1 ische 2 ST (> 3 Trans 4 Eleve	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure: / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / year Time:: 00:00 to 23:59				
2 Signs Onset date c / Check all the ST (> ST (> St (> St (> St (> St (> St (> St (> St (> St (>))))))))))))))))))))))))))))))))))))	s and Symptoms at Presentation and time of ischemic symptoms: <u>month</u> / <u>year</u> <u>100:00 to 23:59</u> at apply: emic symptoms > 10 min duration > 0.5 mm) depression sient ST elevation (> 1 mm) for less than 30 min bated CK-MB ated troponin I or T in a badeide troponin I or ST	Blood pressure: / mmHg systolic diastolic mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / month year Time:: 00:00 to 23:59				
2 Signs Onset date c / Check all the ST (> Steve Eleve 6 Positi None	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure: / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / Time::  Signs of CHF?0 No1 Yes				
2 Signs Onset date c / Check all the ST (> Trans Eleve Feive Fositi None 3 GP II	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure: / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / Time::  Signs of CHF? No1 Yes				
2 Signs Onset date c / Check all the Steve Steve Positi None 3 GP IIb/	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure: / mmHg Heart rate: bpm 1 st 12-lead ECG obtained: Date: / day / Time::  Signs of CHF? No Yes				
2 Signs Onset date c /. Check all the ST (> ST ())))))))))))))))))))))))))))))))))))	s and Symptoms at Presentation and time of ischemic symptoms: <u>month</u> / <u>year</u> <u>00:00 to 23:59</u> at apply: emic symptoms > 10 min duration > 0.5 mm) depression sient ST elevation (> 1 mm) for less than 30 min bated CK-MB ated troponin 1 or T ive bedside troponin 1 assay e of the above <b>Ib/IIIa Inhibitor Administration</b> (IIIa inhibitor administered? <u>0</u> No <u>1</u> Yes son not given (1-6): <u></u> wide data its balance	Blood pressure: / mmHg systolic / diastolic mmHg Heart rate: bpm 1st 12-lead ECG obtained: Date: / month /year Time:: 00:00 to 23:59 Signs of CHF?0 No1 Yes				
2 Signs Onset date c /. Check all the S I (> S I (> S Eleve S Eleve S Eleve S One 3 GP II Was GP IIb/ → If No, reas → If Yes, pro	s and Symptoms at Presentation and time of ischemic symptoms: <u>month</u> / <u>year</u> <u>00:00 to 23:59</u> at apply: emic symptoms > 10 min duration > 0.5 mm) depression sient ST elevation (> 1 mm) for less than 30 min ated CK-MB ated troponin I or T ive bedside troponin I assay e of the above <b>Ib/IIIa Inhibitor Administration</b> 'Illa inhibitor administered? <u>0</u> No <u>1</u> Yes son not given (1-6): <u></u> wide details below:	Blood pressure:      /				
2 Signs Onset date c / Check all the S T (> S Eleve S Eleve 6 Positi 7 None 3 GP II Was GP IIb/ → If No, reas → If Yes, pro	s and Symptoms at Presentation         and time of ischemic symptoms:	Blood pressure:				
2 Signs Onset date of day Check all the 2 ST (> 3 Trans 4 Eleve 6 Positi 7 None 3 GP II Was GP IIb/ → If No, reas → If Yes, pro Medication	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure:				
2 Signs Onset date a /. Check all tha I sche ST (> ST (> ST (> S (> S (>) S (>) S (>) S (>) Was GP IIb/ → If No, reas → If Yes, pro Medication Abciximab Eptifibatide	s and Symptoms at Presentation and time of ischemic symptoms: 	Blood pressure:				

The information contained in this proposal is confidential and the property of Duke University. It is intended solely for the use of the recipient in evaluating whether or not to enter into a research agreement with Duke University, and not for any other purpose. This information is not to be distributed outside the recipient organization.

Draft 1, Version 8 (12 April 2001)

#### Fax this form to the Duke Clinical Research Institute at 001-919-668-7100.

CRF, page 1

Figure 2 (above and following pages). The CRUSADE data collection form.

CRF, page **2** 

CRUSADE			Site Number:	Pa	tient Number:
4 Medications Check	ALL that apply	(at least <u>one</u> m	ust be checked for each	medication).	
	Prior to Arrival	in ED	Admission - Hospital Discharge	At Hospital Discharge	Reason Not Given (1-6)
ACE inhibitor	□,	<b></b> 2	<b></b> 3	4	
Aspirin	Ξ,	2	<b></b> 3	4	
Beta blocker		2	<b></b> 3	4	
HMGCO-A inhibitor	$\Box_{\mathbf{l}}$	2	3	4	
Ticlopidine/clopidogrel		2	3	4	
Additional Medications	(*******)				
Direct thrombin inhibitor		<b>2</b>	<b>□</b> 3	<b>□</b> ₄	
IV unfractionated heparin	$\Box$	2	3 	4	
Low molecular weight heparin	1	2	3	4	
Warfarin	1	2	<b></b> 3		
5 In-hospital Proced	ures				
<u>No Yes Procedure</u>				<u>Date</u>	<u>Time</u>
🔲 o 🔄 Noninvasive ima	ying			///	
🗢 If Yes, performed during	p: 🗌 Rest 🗌 S	Stress		,,	00:00 16 23:59
Diagnostic cath	· · · ·		day	///	reor 00:00 to 23:59
→ IT Tes, vessels with signin	Graft []		None/Insignificant		
🛏 If Yes: 🗌 Nuclear scan		EKG treadmill			
				//	
➡ If Yes:% or [	Normal 🗌 M	ild 🗌 Moderate	e 🛄 Severe	y month )	<i>r</i> eor
				///	
				//	
			day	y month y	rear 00:00 to 23:59
			day	y month y	vear 00:00 to 23:59
6 In-Hospital Clinica	l Events				
<u>No Yes Event</u>		<u>If Yes, Date c</u>	of First Occurrence		
□ <sub>0</sub> □ <sub>1</sub> (Re)infarction	_	/ daymonth	./year		
Cardiogenic Shoc	k _	day month	year year		
□ <sub>o</sub> □ <sub>1</sub> CHF	-	day month	./year		
🔲 o 🔲 I Stroke		/	./	Hemorrhagic?	□ <sub>0</sub> No □ <sub>1</sub> Yes
, Transfusion	_	/	/ <b></b>	<ul> <li>CABG related</li> </ul>	? No, Yes
Died		day month	year /	Overt bleedin	g? 🗋 No 🔲 Yes
	-	day month	year		

The information contained in this proposal is confidential and the property of Duke University. It is intended solely for the use of the recipient in evaluating whether or not to enter into a research agreement with Duke University, and not for any other purpose. This information is not to be distributed outside the recipient organization.

Draft 1, Version 8 (12 April 2001)

Fax this form to the Duke Clinical Research Institute at 001-919-668-7100.

-

CRUSADE		Site N	umber:	Patient Number	r:
7 Labs					
Not Lab Done Date (	Baseline and Time Value	Unit	Date and Time	Peak ( (use same units) (use s	JLN ame units)
Cardiac Markers					
CK (Creatinine Kinase)	nthyear	□_ <sub>1</sub> IU/L □_ <sub>2</sub> %	dayyear		
004	)0 to 23:59	☐_3 <u>mg/mL</u> IU ☐_4 ng/ml	00:00 to 23:59		
CK-MB	nth_/year	□_ <sub>1</sub> IU/L □_ <sub>2</sub> %	///year		
00.1	10 to 23:59	<sub>3</sub> <u>mg/mL</u>  U   <sub>4</sub> ng/ml	00:00 to 23:59		
Troponin 🗌 I 🗔 <sub>atoy</sub> / T	n#ng	ı∕mL <b>OR □<sub>0</sub> Neg</b>			[0 Neg 1 Pos
 Cholesterol	30 to 23:59		00:00 10 23:34		
TC and Chalesteral		🗌, mmol/L oi	mg/dL		
HDL Increte linearratein		, mmol/L oi	a₂ mg/dL		
LDL Density Lipoprotein		1 mmol/L oi	t □ <sub>2</sub> mg/dL		
8 Recommendation	s at Discharge				
NO YES Check 'No' or 'Yes'	for each documented.				
□ <sub>0</sub> □ <sub>1</sub> Smoking cessation o	counseling				
$\Box_0$ $\Box_1$ Dietary modification	n counseling				
o the cardiac rehabilitation of the	on referral				
9 Discharge					
Patient: $\square_1$ Discharged $\rightarrow \{\frac{d\sigma y}{d\sigma y}}$	_///	_			
		, ,			
$\Box_3 \text{ Ironsterred to another}$ $\Box_1 \text{ For cath/PCI/CA}$ $\Box_2 \text{ Other}$	r acute care center → \BG	/ / y month	year		
10 Investigator/Coo	rdinator Signat	lure			
I have reviewed all the data reco	rded on these CRF pages	s and they are ac	curate and complete to	o the best of my kn	iowledge.
				/	/
Investigator Signature			<b>_</b>	day month	year

The information contained in this proposal is confidential and the property of Duke University. It is intended solely for the use of the recipient in evaluating whether or not to enter into a research agreement with Duke University, and not for any other purpose. This information is not to be distributed outside the recipient organization.

Draft 1, Version 8 (12 April 2001)

Fax this form to the Duke Clinical Research Institute at 001-919-668-7100.

CRF, page 3

Figure 2 (cont.).

and advanced age.34-38 The CRUSADE initiative tracks selected objective inclusion criteria (Fig. 1) as well as other high-risk features and relates them to medical and interventional therapy for ACS. Medical therapy potentially indicated for high-risk NSTE ACS patients in the ED includes aspirin, clopidogrel, heparin or low-molecular-weight heparin, GP IIb/ IIIa receptor antagonists, and beta-blockers. Data entered into CRUSADE will document qualifying signs and symptoms, therapy given with timing of administration, disposition, use of interventional therapy, in-hospital outcomes, and medications and referrals at hospital discharge. Participating emergency physicians and cardiologists can compare guideline recommendations for the care of these patients with care actually provided.

The CRUSADE initiative can also be modified over time as changes are made to the guidelines, based on accumulating medical evidence. The recent 2002 update to the 2000 ACC/AHA guidelines are summarized in part in Table 2. In the update, several changes in recommended therapy that potentially impact ED care were made. By placing a date stamp in the CRUSADE database that indicates promulgation of an update, performances before and after the update can be compared. This will allow measurement of acceptance of new recommendations as well as measurement of the success of CRUSADE-related educational interventions put into place after the update is published.

For example, the 2002 update includes substantially different recommendations for the use of the thienopyridine agent, clopidogrel. The update was prompted by the publication of the CURE Trial,<sup>39</sup> which was published after the 2000 guidelines. In 2000, the ACC/AHA recommended the use of clopidogrel only as a substitute for aspirin in aspirin-allergic patients. In the 2002 update, clopidogrel is recommended as additive therapy to aspirin, likely initiated in the ED for patients being medically managed. CRUSADE data will indicate the degree and the pace to which this recommendation is accepted across a wide variety of hospitals in the United States. As more data are published in this field and recommendations are changed or initiated by the ACC/AHA, similar date stamps can mark time intervals in which a change in practice can be expected to occur. This will also afford the CRUSADE investigators an objective means of comparing the relative success of different educational interventions used over time.

## CONCLUSIONS

Treatments for patients with ACS have evolved considerably during the last decade, but the imple-

mentation of practice guidelines that incorporate new treatments has been challenging.<sup>10</sup> Recently completed and ongoing quality improvement studies have delineated multiple steps that are necessary to surmount these challenges and ensure continuous improvement in the quality of care for patients with ACS. The CRUSADE initiative combines a straightforward collection of pertinent data with educational programs that cross medical specialties, with multidisciplinary cooperation between emergency medicine and cardiology. It assesses the diagnostic approach utilized in the emergency department for patients with suspected ACS, with risk stratification strategies directly linked to the use of acute therapies for patients with confirmed ACS.

The CRUSADE initiative aims to track the success of this effort, as well as to provide educational efforts that may enhance that success. It is a truly national project, including a diverse representation (geographic, bed size, type of hospital) of hospitals and specifically encouraging collaboration between emergency medicine and cardiology, with QI feedback that can be used by either or both specialties to improve the care of patients. It will include more patients in its registry than any prior NSTE ACS program, increasing the statistical power of its conclusions. Data specific to the ED care of these patients will be provided for comparison both to published guidelines and to the performance of peer institutions. The large-scale, national focus of this and other programs and the longitudinal description of care for patients with ACS will help to overcome the obstacles that typically hinder QI studies and will help to determine the impact of improved adherence to practice guidelines on clinical outcomes.

## References

- Rogers WJ, Canto JG, Lambrew CT, et al. Temporal trends in the treatment of over 1.5 million patients with myocardial infarction in the U.S. from 1990 through 1999. J Am Coll Cardiol. 2000; 36:2056–63.
- 2. Alexander KP, Peterson ED, Granger CB, et al. Potential impact of evidence-based medicine in acute coronary syndromes: insights from GUSTO-IIb. J Am Coll Cardiol. 1998; 32:2023–30.
- 3. Peterson ED, Canto JG, Pollack CV, et al. Early use of glycoprotein IIb/IIIa inhibitors and outcomes in non-ST-elevation MI: observations from NRMI-4. J Am Coll Cardiol. 2002; 39:303A.
- 4. Braunwald E, Antman EM, Beasley JW, et al. ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction: executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients with Unstable Angina). Circulation. 2000; 102:1193–209. 2002 update posted at: www.acc.org on Mar 15, 2002.

- 5. Ryan TJ, Antman EM, Brooks NH, et al. 1999 Update. ACC/AHA guidelines for the management of patients with acute myocardial infarction: executive summary and recommendations. Circulation. 1999; 100:1016–30.
- Pollack CV, Gibler WB. 2000 ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction: a practical summary for emergency physicians. Ann Emerg Med. 2001; 38:229–40.
- Pollack CV, Gibler WB. Advances create opportunities: implementing the major tenets of the new unstable angina guidelines in the emergency department. Ann Emerg Med. 2001; 38:241–8.
- Bassand JP. Improving the quality and dissemination of guidelines: the quest for the Holy Grail. Eur Heart J. 2000; 21:1289–90.
- 9. Zipes DP. Guidelines: tools for building better patient care. J Am Coll Cardiol. 2001; 38:2087–90.
- Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA. 1999; 282:1458–65.
- Davis DA, Thomson MA, Oxman AD, Haynes RB. Changing physician performance: a systematic review of the effect of continuing medical education. JAMA. 1995; 274:700–5.
- 12. Grol R. Improving the quality of medical care. Building bridges among professional pride, payer profit, and patient satisfaction. JAMA. 2001; 284:2578–85.
- Soumerai SB, McLaughlin TJ, Gurwitz JH, et al. Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. JAMA. 1998; 279:1358–63.
- CCP Project Best Practices Working Group. Improving care for acute myocardial infarction: experience from the Cooperative Cardiovascular Project. Jt Comm J Qual Improv. 1998; 24:480–90.
- Axtell SS, Ludwig E, Lopez-Candales A. Intervention to improve adherence to ACC/AHA recommended adjunctive medications for the management of patients with an acute myocardial infarction. Clin Cardiol. 2001; 24: 114–8.
- Kiefe CI, Allison JJ, Williams OD, Person SD, Weaver MT, Weissman NW. Improving quality improvement using achievable benchmarks for physician feedback. A randomized controlled trial. JAMA. 2001; 285:2871–9.
- Bradley EH, Holmboe ES, Mattera JA, Roumanis SA, Radford MJ, Krumholz HM. A qualitative study of increasing β-blocker use after myocardial infarction. Why do some hospitals succeed? JAMA. 2001; 285:2604–11.
- National Heart Attack Alert Program. Educational strategies to prevent pre-hospital delays in patients at high risk for acute myocardial infarctions. US Dept of Health and NIH Publication. 1997; 97:3787.
- 19. Shine KI. Closing the gap in quality health care for Americans. Circulation. 2000; 101:2325–32.
- French WJ. Trends in acute myocardial infarction management: use of the National Registry of Myocardial Infarction in quality improvement. Am J Cardiol. 2000; 85: 5B–12B.
- 21. Fonarow GC, Gawlinski A, Moughrabi S, Tillisch JH. Improved treatment of coronary heart disease by implementation of a cardiac hospitalization atherosclerosis management program (CHAMP). Am J Cardiol. 2001; 87: 819–22.
- McCarthy M. U.S. heart-guidelines strategy makes promising start [editorial]. Lancet. 2001; 358:1618.
- Braunwald E, Jones RH, Mark DB, et al. Diagnosing and managing unstable angina. Agency for Health Care Policy and Research. Circulation. 1994; 90:613–22.

- 24. Simpson RJJ, Weiser RR, Naylor S, Sueta CA, Metts AK. Improving care for unstable angina patients in a multiple hospital project sponsored by a federally designated quality improvement organization. Am J Cardiol. 1997; 80:80H–84H.
- 25. Krumholz HM, Philbin DM, Wang Y, et al. Trends in quality of care for Medicare beneficiaries admitted to the hospital with unstable angina. J Am Coll Cardiol. 1998; 31:957–63.
- Yusuf S, Flather M, Pogue J, et al. Variations between countries in invasive cardiac procedures and outcomes in patients with suspected unstable angina or myocardial infarction without initial ST elevation. Lancet. 1998; 352: 507–14.
- Reis SE, Holubkov R, Zell KA, Edmundowicz D, Shapiro AH, Feldman AM. Unstable angina: specialty-related disparities in implementation of practice guidelines. Clin Cardiol. 1998; 21:207–10.
- Scirica BM, Moliterno DJ, Every NR, et al. Differences between men and women in the management of unstable angina pectoris (The GUARANTEE Registry). Am J Cardiol. 1999; 84:1145–50.
- 29. Scirica BM, Moliterno DJ, Every NR, et al. Racial differences in the management of unstable angina: results from the multicenter GUARANTEE registry. Am Heart J. 1999; 138:1065–72.
- Stone PH, Thompson B, Anderson HV, et al. Influence of race, sex, and age on management of unstable angina and non-Q-wave myocardial infarction: the TIMI III registry. JAMA. 1996; 275:1104–12.
- 31. The Fibrinolytic Therapy Trialists Cooperative Group. Indications for fibrinolytic therapy in suspected acute myocardial infarction: collaborative overview of early mortality and major morbidity results from all randomized trials of more than 1000 patients. Lancet. 1994; 343:311– 22.
- 32. Kirk JD, Diercks DB, Turnipseed SD, Amsterdam EA. Evaluation of chest pain suspicious for acute coronary syndrome: use of an accelerated diagnostic protocol in a chest pain evaluation unit. Am J Cardiol. 2000; 85:40B– 48B.
- Kontos MC, Jesse RL. Evaluation of the emergency department chest pain patient. Am J Cardiol. 2000; 85:32B– 39B.
- Boersma E, Pieper KS, Steyerberg EW, et al. Predictors of outcome in patients with acute coronary syndromes without persistent ST-segment elevation: results from an international trial of 9461 patients. Circulation. 2000; 101: 2557–67.
- Savonitto S, Ardissino D, Granger CB, et al. Prognostic value of the admission electrocardiogram in acute coronary syndromes. JAMA. 1999; 281:707–13.
- Kaul P, Fu Y, Chang WC, et al. Prognostic value of ST segment depression in acute coronary syndromes: insights from PARAGON-A applied to GUSTO-IIb. J Am Coll Cardiol. 2001; 38:64–71.
- Ohman EM, Armstrong PW, Christenson RH, et al. Cardiac troponin T levels for risk stratification in acute myocardial ischemia. N Engl J Med. 1996; 335:1333–41.
- Antman EM, Tanasijevic MJ, Thompson B, et al. Cardiacspecific troponin I levels to predict the risk of mortality in patients with acute coronary syndromes. N Engl J Med. 1996; 335:1342–9.
- 39. The Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators. Effects of clopidogrel in addition to aspirin in patients with acute coronary syndromes without ST-segment elevation. N Engl J Med. 2001; 345: 494–502.