

Reducing Liability Associated with Acute Coronary Syndromes

Cardiovascular Disease in the U.S.

According to the latest statistics available from the American Heart Association, approximately 70,100,000 Americans have one or more types of cardiovascular disease (CVD). Within that group are 13,000,000 Americans who have coronary artery disease (CAD), including acute coronary syndromes (ACS) such as myocardial infarction (MI) and unstable angina. The incidence of CVD is rising, due to both the aging of the U.S. population and to the alarming increase in the prevalence of known risk factors for CVD, such as hypertension, obesity and type 2 diabetes.¹

More worrisome than the prevalence of CVD is its deadliness. It has been the number one killer in this country in every year since 1900 except 1918. To put these numbers in perspective, "CVD claims about as many lives each year as the next 5 leading causes of death combined, which are cancer, chronic lower respiratory diseases, accidents, diabetes mellitus, and influenza and pneumonia."¹

To make matters worse for physicians and patients alike, ACS must be diagnosed and treated in a matter of minutes to hours in order to minimize the risk of death, stroke and other major complications, and to preserve the quality of the patient's life. Unfortunately, quick diagnosis is not always the case: a Physician Insurers Association of America (PIAA) Myocardial Infarction Study undertaken in 1999 revealed that as many as 40-45 percent of MIs go unrecognized and undiagnosed.²

The physician's task would be made easier if diagnosing ACS were a straightforward matter. There are many reasons why it is so difficult to diagnose. Many patients fail to recognize the symptoms of a heart attack and delay seeking treatment, while others with known heart disease do not report changing or escalating symptoms to their physicians. As many as 35 percent of patients may have "silent" MIs; that is, they do not experience the

(continued on page 2...)

Sudden Cardiac Death (SCD)

Sudden cardiac death, "defined as an unheralded, fatal outcome in an individual with previously stable clinical status, with symptoms occurring less than one hour [prior to] demise,"³ is a major public health concern and a potential professional liability risk. SCD occurs in 300,000 to 450,000 individuals per year in the United States, and in a study of vital statistics from 1998, SCD accounted for 63 percent of total deaths occurring out of hospital, in the emergency department or as dead-on-arrival.¹

SCD rates are strongly associated with coronary artery disease (CAD) and it is logical to apply CAD risk factors to predict SCD. However, SCD is not limited to CAD sufferers, and for different medical reasons can occur in other populations, such as youth and athletes. Despite extensive medical research on this topic, the mechanisms leading to SCD are still not completely understood and, as a result, prevention (outside the traditional CAD lifestyle modification strategies) remains controversial.¹

According to a recent article in the British medical journal *Heart*, current management of SCD is wrought with two overlapping problems:

- "We have a very limited ability to prevent SCD and must therefore depend on risk prediction and prophylactic implantation of an [implantable cardioverter-defibrillator]."
- We are unable to predict SCD risk in patients with preserved ventricular function despite the fact that these patients account for approximately 50% of SCD victims."²

From a professional liability perspective, it is important, then, to identify those patients who *can* be predicted to be at risk for SCD. Because CAD and its comorbidities account for the majority of SCD

(SCD continued on page 2...)

typical signs and symptoms.³ Chest pain, the most common patient complaint, can be caused by a wide variety of conditions, ranging from life-threatening ones—MI, aortic dissection, pulmonary embolus, esophageal rupture, pneumothorax and cardiac tamponade—to less emergent conditions such as muscle strains and heartburn.

(SCD continued from page 1...)

cases, it is obvious to begin with such patients (e.g., patients with a previous MI or who have been diagnosed with congestive heart failure). In managing this high-risk category of patients, physicians are encouraged to communicate honestly and directly about SCD and what can be done to mitigate risk. Patient education materials can be used to support conversations between the physician and patient (and his or her family), and medical records documentation is evidence that verbal or written communication occurred.

It is more difficult to identify at-risk patients who do not have a known cardiac condition. There has been recent media attention on “healthy” pediatric-aged athletes who experienced sudden death on the playing field or shortly after. This has led to increased emphasis on performing preparticipation sports evaluations to screen for unknown cardiovascular disease. While the physical work-up in asymptomatic patients for certain cardiovascular abnormalities can be unimpressive, the key to performing a thorough evaluation is taking a good history. Thoroughly documenting the detailed personal and family history will guide the physician’s approach to further work-up.³ As always, the detailed history, physical examination findings and decision-making rationale to pursue (or not to pursue) specialized testing shows adherence to the standard of care.

In conclusion, while prevention and treatment for SCD remains complicated and limited, candid physician-patient communication, comprehensive history-taking and complete documentation are the fundamental elements of avoiding (or defending) a future malpractice claim. ■

1 Obias-Manno D and Wijetunga M. Risk stratification and primary prevention of sudden cardiac death. AACN 2004; 15(3):404-418.

2 Spector PS. Diagnosis and management of sudden cardiac death. Heart 2005;91:408-413.

3 Cava JR, Danduran MJ, Fedderly RT, Sayger PL. Exercise recommendations and risk factors for sudden cardiac death. Pediatr Clin N Am 2004;51:1401-1420.

Medical Professional Liability Trends

Medical malpractice claims alleging failure to diagnose and appropriately treat ACS are among the most expensive for physicians and professional liability companies alike. In particular, claims involving acute MI have the third highest total indemnity of all malpractice claims, following those involving brain damaged infants and breast cancer.

While this article focuses primarily on the emergency department (ED) setting, claims involving failure to diagnose or treat ACS involve numerous medical specialties in both hospital and outpatient settings. A recent PIAA report (2003) on acute MI claims showed the top five specialties associated with such allegations were: internal medicine, general/family practice, cardiology, emergency medicine and general surgery. This report showed the average per claim indemnity for these claims to be \$208,424 (figure includes all medical specialties).

Several themes from acute MI litigation can be extrapolated to analyze malpractice risk associated with ACS in general. “Diagnosis error” tops the list of medical misadventures associated with acute MI. Other misadventures (less frequently) associated with this condition include the following:

- Failure to supervise/monitor case
- Procedure/test not performed
- Failure/delay in admission to hospital
- Procedure/test performed when not indicated
- Failure to recognize a complication of treatment
- Failure/delay in referral or consultation
- Delay in performance

Associated issues with acute MI claims include the following:

- Problems with medical records
- Premature discharge from institution
- Communication problems between providers
- Lack of adequate facilities or equipment
- Consent issues
- Abandonment
- Problems with patient’s history, exam or work-up

(continued on page 3...)

The following closed case example illuminates several of these themes.

Case Example

Allegation

Failure to diagnose impending MI resulting in death of a 56-year-old man.

The Event

A 56-year-old man with no personal or family history of MI, hypertension or diabetes presented to the ED complaining of chest pain. The patient reported that the pain began two days earlier and occurred primarily with exertion, lasting a maximum of 15 minutes. The pain radiated to his left arm and was associated with shortness of breath. He also reported an episode of pain at rest. The patient had not experienced nausea, vomiting, dizziness or diaphoresis.

The patient's blood pressure was 130/88. Physical examination revealed no apparent distress. The physician noted regular heart rate without murmur and no jugular venous distention.

The patient was monitored for recurrence of pain over a three-hour period. An IV line was started and a transdermal nitroglycerin patch placed. Chest x-ray, Troponin I and CK tests were negative, and although an ECG computer notation read: "Cannot rule out inferior infarct, age undetermined," the physician's review of the strip showed no ominous findings or indications of myocardial ischemia. There was no recurrence of symptoms or changing ECG findings during this observation period.

The ED physician suspected angina pectoris, but felt consultation by the on-call internist was warranted. Based on his evaluation and the test results, the internist agreed with the emergency physician's

(continued on page 4...)

Order NORCAL's Failure to Diagnose Acute Myocardial Infarction CME Course

NORCAL is proud to announce the republication of one of our most popular CME monographs: *Failure to Diagnose Acute Myocardial Infarction*. Released in April of 2005, this distance-learning course presents three new closed professional liability cases that illustrate adverse outcomes related to acute myocardial infarction (MI) cases. In addition to the closed cases, the course contains a more in-depth discussion of various clinical and risk management topics.

This course is intended for all healthcare providers involved in the diagnosis and treatment of cardiovascular disease including general/family practice physicians, internal medicine physicians, emergency medicine physicians, physicians practicing in urgent care settings, cardiologists, radiologists and allied healthcare practitioners. The purpose of this CME activity is to assist physicians and physician practices to do the following:

- Discover the symptoms, signs, patient presentations, physician behaviors and diagnoses most frequently associated with a missed diagnosis of MI.

- Implement practice changes to improve referral processes including tracking, communicating and documenting test results.
- Minimize the number of patients whose diagnoses are missed or delayed due to gaps in communication and follow-up.
- Reduce professional liability exposure.

The course is available in both monograph and Internet formats, and can be ordered by calling the Risk Management Department at (800) 652-1051, ext. 2244. Or, you can preview the course by visiting our website at www.norcalmutual.com/cme.

NORCAL Mutual Insurance Company is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. NORCAL Mutual Insurance Company designates this educational activity for a maximum of 2 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he or she actually spent in the activity. ■

diagnosis of angina pectoris. Unfortunately, however, the patient had failed to report the episode of pain at rest to the internist, who did not consider this when making the diagnosis. The internist felt that the patient was not in any acute distress and discharged him.

The patient was given diltiazem, nitroglycerin patches and a prescription for sublingual nitroglycerin tablets. He was also given instructions to take aspirin, and told that he needed to see his personal internist for a treadmill test to further determine if he was having coronary ischemia. The patient was instructed to return if there was any worsening of his symptoms. The internist did not write any of these instructions on the discharge sheet because he did not feel they were unusual. The only written note on the discharge sheet was the advice for the patient to visit his personal internist.

Sometime after the patient's discharge, the emergency physician dictated his ED summary and revised his initial suspicion from angina pectoris to crescendo angina because of the patient's report of pain at rest. He did not inform the internist or the patient of this.

Upon returning home, the patient continued to suffer from chest pain over the next one-and-a-half days and finished the entire bottle of nitroglycerin tablets. Although the patient called the ED with a complaint of a headache, at no time during this period did he call the hospital for advice regarding his chest pain, nor did he return to the ED.

The patient suffered a cardiac arrest at home. CPR was initiated, and he was transported to the hospital where, despite further treatment, he was pronounced dead. The coroner's report noted coronary artery thrombosis due to coronary atherosclerosis.

Case Analysis

Failure to rule out ACS before arriving at a diagnosis of angina, especially in the presence of rest pain

When patients present to the ED with complaints of new onset of chest pain, distinguishing between stable angina and the more serious conditions of unstable angina, non-ST-segment elevation MI

(NSTEMI), and MI manifested by ST-segment elevation (STEMI) is a primary concern.

Characteristics of stable angina in this case included exertional onset and radiation to the left arm. There were symptoms more consistent with ACS, however, which included rest pain and shortness of breath. Pain at rest represents a progression from angina to unstable angina and MI, and requires further evaluation to rule out ACS.⁴

Failure to obtain a cardiology consult to confirm nondiagnostic interpretation of ECG

The ECG machine's conclusion, "[c]annot rule out inferior infarct, age undetermined," warranted a second opinion from a cardiologist. The patient's death two days later provided credibility to the machine interpretation and called into question the judgment and ECG interpretation skills of the ED physician. (A question is also raised as to the responsibility of the internist in overreading the ED physician's interpretation of the ECG, as well as to the staff cardiologist who presumably reviewed it the next day. These two physicians certainly would have seen that the machine interpretation differed from the ED physician's interpretation, and had they examined the case more closely, may have questioned the ED physician's diagnosis.)

If a physician's interpretation differs from the machine interpretation, it is always best risk management practice to obtain a second opinion, and to document this process and decision-making rationale in the patient medical record.

Failure to obtain and interpret serial cardiac markers

Additionally, the ED physician relied upon a normal chest x-ray and initially negative cardiac enzymes to conclude that the pain the patient was experiencing was due to angina. There are patient safety risks inherent in this conclusion. First, cardiac markers remain negative in unstable angina, which nonetheless is a life-threatening condition that often progresses to MI, cardiac arrest and death. Second, the timing of symptom onset is crucial to correct interpretation of serum markers.

(continued on page 5...)

Depending upon the time of symptom onset, it might have been too soon to detect the markers.

Moreover, American College of Emergency Physicians (ACEP) guidelines caution physicians that the presentation of acute MI frequently begins with preinfarction angina. Preinfarction angina is associated with plaque rupture and intermittent coronary closure and opening as the cycle of platelet aggregation and fibrin deposition is initiated. If the patient's presentation is more consistent with preinfarction angina, or if the time of symptom onset is unknown or unreliable, the ACEP guidelines suggest the time of symptom onset should be referenced to the time of ED presentation.⁵ In this case, repeating the serum markers later during the observation period may have resulted in a more useful result.

Failure to elicit an adequate history and failure to communicate findings

Another contributing factor to this instance of failing to diagnose an impending MI was the internist's failure to elicit information about the patient's pain at rest. Had the internist sought this information, either from the emergency physician or patient, he might have appreciated its significance in terms of indicating a potential MI. It was just as important, however, for the ED physician to inform the internist of the rest pain when he requested the consultation. Better physician-to-physician communication can close gaps in patient history and promote more attentive care. Consistently communicating significant findings, including a revised diagnosis, to all physicians involved in the diagnosis and treatment and to the patient, can significantly increase patient safety.

Failure to provide and document adequate discharge instructions

The internist failed to ensure that the patient understood the diagnosis and the discharge instructions to return with "worsening symptoms." He also did not provide them in writing to the patient or document them. Based on his actions, the patient clearly did not understand that even if his symptoms did not change in nature, he should return to the ED if the pain was not relieved by the nitroglycerin.

As indicated in this case, precise discharge education can have a serious impact on outcomes

of patients who present with chest pain. The American College of Cardiology (ACC) recommends that the education include the signs and symptoms of heart attacks, and how and when to access emergency care. Patients can also benefit from specific parameters for follow-up (e.g., "Follow up with your primary care physician within one week.") At a minimum, the ACC recommends that patients with known disease should be advised to quickly seek medical attention when symptoms occur, especially if the pain is sustained (i.e., noticeably longer than usual), or there are multiple, recurrent episodes.⁶ The American College of Cardiology/American Heart Association (ACC/AHA) guidelines on acute MI also call for educational efforts in simple, understandable terms *during each office visit* that include possible symptoms and the action plan.⁷

Failure to directly and immediately communicate urgent findings

Pain at rest suggests the evolution of a previous anginal pattern, and is an important indication of worsening clinical status. When the emergency room physician in this case revised his diagnosis, he should have immediately contacted the treating physician and, if necessary, the patient. The new diagnosis could have prompted more urgent intervention. The lack of communication deprived the physicians in charge of this patient's care of the opportunity to intervene in a timely manner, which might have prevented the patient's death.

Inadequate telephone screening of medical problems

Finally, the last chance to intervene on behalf of the patient was lost during his call to the ED to complain of a headache. Were he triaged and screened based upon written protocols that mandated obtaining a careful history, his emergent condition might have been discovered before it was too late. (Such protocols might include asking if the patient had had any recent medical care, visits to the ER, visits with his or her primary provider, significant medical or surgical conditions, recent surgery and/or medications.)

Asking the patient why he was calling the ED instead of his primary care physician might have solicited the history of the recent visit for chest pain and the prescription for nitroglycerin.

(continued on page 6...)

Careful questioning about the patient's use of nitroglycerin would have revealed the frequency and intensity of his chest pain and, at that point, the patient would have been instructed to access the emergency care that may have saved his life.

Early Risk Stratification in ACS

The ACC/AHA Guidelines on Unstable Angina (2002) and Guidelines for ST-Elevation Myocardial Infarction (2004) clarify the time parameters pertinent to the execution of chest pain protocols.^{7,8} Using the history, physical, ECG and serum markers, the physician is encouraged to answer two questions as urgently as possible:

- 1) What is the likelihood that the signs and symptoms represent ACS?
- 2) What is the likelihood of an adverse clinical outcome, including death, MI (or recurrent MI), stroke, heart failure, recurrent symptomatic ischemia and serious arrhythmia?

Once the physician has performed the history and physical exam, evaluated the ECG and completed the initial patient risk assessment, he or she assigns a diagnostic category to the patient. In general, chest pain protocols divide patients into three groups:

- 1) Those with a clear diagnosis of acute MI, unstable angina, or NSTEMI, who are admitted and treated according to the ACC/AHA protocols. (Correct diagnosis and treatment, improved likelihood of good outcome and decreased likelihood of an alleged professional liability.)
- 2) Those for whom a diagnosis cannot be made at the current time. This includes patients who have CAD or risk factors for CAD, and may be at risk for adverse events; these patients will be observed, tested and reevaluated. (Diagnosis, treatment, outcomes and liability yet to be determined.)
- 3) Those patients who clearly do not have CAD and are not at risk of adverse cardiac events; an alternative diagnosis is sought and the appropriate treatment is provided. (If correct diagnosis and appropriate treatment, improved likelihood of good outcome and decreased liability.)

To promote patient safety and decrease their liability exposure, physicians are encouraged to carefully monitor the second group until ACS is ruled out, and to be very conservative in assigning patients to the third group.

Risk Management Recommendations for Emergency Department Physicians

- Perform a risk stratification analysis on all patients presenting with chest pain.
- Develop and refer to protocols for evaluation, treatment and management of chest pain.
- Ensure that chest pain protocols address when physicians should be notified regarding significant signs, symptoms and laboratory results. Consulting physicians and allied healthcare providers should report significant signs, symptoms and laboratory results to the physician.
- Write specific orders for monitoring patients, confer with nurses and read the nurses' notes before discharging the patient.
- Exercise special caution when evaluating chest complaints in women, whose presentation and symptoms may vary from those typically seen in men.
- Know and screen for cardiac risk factors in all patients presenting with chest pain.
- When cardiac risk factors are present, perform repeat ECG and serum markers, and perform noninvasive testing before arriving at the final diagnosis and disposition.
- Rule out ACS, especially in the presence of rest pain, before diagnosing angina.
- Observe patients with ischemic chest pain and nondiagnostic ECGs, obtain repeat ECGs and serum markers, and consider additional noninvasive testing before discharging such patients.
- Keep ECG interpretation skills current.
- If available, make use of prior ECGs for comparison.
- Obtain a cardiology consult if your interpretation differs from the computer, or if there is a need to evaluate nonspecific ECG changes.

(continued on page 7...)

- Provide patients with discharge instructions that clearly state the patient's primary diagnosis as well as the differential diagnosis, including worst-case scenarios and symptoms that require immediate action.
- Confirm and document that the patient understands the discharge instructions, including his or her diagnosis and treatment plan, before discharge from the ED.
- Communicate a patient's ED visit and diagnosis to the patient's primary care physician. Document your efforts in the medical record.
- Communicate diagnoses and clinical impressions to other treating physicians.

Risk Management Recommendations for Cardiologists

- Establish and refer to written policies and procedures that clarify the following for your office practice:
 - Which results indicate life-threatening conditions and need to be communicated directly and immediately, and
 - How that communication will take place
- If the cardiology review of an ECG results in new findings *after* the patient has been discharged from the hospital, contact the ED physician or primary care physician immediately. When neither physician is available, contact the patient directly.
- Document your communications with other providers and (if applicable) the patient in the medical record.

Risk Management Recommendations for Primary Care Physicians

- Establish and refer to written protocols for office staff. Ensure that such protocols address the following:
 - Handling of telephone calls about chest pain.*
 - Instructions for accessing emergency care.

- Encourage patients to present to the ED as soon as possible after the onset of chest pain.
- Document telephone encounters and advice given to patients in the medical record.
- Establish and refer to written policies regarding reports from the ED. Ensure that ED reports are addressed in the next patient visit or, if necessary, schedule a new patient visit for follow-up.

CONCLUSION

From a patient safety and risk management perspective, healthcare providers are encouraged to standardize immediate care for all patients presenting with chest pain. Physicians are urged, above all, to refer and/or admit a patient presenting with any symptoms that could be associated with ACS *until the diagnosis has been ruled out*. Evidence-based, peer-reviewed clinical guidelines and chest pain protocols play a primary role in making safe diagnostic and treatment decisions. Most guidelines emphasize the importance of physician skill and competence in performing diagnostic procedures and interventions. Stay apprised of developments in the diagnosis and treatment of heart disease, and ensure that your organization is aware of such developments as well. Following the guidelines, documenting your decision-making rationale and communications with other providers, and obtaining and documenting informed consent from the patient can go a long way in defending a claim should one be brought against you. ■

Endnotes

- 1 American Heart Association (AHA). Heart Disease and Stroke Statistics—2005 Update. AHA website. Available at: www.americanheart.org. Accessed 6/21/05.
- 2 Physician Insurer's Association of America (PIAA). Enduring Material of Acute Myocardial Infarction Claims. Rockville (MD): Physician Insurers Association of America; 1999.
- 3 Sheifer SE, et al. Unrecognized myocardial infarction. *Ann Intern Med* Nov 6, 2006;135:801-11.
- 4 Chesebro JH. Acute coronary syndromes: pathogenesis, acute diagnosis with risk stratification, and treatment. *Am Heart Hosp J*. 2004 Fall;2(4 Suppl 1):21-30.
- 5 American College of Emergency Physicians. Clinical Policy: Critical Issues in the Evaluation and Management of Adult Patients Presenting with Suspected Acute Myocardial Infarction or Unstable Angina.
- 6 American College of Cardiology (ACC) Position Statement. Approaches to the Early Triage of Patients with Chest Discomfort. Available at: www.acc.org/clinical/position/72511.htm. Accessed: 1/20/05.
- 7 ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction: Implications for Emergency Department Practice. Available at: www.americanheart.org. Accessed: 6/3/05.
- 8 ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction. Available at: www.americanheart.org. Accessed: 6/3/05.

* The following books can assist physician practices in establishing telephone protocols: Katz, Harvey P. Telephone Medicine. 2nd edition. FA Davis Company, 2001, and Briggs, Julie. Telephone Triage Protocols for Nurses. 2nd edition, Lippincott, 2002.

NORCAL *Claims Rx* Editorial Board

Editors

Jane Mock
Risk Management Analyst, NORCAL

Jo Townson
Risk Management Analyst, NORCAL

Content Advisors

James R. McFarland, MD
Vice Chairman, NORCAL
Board of Directors

David R. Holley, MD
Secretary/Treasurer, NORCAL
Board of Directors

Harry B. Richardson, Jr., MD
NORCAL Board of Directors

William R. Vetter, MD
NORCAL Board of Directors

Michael Stephens
NORCAL Board of Directors

Newell E. Warde, PhD
NORCAL Board Advisory Council
Executive Director,
Rhode Island Medical Society

James Sunseri
President & CEO, NORCAL

Stephen M. Farber
Vice President, Risk Management, NORCAL

Margaret D. Ramirez, MPA, ARM
Manager, Risk Management, NORCAL

Kathy Swanson, MS, RN
Manager, Risk Management, NORCAL

NORCAL Risk Management Specialists

Barbara Halliday, CPCU
Supervisor, Claims Department, NORCAL

Neil Simons
Director, Underwriting Operations, NORCAL

Jane Tishkoff, Esq.
Associate Vice President and
Assistant General Counsel, NORCAL

Copyright © 2005 NORCAL Mutual Insurance Company.
Reproduction permissible with written permission and credit.

Direct inquiries to:

NORCAL Mutual Insurance Company
Risk Management Department
560 Davis Street, 2nd Floor
San Francisco, CA 94111-1902
(800) 652-1051

The information in this newsletter is obtained from sources generally considered to be reliable; however, accuracy and completeness are not guaranteed. The information is intended as risk management advice. It does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about topics covered in this newsletter should be directed to your attorney.

Guidelines and/or recommendations contained in this publication are not intended to determine the standard of care, but are provided as risk management advice. Guidelines presented should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of the individual circumstances presented by the patient.

Visit NORCAL Mutual on the Internet at
www.norcalmutual.com.

385g-RM

PRESORTED
FIRST CLASS
U.S. POSTAGE
PAID
PERMIT 2325
SAN DIEGO, CA

 **NORCAL**
Mutual Insurance Company
Risk Management Department
560 Davis Street
San Francisco, CA 94111-1902