



**National Heart Attack Alert Program
Coordinating Committee
and Subcommittees**

**MEETING
SUMMARY
REPORTS**

**October 28–29, 2002
Bethesda, Maryland**



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**NATIONAL HEART ATTACK ALERT PROGRAM (NHAAP)
COORDINATING COMMITTEE MEETING**

**October 28-29, 2002
Bethesda, Maryland**

HIGHLIGHTS

- Dr. Stephen Cantrill was welcomed to the Coordinating Committee as the new representative of the American College of Emergency Physicians. Dr. Cantrill is Associate Director of the Department of Emergency Medicine at the Denver Health Medical Center and an assistant professor in the Division of Emergency Medicine, Department of Surgery, at the University of Colorado Health Sciences Center. He succeeds Dr. Mark Smith.
- The following substitutes were welcomed to the meeting:
 - Ms. Kemlee White of the American Association of Occupational Health Nurses
 - Ms. Pat Bonifer-Tiedt of the American Red Cross
 - Mr. Jonathan Moore of the International Association of Firefighters
- Dr. James Atkins reported that the Executive Committee reviewed the activities of the *Act in Time to Heart Attack Signs* and discussed pursuing further such issues as the identification of prodromal symptoms, the appropriate timeline between symptom recognition and treatment, and quality assurance initiatives through the collection of additional information and discussion with appropriate experts.
- The chairs of the Education, Health Systems, and Science Base Subcommittees reported on their activities and plans.
- Dr. Gerald DeVaughn gave a presentation on the activities and programs of the National Cardiovascular Health Conference entitled *Cardiovascular Health for All*, held April 11 to 13 in Washington, DC.
- Ms. Mary Hand reminded participants that Drs. Atkins and Joseph Ornato both made presentations at this conference and that these presentations were Webcast. She urged participants to view these Webcasts on the Program's Web site.
- Ms. Terry Long, Senior Manager for Communications of the National Heart, Lung, and Blood Institute's (NHLBI) Office of Prevention, Education, and Control (OPEC), reviewed the media activities that were conducted in conjunction with the above-mentioned conference.
- Mr. Alan Mertz, Executive Vice President of the Healthcare Leadership Council and Chairman of the Confidentiality Coalition, reviewed the ramifications of the new Health Insurance Portability and Accountability Act (HIPAA) regulations.

- Dr. Jeanette Guyton-Krishnan, a Public Health Analyst in the NHLBI's OPEC, provided an update of data sources related to NHAAP-relevant Healthy People 2010 data sources.
- Dr. Wayne Giles of the Centers for Disease Control and Prevention discussed a baseline data report relevant to one of the pertinent Healthy People 2010 objectives.
- Ms. Long discussed the progress of the *Act in Time to Heart Attack Signs* social marketing campaign and reviewed its various products and activities and the response to them.
- Ms. Pat Bonifer-Tiedt, Director of Research and Product Development for Health, Safety, and Community Services of the American Red Cross, updated the Committee on activities conducted by the American Red Cross in support of the campaign. These activities include placing materials on the national Web site, providing materials for newsletters, providing the NHLBI with mailing labels so that kits could be mailed to every Red Cross chapter in the country, incorporating *Act in Time to Heart Attack Signs* messages and products into another cardiovascular health training program, and developing complementary materials for Spanish-speaking audiences.
- Ms. Eva Grace, Project Coordinator for the American College of Cardiology's Emergency Cardiac Care committee, reported that an *Act in Time to Heart Attack Signs* section was prepared for the organization's Web site, including the NHLBI contact information and an article prepared for the e-newsletter. A short news article on *Act in Time to Heart Attack Signs* was placed at the centerfold of *Cardiology*, the monthly periodical.
- Dr. Lee Garvey, Society of Chest Pain Centers and Providers, reported that materials have been sent to all Society members in the past 6 months, as well as new members planning chest pain centers in their institutions. In addition, the Society has launched a local, community-focused initiative in Charlotte to spread the news about *Act in Time to Heart Attack Signs*.
- Dr. George Sopko of the NHLBI reviewed the recommendations that resulted from an NHLBI workshop conducted earlier in the month on Women's Ischemic Syndrome Evaluation (WISE).
- Dr. Harry Selker of the Society of General Internal Medicine discussed the recommendations that resulted from the NHLBI WISE workshop where he addressed "Key Messages About Symptoms of Acute Ischemic Heart Disease (IHD) in Women and Recommendations for Practice."
- Dr. Robert Zalenski of the Society for Academic Emergency Medicine made a presentation entitled "When the Family Becomes the Patient: Caring for Survivors of Patients Who Have Sudden Death from Cardiovascular Causes."
- Dr. Daniel Stryer of the Agency for Health Care Research and Quality called the Committee's attention to a series of articles on the Cardiac Arrhythmia Management

Patient Outcomes Research Team (PORT-II) that appeared in the September issue of the *American Heart Journal*.

- Mr. David Bryson of the National Highway Transportation Safety Administration reported on the National Emergency Medical Services (EMS) Research Agenda meeting that was held in June.
- Ms. Hand asked participants if they would like to pursue electronic registration for future meetings, and the majority of members agreed. She then thanked participants for attending and adjourned the meeting.



National Heart Attack Alert Program

Coordinating Committee Meeting

**October 28–29, 2002
Bethesda, Maryland**

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)
NATIONAL HEART ATTACK ALERT PROGRAM (NHAAP)
COORDINATING COMMITTEE MEETING**

**Meeting Summary
October 29, 2002**

WELCOME AND INTRODUCTIONS [Ms. Mary Hand]

Ms. Hand welcomed the Committee members and acknowledged Dr. James Atkins, Chair of the National Heart Attack Alert Program (NHAAP) Coordinating Committee, to her right and Dr. George Sopko, a medical officer with the Cardiovascular Medicine Section of the Division of Heart and Vascular Diseases at the National Heart, Lung, and Blood Institute (NHLBI) and an advisor to the Committee, to her left.

Ms. Hand welcomed a new member to the Committee, Dr. Stephen Cantrill. Dr. Cantrill represents the American College of Emergency Physicians. He is currently Associate Director of the Department of Emergency Medicine at the Denver Health Medical Center in Denver, CO, and an associate professor in the Division of Emergency Medicine of the Department of Surgery at the University of Colorado Health Sciences Center. Like his predecessor on the Committee, Dr. Mark Smith, one of Dr. Cantrill's interests is in the area of information technology as applied to improving medical practices.

Ms. Hand then introduced substitutes for several organizations: Ms. Kemlee White, representing the American Association of Occupational Health Nurses; Ms. Pat Bonifer-Tiedt, Director of Research and Product Development at the Health, Safety, and Community Services division of the American Red Cross (ARC); and Mr. Jonathan Moore, representing the International Association of Firefighters.

Ms. Hand offered her appreciation for the members' attendance at the meeting. The focus of the NHAAP is the early recognition and treatment of patients with acute coronary syndromes (ACS), including sudden cardiac arrest. The American Heart Association (AHA) estimates that an American citizen suffers a coronary event every 29 seconds, and a death from coronary disease occurs every minute. Cardiovascular disease remains the number one cause of death in the United States. Much work remains in the in the area of educating the public and health care providers about the availability and benefits of early treatment for heart disease.

Ms. Hand explained that this meeting will include highlights from the National Cardiovascular Health Conference, which took place in April 2002; an overview of the Health Insurance Portability and Accountability Act (HIPAA) and its implications for health care systems and the management of patients with ACS; an update of the Healthy People 2010 program objectives for the Nation as related to heart attack alert issues; a progress report on the *Act in Time to Heart Attack Signs* campaign; a report from an NHLBI workshop on the manifestation and detection of acute and chronic coronary heart disease (CHD) in women; and reports from several committee members with information from their organizations.

Ms. Hand reviewed the contents of the agenda folder. Included were the Subcommittee priority areas for the next 5 years; two versions of a *Circulation* 2002 article by Dr. Richard Gillum on emergency department (ED) and hospital preventive care of elderly next-of-kin of victims of sudden cardiac death and fatal acute myocardial infarction (AMI); a listing of the Agency for Healthcare Research Quality (AHRQ) Sudden Death Patient Outcomes Research Team journal articles to be discussed by Dr. Daniel Stryer; a copy of the October *ComCare Insider* newsletter, which includes an article on communications for coordinated assistance and response to emergencies; a paper published in the April 2002 issue of the *American Heart Journal* by the Coordinating Committee Writing Group entitled “Critical Pathways for Management of Patients With Acute Coronary Syndromes: An Assessment by the National Heart Attack Alert Program”; the *ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction*; a copy of an adult clinical cardiology self-assessment program that provides an overview of current myocardial infarction (MI) fundamentals; and a Centers for Disease Control and Prevention (CDC) *Morbidity and Mortality Weekly Report (MMWR)* on “State-Specific Mortality From Sudden Cardiac Death—United States, 1999.” Dr. Wayne Giles, the CDC representative to the Committee, was instrumental in the writing of this report.

EXECUTIVE COMMITTEE REPORT [Dr. James Atkins]

Dr. Atkins reported on the morning’s Executive Committee meeting. Dr. Atkins then invited Ms. Hand to the podium and presented her with an award from the Coordinating Committee. Normally, awards are presented at the 10-year retreat meeting, but Ms. Hand had not been with the Committee for 10 years at the time of the 10-year meeting held in June 2001. (She had served 9 years and 10 months.) The Executive Committee voted to present her with an award at today’s meeting, which included a plaque engraved with the words: *Presented to Mary Hand in appreciation of uncompromising professionalism, dedication to the National Heart Attack Alert Program, infectious enthusiasm, and enduring friendship, National Coordinating Committee, October 2002.* Dr. Atkins also stated that \$250 would be donated to a charity of Ms. Hand’s choice.

SUBCOMMITTEE REPORTS

Education Subcommittee [Dr. Christine Crumlish]

Dr. Crumlish presented the Education Subcommittee report. A description of the Subcommittee’s priority areas were included in the meeting packet. Dr. Crumlish reviewed the progress that had been made on the first priority area, dissemination and implementation of the NHAAP’s “Act in Time to Heart Attack Signs” campaign. The AHA is working to integrate the *Act in Time* materials and activities into its Operation Heartbeat sites nationally. The National Council on the Aging has promoted *Act in Time* on its Web site and has provided information on this program to all of its chapter organizations. Since last February, more than 700 Web links to the *Act in Time* Web site have been instituted by various organizations. Dr. Charles Curry, the National Medical Association representative to the Committee, participated in a satellite media tour promoting *Act in Time*, and multiple organizations have provided the *Act in Time* marketing flyer either in preconference or conference packets. Finally, many organizations have included information about the *Act in Time* campaign in their newsletters.

A second dissemination goal was to contact more than 100,000 health care professionals and program managers. This goal has been exceeded—117,567 contacts have been made, including office-based cardiologists, patient educators in physician’s offices, home health care managers, hospital-based educators, senior adult health specialists, community-health workers, health educators, and managed care organization managers. Information also has been provided to specialty groups, specifically through the Association of Women’s Health, Obstetric and Neonatal Nurses. The obstetrician/gynecologist (OB/GYN) group was targeted because OB/GYNs are, for many women, the primary health care point of contact. Representatives of *Act in Time* have met or spoken with 185 editors of key specialty journals and trade publications, and articles have been published on a space-available basis. The 2,246 members of the American Association of Cardiovascular and Pulmonary Rehabilitation Specialists were contacted by direct mail, in addition to postings on their Web site and the distribution of conference information. Direct mail also was used to reach 12,599 employers and managers of employee health promotion programs. The American Association of Occupational Health Nurses published an *Act in Time* article in its newsletter and republished it on its Web site. Finally, a partnership has been established with Corporate Fitness Works, a health management company for corporations such as Sprint and Aetna, to distribute materials at the fitness centers they manage for more than a quarter of a million employees nationwide.

In summary, more than a quarter of a million *Act in Time* educational materials have been distributed. These include 3,700 Small Group Session kits that are used for group education sessions. There have been more than 4,000 downloads of *Act in Time* materials for Palm operating systems (OS). Additionally, the *Act in Time* campaign won seven major awards in this time period. Three additional educational materials are under development: a small group kit in Spanish, an easy-to-read brochure, and a new women’s brochure.

Dr. Crumlish emphasized that it is critical to keep track of the dissemination activities. Mr. Win Morgan of Prospect Associates, Ltd., is maintaining a database recording all of the dissemination efforts. All involved organizations should update Mr. Morgan or Ms. Hand regarding their *Act in Time* efforts.

The second priority area, informatics, will be addressed at an NHAAP Coordinating Committee meeting planned for February 2004. The third priority area—approaches to reducing treatment-seeking delay for patients with acute cardiovascular disease—is the topic of a forthcoming paper from the AHA Writing Group, chaired by Drs. Debra Moser and Laura Kimbell.

Health Systems Subcommittee [Dr. Bruce MacLeod]

Dr. MacLeod reviewed the activities of the Health Systems Subcommittee meeting. He reported that the meeting began with a discussion by Mr. Alan Mertz of the possible effects of the implementation of HIPAA on access to care for patients. He noted that Mr. Mertz would provide this and additional information during the course of the full meeting.

The Subcommittee next discussed priority areas. Working groups were organized around three topics. The first group will use the Rapid Early Action for Coronary Treatment (REACT) data to examine the optimal use and underuse of Emergency Medical Services (EMS). A second

group, led by Dr. Mary Beth Michos, will organize a stakeholders' meeting to investigate strategies to improve EMS response for cardiac care patients. A third group will identify technologies and strategies that have a strong evidence base for use in the field but are underutilized by providers. The Subcommittee discussed the challenges of implementing individual and organizational behavior change in relation to translating scientific information into action.

Dr. Robert Christenson made a presentation on the CRUSADE program, which is attempting to answer the following question: Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes With Early Implementation of American College of Cardiology (ACC)/AHA Guidelines? CRUSADE is a quality-improvement initiative that is currently operating in 400 sites across the country. The goal of the program is to provide feedback to practitioners related to their care of patients with non-ST segment-elevation MI, including unstable angina. The program facilitates cooperation between ED physicians and cardiologists.

Lastly, the Subcommittee discussed whether the use of regulatory or credentialing assessments would aid in quality improvement for health systems or practitioners. Several members of the Committee have had discussions with officials at the National Committee for Quality Assurance (NCQA) concerning variables that might be included in the NCQA dataset in order to ascertain quality control in health systems. These discussions are continuing. Dr. MacLeod asked whether any organizations represented on the full Coordinating Committee had experience with regulatory or credentialing agencies that might include AMI or ACS variables in their evaluation dataset. He said that the input of those organizations would be appreciated.

Science Base Subcommittee [Dr. Joseph Ornato]

Dr. Ornato presented an overview of the Science Base Subcommittee's activities. He reported that four major areas were discussed during the Subcommittee meeting. First, priority areas were reviewed. Then, the in-progress work on ACC/AHA guidelines for ST-elevation MI was presented via conference call by Dr. Elliot Antman, who chairs the committee that is in the process of rewriting these guidelines. Dr. Antman's chief issue for the Subcommittee's input was the time-to-treatment recommendations for the initiation of reperfusion treatment—time-to-thrombolytic therapy and time-to-percutaneous coronary intervention (PCI) in patients who are being treated clinically with either of these modalities. The ACC/AHA committee members realized the importance of starting the time-to-treatment clock with the onset of patient symptoms, rather than patient presentation to medical care. It was understood that this presents an incredible challenge to the health care system to rapidly deliver treatment; it is acknowledged that most of the delay still lies in the hands of the patient.

Dr. Antman described the working diagram that the task force developed. After symptom onset and then medical contact occur, the medical caregiver must make a clinical judgment as to whether to route the patient to thrombolytic therapy or PCI. In addition to the patient's medical situation, factors that affect this decision include a perceived unavailability of PCI, a delay to PCI, or the possibility of routing the patient to primary angioplasty and coronary intervention. The task force's current thinking is to recommend a 60-minute timeline from

symptom onset to initiation of thrombolytic therapy for patients who are to be treated primarily with thrombolytics. This figure is consistent with the NHAAP's 60-minute-to-treatment recommendations of almost a decade ago. The goal for PCI therapy was set at 90 minutes from symptom onset to treatment. The task force recognizes that neither of these goals is likely to be attained by any health care system in the United States under current conditions. However, the original 60-minute goal was pivotal in increasing the awareness of hospitals of the importance of time. In essence, this resulted in a 30-minute challenge for door-to-needle time or door-to-drug time, and many hospitals have either attained this goal or are close to the 35- to 38-minute mark. The Subcommittee invited Committee members to submit their comments or suggestions regarding the guidelines.

Next, Dr. Christenson reported on a workshop that he attended, on behalf of the NHAAP, concerning the new definition of AMI. The last major item was a presentation by Dr. Christenson on the use of the REACT database to explore a variety of hypotheses relating to prodromal symptoms. In response to the issues raised by this presentation, the Subcommittee recommended that the NHAAP request funding for a workshop or literature review on the topic of prodromal symptoms.

Dr. Ornato invited questions and comments from the full Committee. Dr. Selker stated that as the medical community moves towards trying to get people with potential acute coronary syndromes to the hospital within 60 minutes, a laboratory test that successfully differentiates presenting individuals is in development. The ideal test will be highly specific, highly sensitive, inexpensive, and able to be administered by individuals with a lower level of training. This will be a difficult challenge.

Dr. Curry requested input from the participants concerning the impact of the troponin test on the frequency of diagnosis of MI. The use of increasingly sensitive troponin tests has resulted in a significant increase in the number of MIs diagnosed each year. Previously, these patients would have been diagnosed with angina. It is important to determine how statisticians and epidemiologists will deal with this issue.

Dr. Wayne Giles responded that specific studies that look at the exact criteria used to make a diagnosis are needed to differentiate the additional cases. He agreed that the issue adds another layer of difficulty to the interpretation of MI statistics. Additionally, when looking at heart disease, it may be necessary to consider broader coronary categories, such as International Classification of Diseases (ICD) 410 to 414, as opposed to more specific codes, for example *AMI*. The broader categories will not be affected by troponin results.

Dr. Ornato responded that since the MI/troponin redefinition occurred, it appears that individuals responsible for hospital coding are looking carefully for troponin elevation. When this situation was examined more closely, it was discovered that many sick people who have sepsis, trauma, and other conditions that also cause small elevations in troponin are given a diagnosis of (among other conditions) MI (even if they do not have a history of heart disease) when they die; such a diagnosis artificially elevates statistics. Therefore, the epidemiological consequences of the revision of troponin figures have produced results that were not anticipated initially.

Dr. Giles noted that another area in question is the cut line between unstable angina and non-ST-elevation MI. A point can be selected arbitrarily for epidemiological purposes, but this will not always constitute a definition of the patient's clinical condition. Dr. Daniel Stryer expressed his concern that the coders appear to be defining MIs based solely on troponin levels. The new definition is a medical record diagnosis of MI, not just a laboratory diagnosis, and involves inclusion of a clinical picture of an MI.

Dr. Ornato agreed that elevated troponin levels often are associated with coexisting morbidity and mortality in elderly patients, complicating epidemiological evaluation. Dr. Christenson suggested that an NHAAP statement be issued to the effect that the MI diagnosis is dependent on troponin levels existing in the context of acute cardiac ischemia. Dr. George Sopko added that Dr. Fred Apple in Minneapolis is conducting a study, funded by the NHLBI, to review more than a thousand AMI cases. The study will focus on troponin specificity and sensitivity, as well as on gender and race differences. Some aspects of what the Committee is discussing today may be clarified by the results of this study, which should be completed shortly.

Dr. Selker recalled that the NHAAP's original focus was on AMI, which was expanded to include unstable angina. Now, the use of a new assay is complicating diagnosis. It was suggested that this Committee recommend that there be a subcategory in the coding procedures for nonspecific elevation of troponin due to medical causes other than MI, as opposed to including it in the MI category. This would avoid artificial elevation of reported cardiac deaths.

NATIONAL CARDIOVASCULAR HEALTH CONFERENCE REPORT [Dr. Gerald DeVaughn]

Ms. Hand introduced Dr. Gerald DeVaughn, who represents the Association of Black Cardiologists on the NHAAP Coordinating Committee. He also served as the NHAAP's representative to the National Cardiovascular Health Conference Planning Committee. That conference, titled "Cardiovascular Health for All," was held on April 11–13, 2002, in Washington, DC.

Dr. DeVaughn presented a report on this conference (see slides in Attachment C). The attendance at this conference was 1,200; however, many attendees represented larger organizations, so the impact of the conference should be more robust than it was originally thought to be. The purpose of the conference was to address the cardiovascular challenges set forth in Healthy People 2010. The overarching goal of this campaign is to increase the quality and quantity of years of life.

Dr. DeVaughn noted that Dr. Lynn Smaha opened the conference with a discussion of the changes in life expectancy over the last century. The life expectancy of a boy born in 1900 was 47 years, while a boy born in 2000 has a life expectancy of 74 years. This change can be attributed to many advances made in the 20th century related to treating infections. The challenge for the 21st century is addressing cardiovascular disease. It was recognized many organizations around the country are dealing with matters of cardiovascular health, but redundancy exists, and many organizations do not work together. According to Dr. DeVaughn, it was Dr. Smaha's view that collaboration should be fostered among these groups. In fact, one purpose of the conference was to encourage interaction and networking among the participants.

A critical area of needed improvement in cardiovascular health is a lack of compliance with recognized guidelines by practitioners. A review of discharge summaries for patients admitted with cardiovascular disease (CVD) found that compliance with prescribing aspirin is 78 percent, compliance with angiotensin-converting enzyme inhibitors is 59 percent, compliance with thrombolytic therapy is 67 percent, compliance with beta blockers is 49 percent, and compliance with recommendations to quit smoking is about 40 percent. This offers a tremendous opportunity in the field of CVD to increase compliance and make a long-term impact on outcomes.

The goals for CVD and stroke in the Healthy People 2010 program include:

- Preventing the development of risk factors
- Detecting and treating risk factors
- Recognizing early indications of ACS and stroke
- Preventing recurrence of CVD

In 2002, virtually all Americans will have had their blood pressure checked at least once during the year. In the last decade, one improvement was that the mean blood pressure dropped by 10 mmHg. However, the Healthy People 2010 objective has not been met yet. In fact, 50 percent of Americans today still have uncontrolled high blood pressure.

Another factor that is adversely affecting the cardiovascular health of the Nation's population is obesity. Since 1980, the prevalence of obesity has doubled in adults and has tripled in young children and adolescents. Obesity is approaching tobacco as the leading cause of preventable cardiovascular death. Proposed initiatives in the area of obesity include requiring physical education in all school grades and providing safe and accessible recreation facilities for all age levels.

Drs. Atkins and Ornato of the Committee participated in the National Cardiovascular Health 2002 Conference. Dr. DeVaughn reported that Dr. Atkins spoke on a new agent for the treatment of myocardial salvage. This agent is effective, inexpensive, and able to decrease infarction size by 56 percent and mortality by 86 percent. This new agent is time. The effect of time on myocardial salvation is well known to the Coordinating Committee. The greatest benefit is in the first 2 or 3 hours, particularly in the first hour. Dr. Atkins reinforced his argument with results from the Myocardial Infarction Treatment and Intervention Project (MITI) trial. Patients treated with thrombolytic therapy at the hospital within 70 minutes of symptom onset had infarct sizes of 4.9 percent and a 30-day mortality of 1.2 percent. Patients treated more than 70 minutes from onset of symptoms had infarct sizes of 7.2 percent and a 30-day mortality rate of 8.7 percent. Dr. Atkins also discussed the NHAAP, informing the audience that the Program was created by the NHLBI to address the effectiveness of dealing with patients with AMI. Dr. Atkins proposed several action steps:

- Developing a system to improve message delivery to at-risk groups, minorities, and the elderly
- Educating patients about what to do if they have symptoms
- Developing action plans with patients
- Developing community planning

Next, Dr. DeVaughn reported that Dr. Ornato spoke about the challenges of dealing with patients with ACS in a prehospital environment. He noted that two-thirds of patients presenting to the ED with chest pain are admitted; however, only 15 percent of these patients have MIs, and another 15 percent have ACS. This results in an unnecessary 600,000 admissions to the Nation's hospitals each year.

One cause of this problem is ambulance avoidance. Only 50 percent of patients presenting to hospitals with chest pain arrive via EMS. Dr. Ornato informed the Committee about an initiative in Richmond—the Vertically Integrated Chest Pain Program. In this program, ambulances are placed throughout the city of Richmond with their locations periodically changed in response to historical data about the need for ambulance service. EMS technicians are equipped with chest pain protocols. However, despite the sophistication of this program, patient outcomes have not changed significantly.

Dr. Ornato also spoke about new technology, including the 80-Lead Body Map. This device is able to diagnose AMIs with a greater degree of sensitivity and ease of interpretation, particularly in the field, and possibly even in the home environment. Dr. Ornato noted that the current EMS is not optimally configured to meet the needs of chest pain patients, although the technology does exist to better respond to patient's needs in the outpatient setting.

Finally, Dr. DeVaughn highlighted several other sessions relevant to the NHAAP's issues: Dr. John Finnegan, Jr., and Ms. Terry Long presented and discussed the REACT trial, and the resulting "Act in Time to Heart Attack" campaign, which was well received. Dr. Christenson made a presentation on the new definition of MI, and Dr. Kathleen Dracup talked about some of the behavioral ramifications of patients being told they have sustained an MI, based on troponin elevations. Dr. Raymond Bahr and Dr. Jean McSweeney talked about catching patients further upstream, notably through prodromal recognition of patients with ACS.

Dr. DeVaughn concluded by noting that extensive information regarding the conference, including a Webcast, is available at <http://hp2010.nhlbihin.net/cvh2002>. Information concerning Healthy People 2010 is available also on the Web site.

MEDIA EVENTS RELATED TO THE NHAAP [Ms. Terry Long]

Ms. Hand introduced Ms. Terry Long, Communications Director for the NHLBI, to describe the media events related to the NHAAP that took place in conjunction with the National Cardiovascular Health 2002 Conference (see slides in Attachment D). She encouraged the Committee members to view the archived Webcasts of the conference presentations that are available on the conference Web site.

Ms. Long noted that the NHAAP tried to stimulate and plan for media coverage at all of the organizations' national meetings. Coverage was particularly successful at this conference because of the high interest in presentations on heart attack. Dr. Ornato's presentation was of tremendous interest to the media. The story was covered by the Associated Press, which translated into newspaper coverage throughout the United States. The television coverage alone resulted in about 6.4 million media impressions (a measurement of aggregate viewership of all of the television stations).

Dr. Jean McSweeney's presentation also received significant attention. She presented preliminary data on heart attack symptoms in women; these data suggest that women may experience symptoms even 6 months before a heart attack. She also presented data comparing symptoms between African-American and Caucasian women that were of tremendous interest to the media. The Associated Press and various television outlets picked up this story as well, and the television coverage was estimated to have resulted in 14.5 million media impressions. The conference generated additional coverage for African-American media outreach for *Act in Time to Heart Attack Signs*.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT **[Ms. Hand]**

Ms. Hand reported that at the 10-year NHAAP Coordinating Committee Meeting, there was an interest in examining the implications of HIPAA on health care systems and the management of patients with ACS. This issue is a part of the Health Systems Subcommittee's 10-year objectives but is a crosscutting issue as well. Ms. Hand introduced Mr. Alan Mertz, Executive Vice President of the Healthcare Leadership Council (HLC), an association representing 50 chief executives from the leading health care companies and institutions in the United States. In this role, Mr. Mertz chairs the Confidentiality Coalition, a group of 130 organizations working toward the goal of workable medical privacy laws and rules. As chair of the coalition, he led the successful 4-year campaign to fix serious problems with the HIPAA privacy rules, culminating in workable regulations that were issued in August 2002. Mr. Mertz is a recognized expert and speaker on HIPAA, medical privacy, and other health care issues.

Mr. Mertz discussed the 4-year process that resulted in the recent revisions to the privacy regulations of HIPAA (see slides in Attachment E). The original 1996 HIPAA legislation was not intended to address privacy but instead dealt with portability of insurance and antidiscrimination. The portability provisions of the bill originated in the Senate. The House of Representatives wanted input on the bill and suggested an initiative to simplify health care administration with standardized claim forms and electronic transmission of claims. The privacy provision related to this was meant to protect patients from privacy violations resulting from greater electronic transmission of data. Congress gave the Department of Health and Human Services (HHS) the right to issue regulations to this effect if Congress did not act within 3 years (which it did not). The HHS initiated the formation of the regulations in 1999. In April 2001, the regulations became effective. Modifications were proposed in March 2002, and the final rule was issued in August 2002. The deadline for compliance is April 14, 2003.

All persons who deal with identifiable health information are covered by these regulations. The law identifies three entities: health plans, providers, and clearinghouses. Only these three entities can actually be penalized for infractions (up to \$250,000 and 10 years in jail). The information covered by the regulations includes 18 identified characteristics considered personally identifiable. Any one of these items causes information to fall under the privacy rule. The bill is supposed to apply to electronically transmitted information, but there is a very broad definition of such information: virtually all paper records and even oral communications are covered.

The exact wording of the rule is, “A covered entity may not use or disclose protected health information, except as permitted or required by [this rule].” Therefore, the rule essentially states that every use and disclosure of health care information would be prohibited unless it was listed specifically in the HIPAA regulations. Two approaches to the construction of the rule were possible. The first option would have exempted activities considered under the umbrella term “health care operations” from regulation under this legislation. The second option was that every use and disclosure of health care information would be prohibited unless it was specifically listed in the HIPAA regulations. This more exclusionary option was adopted by the HHS, resulting in a 366,000-word document of allowable disclosure situations.

Key requirements included the provision that if the provider was going to use the information for treatment, payment, or health care operations, the prior consent of the patient was required. This approach was actually tested for 12 days in Maine in 1999 and resulted in the repeal of emergency legislation because it was found to be unworkable. However, the HHS based its 2000 regulations on the failed system from Maine.

It took nearly 2 years to apply hard-won modifications to the exclusionary options. It is now optional for providers to obtain consent. This has resulted in more reasonable criteria: health providers are now allowed to share information with other providers and pharmacists without obtaining prior consent. Any disclosure outside of the regulations requires authorization, and a record must be kept of the disclosures. Providers have to give a notice of privacy practices to patients and must make a good-faith effort to receive an acknowledgement from the patient that the privacy papers have reached their destination.

Some good faith exceptions in emergency situations are allowed. A “minimum necessary clause” states that providers must use the minimum amount of information necessary to provide adequate care. Finally, patients must have access to their own records, similar to what most State laws require. The actual consent form is nine pages long.

The HHS has identified a category of physician contacts called “business associates,” which includes any individual hired by a provider to perform a function on his/her behalf. The provider is responsible for the use of identifiable information by the business associates. Providers must have a legal contract with each associate, and they are liable for any penalties incurred because of business associates’ use of identifiable information.

Special rules for disclosure of research have been written. Research is defined as “a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.” If information is being used in this manner, the prior authorization of the patient is required, unless waived by an institutional review board (IRB). Requirements for an IRB waiver include:

- Minimal risk to privacy
- Adequate plan to protect the information
- Destruction of identifiers following completion of research
- No reuse or disclosure to others after research completion
- Impossibility of the research without that information

Records must be kept for all IRB waivers. However, if the information can be de-identified, prior authorization is not required.

Patient registries specifically are allowed to include identifiable disclosures without prior authorization if they are mandated or required by law or by the Food and Drug Administration (FDA). Registries that are required for public health reporting, such as to the CDC, are allowed. However, any private registry will require informed consent and will fall under the above-mentioned IRB waiver requirements.

Any kind of reporting to a Government body (i.e., to the CDC or a public health department) is a permissible disclosure. Also, any information that has to do with outcomes, epidemiology, or disease tracking is exempt, and any voluntary reporting of adverse events resulting from any kind of device or pharmaceutical product or equipment is allowed. The original regulation stated that information could only be disclosed to the manufacturer if it was mandated or required by the FDA. Since adverse event reporting is generally voluntary, the regulation was changed for this situation. Hospitals may share identifiable information for quality assessment-improvement activities (a type of outcomes research), but not for generalizable knowledge. Any kind of law enforcement reporting or disclosure is allowed, but it is advisable for providers to keep accurate records of these disclosures.

Many improvements have been made to the rules, but they are very fluid and political. Major areas of concern are prior consent, the ability to deidentify information and use it in research without authorization, and the voluntary reporting by providers to manufacturers about adverse events. Also, marketing—originally considered any exchange with a patient, even giving the patient a free drug sample—would have required prior authorization. This provision was revised, and providers can now communicate with patients concerning different treatments, refill reminders, and so forth.

Mr. Mertz concluded by noting that forces in Congress favor a return to the original consent requirement format, and it is always possible that the HHS could change the regulation in any particular year. Bills have been introduced in Congress to reverse these clauses, although they have not been passed. The rules will need constant attention to avoid reversal.

HEALTHY PEOPLE 2010 OBJECTIVES [Dr. Jeanette Guyton-Krishnan]

Ms. Hand introduced Dr. Jeanette Guyton-Krishnan, a public health analyst in the Office of Prevention, Education, and Control, NHLBI. Dr. Guyton-Krishnan presented an update on data sources related to the U.S. Public Health Service's Healthy People 2010 NHAAP-related objectives for the Nation (see slides in Attachment F).

Dr. Guyton-Krishnan stated that within the Healthy People 2010 agenda, 467 objectives address issues focusing on diseases, conditions, behavior, and the environment. Heart disease and stroke are one focus area and include developmental objectives for which current data are not available but are in development.

The first NHAAP-specific objective, 12.2, focuses on the awareness of the early warning symptoms and signs of a heart attack and the importance of calling 9-1-1. The data source for

this objective was the 2001 National Health Interview Survey (NHIS), for which data collection is complete. This objective addresses two questions:

- Which of the following would you say were the symptoms that someone may be having a heart attack?
 - Pain or discomfort in the jaw, neck, or back
 - Feeling weak, lightheaded, or faint
 - Chest pain or discomfort
 - Pain or discomfort in the arms or shoulders
 - Shortness of breath

- If you thought someone was having a heart attack, what is the BEST thing to do right away?
 - Advise them to drive to the hospital
 - Advise them to call their physician
 - Call 9-1-1 (or another emergency number)
 - Call spouse or family member
 - Other

The next objective, 12.3, focuses on increasing the proportion of eligible heart attack patients who receive artery-opening therapy within an hour of symptom onset. The dataset for this objective is the National Registry of MI (NRMI) supported by private industry. Dr. Guyton-Krishnan did not have an update on the data collection for this objective.

The next objective, 12.4, deals with increasing the proportion of adults aged 20 years or older who call 9-1-1 and administer cardiopulmonary resuscitation (CPR) when they witness an out-of-hospital cardiac arrest. The data source also is the 2001 NHIS. The questions asked under this objective are:

- Have you ever received formal training or certification in CPR for adults?
 - If yes, how long ago?
 - ▶ 1 year or less
 - ▶ More than 1 year, not more than 2 years
 - ▶ More than 2 years, not more than 5 years
 - ▶ More than 5 years

The last objective, 12.5, pertains to the proportion of eligible persons with witnessed out-of-hospital cardiac arrest who receive their first therapeutic electrical shock within 6 minutes after collapse recognition.

Dr. Guyton-Krishnan concluded by summarizing the status of the NHAAP-related NHIS data. In 2000, the above-listed objectives were drafted and finalized. In 2001, census personnel went into the field with these questions, using the Computer-Assisted Personal Interview (CAPI). At the present time, the data are being processed at the National Center for Health Statistics (NCHS). Baseline data should be available by December 2002.

Mr. Jimm Murray observed that the questions related to objective 12.4 would not in fact answer this objective. Dr. Guyton-Krishnan replied that in some cases, information from other portions of the survey was used to augment questions and complete the analysis; this may be the case with objective 12.4. Dr. Giles stated that an additional problem with survey questions was related to the number of people who have been trained in CPR, witnessed an arrest, and administered CPR, which was very low and got proportionally lower with each level of the question. Multiple-year aggregate data will be needed if this information is to be provided from surveys.

Ms. Hand asked Dr. Giles to discuss a baseline report related to one of the objectives that will be published in the next few months. Dr. Giles described two CDC surveys that have been conducted in conjunction with the NHIS. The first is the Behavioral Risk Factor Surveillance System (BRFSS). This is a State-based survey that CDC conducts in conjunction with State health departments. Approximately 200,000 participants are interviewed each year. In addition to the core survey, each State has a choice of optional modules. In 2001, a total of 18 States participated in a heart attack signs and symptoms module, which included questions similar to the NHIS queries. A decoy question (related to stroke symptoms) was included as well, because it has been found that people tended to answer “yes” to most of the questions automatically. Only about 10 to 11 percent of the people in the 18 States were able to correctly answer all of the questions. Older and younger people, racial and ethnic minorities, and women were less likely to be aware of the symptoms. People who have risk factors or are at a higher risk for heart disease were much more likely to be aware of the symptoms.

The second survey that has been initiated in 26 communities across the country is called Racial and Ethnic Approaches to Community Health (REACH). These communities receive upwards of \$1 million per year to eliminate disparities in health. As a part of the evaluation of REACH, a mini-BRFSS has been included for each participating community; it includes questions similar to the NHIS questions. About 20,000 people are surveyed yearly in these communities and include such racial-ethnic subgroups as Korean Americans and Japanese Americans. Data concerning the knowledge of these groups related to heart attack signs and symptoms and the importance of calling 9-1-1 should be published early next year.

ACT IN TIME TO HEART ATTACK SIGNS PROGRESS REPORT

At the February 2002 meeting of the Committee, Ms. Long and Ms. Hand reviewed the background of the *Act in Time to Heart Attack Signs* campaign. The campaign was developed based on lessons learned from the REACT research program and REACT intervention materials. At that time, campaign materials and an electronic marketing package were provided to Committee members for dissemination through their various organizations.

Overview of Progress [Ms. Long]

Ms. Long presented an update on the progress of the *Act in Time* campaign since February 2002 (see slides in Attachment G). There has been widespread dissemination and implementation of *Act in Time to Heart Attack Signs* campaign by the NHAAP Coordinating Committee and its partner organizations. The materials have won seven awards of excellence, several for the campaign as a whole and some for specific materials. Awards are:

- A Silver National Health Information Award from the Consumer Health Publishers' Association and the Online Health Association.
- Three Health Communicator Awards, including the highest award—the Crystal Award of Excellence—in the international field of communications. One of these awards was for the video.
- Two Silver Inkwell Awards from the International Association of Business Communicators.
- Two APEX Awards for excellence in publication on a national level.
- The National Institutes of Health Plain Language Award for the core brochure.

At the last meeting, the importance of disseminating these materials was stressed. Excellent progress has been made, although there is still more to do. A key strategy has been to provide help to the various organizations through the use of the advocacy kit, in order to facilitate the dissemination of materials. The advocacy kit (mailed to members in the Spring of 2002 and again in mid-October) contained PowerPoint slides with information on *Act in Time*; drop-in articles and announcements for newsletters; ready-made Web-link text, buttons, and banners; HTML and text e-mail templates; and additional ideas for advocating for *Act in Time*.

The AHA, whose staff member was not able to attend this meeting, has been a key partner in *Act in Time*. The AHA has promoted the campaign through its affiliates, which have the ability to integrate these materials and messages into their established educational activities (e.g., Operation Heartbeat, American Heart Walk). This effort is ongoing and will incorporate new materials in the future.

The National Council on the Aging is also a key partner in the campaign and has been active in the dissemination of materials. The Council made a pledge to present the small group session in a thousand senior centers across the country, and so far, approximately 500 senior centers have ordered the materials and held classes using them. This method of distribution helps to institutionalize the product and allows for exponential dissemination.

The direct-mail campaign has included more than 100,000 marketing flyers to a variety of health care providers, as mentioned earlier by Dr. Crumlish, and many orders have been received as a result of this approach. Employers are included in the outreach effort; they also are an important group to reach, as the workplace is an obvious site to use the Small Group Session Kit.

Internet marketing is an important strategy for this campaign. The NHLBI has its own Health Information Network, which includes about 40,000 health professionals who are continually updated with new materials and information. Also, more than 250 health-related Web sites link to the *Act in Time* pages on the NHLBI Web site.

About 286,000 items have been ordered and distributed thus far as a result of the dissemination campaign, some for free and some to paying customers. The wallet card has been a huge success: 110,156 cards were ordered. Both the card and core brochure are in the reprinting stage. Additionally, more than 4,000 downloads of the *Act in Time* Palm OS program have been accomplished.

Media relations have been an important part of the effort. The National Cardiovascular Health Conference was successful in this regard, as mentioned earlier. Also, when the *Act in Time* campaign was launched, approximately 36 million audience impressions were estimated to have occurred, with an additional 20 million audience impressions occurring since then. A specific goal was to target African-American media, which included a successful satellite media tour with Dr. Charles Curry (in April 2002) for market areas with high African-American populations and high rates of heart disease mortality. This piece of the campaign reached more than a million viewers. Ms. Long showed Committee members a portion of this televised clip.

New materials planned include a Spanish-language version of the Small Group Session Lesson Plan and Video, which will be part of the Salud health program for Latinos; a low-literacy piece using illustrations; and a strong message on heart attack symptoms for women.

A marketing database has been set up to track dissemination and will be used for a process evaluation for the campaign. Ms. Long encouraged Committee members to contact the database coordinators with any of their organization's dissemination information. The goal is to have this campaign become an integral part of medical practice, especially primary care physicians.

American Red Cross [Ms. Pat Bonifer-Tiedt]

Ms. Hand introduced Ms. Pat Bonifer-Tiedt of the ARC National Headquarters, who presented an initial report at the last meeting and provided an update on ARC activities related to the *Act in Time to Heart Attack Signs* campaign. Ms. Bonifer-Tiedt is the Director of Research and Product Development within Health, Safety, and Community Services at the ARC National Headquarters in Falls Church, VA.

Ms. Bonifer-Tiedt reviewed the earlier activities of the ARC for dissemination of *Act in Time* materials, which involved making information about *Act in Time* available through the wide range of ARC national communication channels. This includes placing materials on the national Web site, providing materials for newsletters, and providing the NHLBI with mailing labels so that kits can be mailed to every Red Cross chapter in the country. The ARC chapters are the entities that actually implement the education. A program release announcement, which is the ARC mechanism for informing chapters of new programs or materials, was issued also.

The ARC has developed a 1-hour module called "Your Heart Matters," which promotes cardiovascular health. The *Act in Time* program was combined with this, and the individual and combined sessions were assigned course codes for tracking. Between January and June 2002, 67 sessions were delivered, and approximately 1,200 people were reached. The sessions were evenly split between combined sessions and individual *Act in Time* sessions, so the chapters are using both methods. In addition, since February, presentations have been made to the urban initiative chapters and the Red Cross Advisory Committee on First Aid and Safety.

In the future, the ARC plans to continue to track the numbers, do another mailing to chapters, and utilize the Spanish-language materials. An obstacle to dissemination to Spanish-speaking populations is the fact that chapters in areas with large Hispanic populations do not have enough capacity in terms of their volunteers to reach the population. A pilot program has

been started to increase chapter capacity by helping these chapters identify and recruit volunteers. More efforts also are being made to collaborate with Hispanic organizations to reach this community. It is hoped that the Spanish-language module will be useful in helping chapters increase capacity and draw people in.

American College of Cardiology [Ms. Eva Marie Grace]

Ms. Hand introduced Ms. Eva Marie Grace, Project Coordinator at the ACC in Bethesda, MD. Ms. Grace reported on the important steps that the ACC is taking to inform the cardiology community about the *Act in Time* campaign.

Ms. Grace is the staff coordinator for the ACC's Emergency Cardiac Care Committee, of which Dr. Atkins is a member. Dr. Atkins made the initial contact with the ACC through Ms. Grace, to solicit ACC participation in the *Act in Time* campaign. The Emergency Cardiac Care Committee met soon after, and *Act in Time* was one of the agenda items. The committee was enthusiastic about the idea.

A section regarding *Act in Time* was prepared for the ACC Web site and included the NHLBI contact information. On the homepage of the Web site was a headline and link to the *Act in Time* article, which remained at the top of the page for about a month. Using this article on the Web site as a link, it was included in the next *ACC News Weekly*. This is a relatively new weekly electronic newsletter that is sent to all ACC online members. Only six to eight items are included in each newsletter, and this article appeared in a prominent position.

The ACC Communications Department drafted a short news article for the ACC news section that is placed at the centerfold of *Cardiology* each year. The article included information about the program and the uniform resource locator (URL) for the article on the Web site. A news brief also was placed in the monthly e-communication sent to ACC leadership and staff and used in Online Site for Chapters to Access Resources (OSCAR).

Everyone contacted at ACC was enthusiastic about this program, making it easy to disseminate. ACC staff agreed that it was important to let physicians know that the materials were designed for them to allow them to help their patients—the materials are easy to obtain and inexpensive and will maximize the time that they spend with their patients.

Dr. Christenson asked whether any efforts have been made to tie the program to continuing medical education (CME). This has not been done yet. Some of the materials are for the public, and some are for professionals. A package for professionals must be developed for CME application, although it was agreed that this was a good idea. If the program is on the agenda at annual meetings, continuing education units and CMEs may be obtained via meeting attendance.

Society of Chest Pain Centers and Providers [Dr. J. Lee Garvey]

Ms. Hand introduced Dr. J. Lee Garvey, who represented the Society of Chest Pain Centers and Providers (SCPCP) on the Committee, to discuss a major *Act in Time* initiative recently begun by the SCPCP (see slides in Attachment H).

Dr. Garvey thanked Ms. Hand for attending the Society for Chest Pain Centers' Fifth National Congress in September and for presenting the intent and impact of the *Act in Time* campaign. Approximately 200 health care systems were represented at the meeting, and Ms. Hand's presentation was well received. In addition, materials have been sent to all society members in the past 6 months as well as to new members planning chest pain centers in their institutions.

Dr. Garvey discussed a local, community-focused initiative in Charlotte, NC, to spread the news about *Act in Time* to the community. The Carolinas Medical Center in Charlotte has partnered with the AHA and the NHAAP to organize a cross-departmental approach to emphasizing emergency medicine and cardiology. Support from pharmacy and the medical center marketing and public information staff, the Chest Pain Evaluation Center, and others has been organized. Charlotte is located in Mecklenburg County, and both the city and the county have a relatively high rate of cardiovascular deaths as compared to the rest of the State. This is true for women as well as for men. The African-American population in North Carolina has a disproportionate share of deaths due to CVD. The emphasis is on targeting the high-risk population, including female, African-American, and elderly patients as well as patients with identifiable high risk. Those that have known coronary artery disease will probably be the easiest to reach, as well as the most at-risk group. Hypertensives, diabetics, and smokers are targeted also.

Questions that were asked when planning the initiative include:

- Who are these patients, and where are they? How do we interact with them?
- What resource materials do we use to reach them?
- How do we pay for this?

To address these questions, strategies have included sharing common resources and coordinating common efforts. A number of partnerships have been established to this end. The four hospitals in the county and three outpatient pharmacies have a data management system in place that allows query by ICD-9 codes and demographics. A geographic information system mapping group funded through the Healthcare Center has graphed some of these data to identify regions of the city with high-need populations. The mapping shows a significant number of elderly patients being diagnosed with ACS, along with their geographic spread and density. This process allows identification of the location of the target population and possible ways and destinations for targeting educational materials. In addition, the nonspecific chest pain diagnosis population has been mapped also.

The tools being used are primarily those of the *Act in Time* campaign. They include direct patient materials, and family and workplace educational programs in conjunction with the AHA's Operation Heartbeat. The program is working to identify media placements, such as billboards, as a way of delivering a bulleted message to a targeted population that is known to be effective. The pharmacies have been cooperative in encouraging and delivering patient education, with onsite education efforts and a computerized tracking system for recording prescriptions and educational exposure for each patient. This will allow a retrospective analysis of the effects of education within a few years.

The Chest Pain Evaluation Center is considered a “captive audience” for education about the signs and symptoms of a heart attack, lifestyle, and risk factor modification. The nursing staff is eager to provide patient education to family members as well as to patients.

The Hospital Discharge Planning Group has developed a new set of critical pathways for discharge strategies, including prompts for appropriate medications (i.e., aspirin, beta blockers) that are appropriate for the treatment of an acute event, specific instructions that address risk factor modifications, how and why to take the medications, signs and symptoms of a heart attack, and action plans based on the *Act in Time* campaign. Directed educational efforts have been conducted primarily in conjunction with the AHA’s Operation Heartbeat, a program for businesses to install automated external defibrillators. Educational materials on symptom recognition are distributed at the defibrillator training programs.

The program is in the process of developing an alliance with the local parish nurse association, which runs the health awareness events at local faith-based parishes. There is participation in some of the larger community health events, such as the Southern Women’s Show. The group also hopes to develop a partnership with one of the local television affiliates as well as with other good “corporate citizens” who might want to be affiliated with this effort. The package of materials for the television collaboration is expected to cost \$100,000 per year, including paid advertisements, health news, and public service announcements.

Dr. Selker commented that this was an exemplary program. He asked how the message of the chest pain center is articulated to the public. The center is marketed to the medical community, in the hopes of reaching the most at-risk patients first. The input of pharmacies is crucial. The primary audience is the most at-risk population, not the general community, so this targeted group is hopefully motivated to listen to the message. The emphasis is on the outreach message.

Ms. Hand added that her office would continue followup by phone with each Committee member to obtain input about what options might work best with which organization and to emphasize the Committee members’ role as advocates for the *Act in Time* program. Members are encouraged to present this campaign at their organizations’ annual meetings and to play an active role in conveying the importance of this campaign to their organization’s members.

WOMEN’S HEART HEALTH

Women and Ischemia Syndrome Evaluation Workshop: Recommendations [Dr. George Sopko]

Ms. Hand introduced Dr. George Sopko, who spearheaded an NHLBI workshop last month on “Women’s Ischemic Syndrome Evaluation” (WISE).

Dr. Sopko explained that the NHLBI workshop focused on detection and diagnosis of ischemia in women. It was based on the WISE study, an ongoing study of 1,000 women who had coronary angiograms as part of the evaluation of their chest pain and other ischemic symptoms. More than 40 international experts on women’s health attended the workshop in order to provide the NHLBI with recommendations regarding what could be done and what needs to be done in the near future concerning this issue. Seven sessions, covering the full

spectrum of relevant topics, convened. Both stable coronary disease and acute symptoms were addressed. Discussion focused on whether women have a different presentation of symptoms and how to deal with women who have relatively normal coronary arteries but who present with acute ischemia. One of the concepts that emerged was that perhaps women have a better early-warning system than men, which might account for the different temporal presentation of symptoms. Participants agreed that the materials available to the public regarding acute ischemia are appropriate and sufficient; however, both the professionals and the public must receive greater exposure to these educational materials.

The workshop focused on three major areas: better understanding of the path of physiology of ischemia in women with and without significant macrovascular disease, better understanding of the effects of hormonal replacement therapy, and clarity regarding how to optimize the public message and education. Specific recommendations are still being developed as a result of the workshop discussion outcomes.

Acute Symptom Message [Dr. Harry Selker]

Dr. Selker summarized the recommendations from the NHLBI workshop panel entitled *Key Messages About Symptoms of Acute Ischemic Heart Disease in Women and Recommendations for Practice* (see slides in Attachment I). Studies show that women take longer to get to the hospital than men. It is unclear why this is the case, but it may well mean that the message concerning the importance of time in acute cardiac situations may not be reaching women. This may be because women believe that they are at less risk for heart disease or because they are more focused on messages concerning areas such as breast cancer. In addition, the general feeling among the public seems to be that women have a different model of presentation than men.

Data from REACT and other studies are consistent: women who present tend to be older (by 5 to 10 years), with more comorbidity (e.g., diabetes) and more shortness of breath due to congestive heart failure. Fundamentally, however, they have the same symptoms as men. Both the public and professionals are not sufficiently aware of this fact. Younger women are more likely to have ACS misdiagnosed in the ED. African-Americans are more likely to be sent home; patients with shortness of breath rather than chest pain also are more likely to be sent home; and those with less striking electrocardiogram (ECG) changes are most likely to be sent home. It is important to be aware of the broader range of symptoms. The differences, which are subtle, tend to get more media attention than the major characteristics, which are similar.

Dr. Selker noted that although the frequency of symptoms in men and women was strikingly similar, the temporal sequence might be different. Women are more likely to be diabetic, and diabetics are more likely to have cryptic symptoms and less pain. Women also are more likely to be physically sensitive to pain, so they may describe the pain differently. These factors contribute to the message that the public is receiving—that the symptoms between the sexes are totally different.

The Committee raised a number of questions. Should the subtle differences be emphasized, since many professionals do misdiagnose coronary disease in women? It may be better if more professionals took this route. Do male physicians ask questions differently of

female patients? How much of a role does this play? Do women communicate differently to women? Do women have more prodromal symptoms? It might be important to view the symptoms from a period of weeks prior to the event. Although there is a fair amount of literature available on patient-provider communications by gender, race, and other factors that shows marked differences depending on these factors, this is a complex area of study.

The classic group that has provided the research base are men aged 40 to 60, who provided data in the 1940s and 1950s. Now, there are more women, the patients are older, more are diabetic, and many have left ventricular hypertrophy (LVH), which, as known from the Framingham study, makes more of the events silent. The men presenting also are older and tend to have diabetes and LVH. The aging phenomena that modify the risk factors may be more important than the gender differences. It is a complex issue, and many factors must be considered.

Dr. McNutt brought up the use of timeback calendar studies, a methodology that dramatically changes the descriptions of illnesses by patients. Some publications on studies using this technique may significantly change the symptom complex related to CHD.

Ms. Hand added that her office plans to summarize the science on acute symptoms in women as presented at the workshop, including databases from the REACT study and the NRMI. Her office will develop a women's brochure about symptoms, based on the best information available.

WHEN THE FAMILY BECOMES THE PATIENT: CARING FOR THE SURVIVORS OF PATIENTS WHO HAVE SUDDEN DEATH FROM CARDIOVASCULAR CAUSES [Dr. Robert Zalenski]

Ms. Hand introduced Dr. Robert Zalenski, who represented the Society for Academic Emergency Medicine on the Committee. The original NHAAP goal included rapid identification and treatment of individuals with heart attack symptoms to reduce AMI morbidity and mortality, "thereby improving the quality of life for patients *and those around them.*"

Dr. Zalenski noted that there are approximately 350,000 episodes of sudden cardiac death each year. In the 35- to 45-year-old age group, there are about 13,000 episodes of sudden cardiac death. This translates into about 3 deaths per 100 ED visits. The focus of his talk was on the "other" victims—the family members or, more broadly defined, the loved ones of the deceased (see slides in Attachment J). The question posed is: Have we, in the emergency cardiac community, optimized the care for these other victims? The answer to this question may identify a common ground for proceeding forward.

Evidence suggests that psychological stress is associated with increased risk of CHD, bereavement is associated with cardiovascular mortality, and opportunities exist for improvement in bearing bad news and comforting the survivors. In the 2000 *Annals of Emergency Medicine*, it was acknowledged that "most resuscitations end with patient-survivors, not surviving patients, and we have no systemized way of caring for these patient-survivors."

Rozanski and others (*Circulation*, 1999) completed an extensive review of the impact of psychological factors on the pathogenesis of CVD. Essentially, they found that psychosocial

stressors, such as anger, grief, and hopelessness, can result in two different pathways that affect cardiovascular events and mortality. These stressors can affect one's behavioral risk, in that depressed persons stop caring for themselves (e.g., not taking prescribed medications). Additionally, psychosocial stressors themselves, through neuroendocrine and other mechanisms, can cause atherosclerosis or can accelerate its development, translating into clinical cardiac events.

Acute stress after learning of the death of a loved one can precipitate systemic nerve stimulation, which in turn can lead to platelet activation and increased thrombosis. It also can affect the functioning of the endothelium and lead to more vulnerable plaque. It can increase the proarrhythmic potential and cause arrhythmias. It can also lead to increased heart rate, blood pressure, and vasoconstriction, all of which can cause myocardial ischemia or infarction.

Rozanski reviewed the link between depression, anxiety, and cardiovascular events. Numerous studies have shown a prospective relationship between major depressive episodes and the incidence of cardiac events. Also, a dose-effective relationship with the magnitude of depression and of hopelessness appears to exist.

Kaprio described in an article published in the *American Journal of Public Health* (1987:77:283–287) a prospective study of bereavement, which evaluated 95,647 people for 4 to 5 years. The highest mortality occurred immediately following the loss of a spouse, with a more than twofold greater risk for men and a threefold greater risk for women. Most of the effect occurred in the first month following bereavement. The opposite effect occurred in parents who lost a child. A recent study published by Li and others in *Circulation* 2002 (106:1634–39) found a longer term risk of both fatal and first MI in parents who had suffered the loss of a child. This may be because of an additive effect to the cardiovascular risks of aging.

ED physicians have little training in the communication of sudden death. Schmidt and others documented, in a study published in the *Annals of Emergency Medicine* (1990), a survey of ED physicians that found that one-third had training in death notification in residency and one-half had such training in medical schools. Ninety-four percent felt the need for improved education in this area. In an article entitled “Caring for Survivors,” which appeared in the *Annals of Emergency Medicine* (2002), C. Hott advocated a systematic team approach for helping survivors deal with loss.

Dr. Gillum, the NCHS representative on the NHAAP Coordinating Committee, suggested an innovative and provocative approach to this end in his 2002 letter to the editor in *Circulation*. He identified a vulnerable, elderly subgroup for which the following services might be provided:

- Early evaluation (in the ED) of surviving family members for symptoms and signs of cardiovascular disease
- Early followup with personal or referral physician to reinforce the need to continue all medication
- Prescription of short-term pharmacotherapy for sedation
- Provision of information on cardiovascular risk to the survivors

Dr. Cantrill remarked that this issue is further complicated by the trend towards cessation of resuscitation attempts in the field. Very often, the patient's body is taken to the morgue, and the ED staff does not have the opportunity to interact with family members at all. Other hospitals bring the body into the ED regardless. Dr. Gillum said that it would be interesting to learn what the approach was in various areas. He agreed that this is an opportunity for teaching as well as for making a compassionate outreach effort. Another suggestion was standardized training in this area for residents with videotaping and feedback, as well as education directed to EMS personnel.

Dr. Ferguson observed that the amount of time the ED physician spends with the family following the patient's death is brief, although the grieving process is only beginning and extends indefinitely. A facilitated transition to a pastoral care or a grief specialist might be an additional course of action.

Dr. Zalenski added that allowing families to witness resuscitation attempts seems to be helpful: the family is able to see how hard the team works to save the patient. However, a team response to this "second" emergency is called for in these situations. The physician needs to be the one delivering the words; then a team to provide additional support can be called in.

This situation can be considered the emotional equivalent of a physical stress test for the survivors, producing many of the same symptoms. The least that can be done is that the vital signs of the survivor can be taken, especially if the patient is at high risk. A screening, followed by referral to the primary physician, might be warranted. There is also a phobia about prescribing psychoactive drugs for elderly people. The establishment of a specific protocol would be a positive step.

Dr. Garvey was asked whether the chest pain centers have a system for handling this problem. He stated that there is currently no organized effort, but this might be included in an outreach approach.

The Committee agreed that the physician's and team's behavior in notifying the family that a loved one has died is a unique opportunity to either lessen the pain that would inevitably follow or to create anger, hostility, or guilt. The NHAAP could raise the visibility of the importance of this issue. Dr. Zalenski suggested three potential roles for the NHAAP:

- Examining optimal training of the ED team for "bearing bad news"
- Promoting professional training in bereavement and bereavement support
- Promoting assessment of potential cardiovascular risk

In addition, Dr. Zalenski suggested that because of the busy agenda of the NHAAP, a catalyzed approach among the member organizations might be the best approach. The NHAAP has offered to coordinate the approach among the member organizations. Anyone interested should contact Ms. Hand or Dr. Zalenski.

Mr. David Bryson added that the National Highway Traffic Safety Administration (NHTSA) and the Department of Health and Human Services' Maternal and Child Health Bureau are under a contract with the American Trauma Society and the American Public Health

Association to develop a second trauma program. This program will deal with the families in both in-hospital and out-of-hospital settings. Mr. Bryson is certain that the developers of this program are not aware of the cardiovascular risks. He suggested that the NHAAP contact Mr. Harry Teter at the American Trauma Society, who is leading this effort. Mr. Bryson offered to facilitate this contact.

CARDIAC ARRHYTHMIA PORT [Dr. Daniel Stryer]

Ms. Hand introduced Dr. Daniel Stryer, the AHRQ representative to the Committee. Dr. Stryer had asked for the opportunity to bring to the Committee's attention a series of articles related to arrhythmias that appeared in the September issue of the *American Heart Journal* and came from the Cardiac Arrhythmia Patient Outcomes Research Team (PORT).

Dr. Stryer stated that, seven studies were published from the Cardiac Arrhythmia PORT in the September issue of the *American Heart Journal*. This is a comprehensive effort to improve the understanding of screening and management of patients at risk for sudden cardiac death. The studies track the use of ICDs over the last few years, and results show that outcomes are improving when ICDs are used. The studies also provide some data to inform the use of ICDs, including information on quality of life and cost-effectiveness. One of the major challenges is trying to decide for whom these devices are most appropriate, without decreasing their rate of effectiveness and increasing their costs.

Dr. Stryer added that Dr. Selker had published an article in July 2002 in the *Annals of Internal Medicine* on the effectiveness of the thrombolytic predictive instrument, which is a computerized decision support tool designed to help facilitate the use of thrombolytics or PCI. The study showed that although this methodology did not have an effect on the use of artery-opening therapies overall, an effect was seen in certain subgroups. These subgroups were considered at higher risk for underuse of reperfusion therapy and included women, inferior MI patients, and patients treated at hospitals in which there was not a specialist onsite. There were too few minority participants to see whether the effects applied to them also. The study also found that application of the thrombolytic predictive instrument improved the use of reperfusion therapy by 30 percent for EMS units under medical control.

NATIONAL EMS RESEARCH AGENDA [Mr. David Bryson]

Ms. Hand introduced Mr. David Bryson of the NHTSA, who reported on the National EMS Research Agenda Meeting that was held on June 3–4, 2001 in Alexandria, VA.

Mr. Bryson passed out copies of the *National EMS Research Agenda* to Committee members. Mr. Bryson attended today's meeting on behalf of Dr. Jeffrey Michael, who was not able to attend. Susan McHenry is the project director of this project and will be happy to answer any questions concerning the agenda. This agenda has been driven by a series of agendas: the *1996 EMS Agenda for the Future* and the *1998 Implementation Guide for the Agenda* (which focused on creating the research agenda). The *National EMS Research Agenda* is an effort to move the prehospital setting and EMS system into research. The NHAAP represents a model for the proper manner in which to conduct research for other organizations in the field.

The NHTSA research agenda identified objectives for and barriers to research. In addition, a number of Internet sites were mentioned in the appendix as excellent sources of research information. Hopefully, this product will allow the NHTSA to obtain strong, evidence-based data to drive the national standard curricula and improve the efforts of prehospital providers.

FINAL COMMENTS AND ADJOURNMENT [Ms. Hand]

Ms. Hand stated that her office is considering converting the registration process for the Coordinating Committee to an Internet-based, electronic format. She described the proposed concept to the Committee. Members would be provided with a URL to access the registration site, which would be the homepage of the NHLBI Meeting Center. Choices would include “Upcoming Meetings,” “Past Meetings,” and “Rosters of Current Members.” Members would click on the highlighted text under the “Upcoming Meetings” section. For example, for this meeting, the choice would be the NHAAP Coordinating Committee Meeting (October 28–29, 2002). The “Coordinating Committee Meeting Registration” page would then appear. Members would type in their e-mail address and password and then would click “log-on.” Members would indicate whether or not they will attend the selected Coordinating Committee meeting. There would also be access to the agenda, registration, logistics, and driving directions from this page. Registration would be confirmed after the “Submit Registration” button was clicked. An e-mail confirmation of the transaction would be provided. Members would have the ability to go back at any time and update or view the information regarding the Coordinating Committee meeting.

Several other Committees are being queried as to interest in pursuing this electronic registration technology. Unanimous interest and the capacity among all of the organizations to move forward with this plan will be necessary to implement it.

Ms. Hand requested a show of hands of all members who would use this system, if it were available. Nearly all members indicated positive interest.

Ms. Hand thanked the members for honoring her with the plaque. She stated that it was an honor to work with people who were truly committed to the heart attack awareness mission and emphasized that the potential exists for the Program to have a positive impact on many patients. The issues are challenging and complex, but the NHAAP has moved forward with the best evidence possible. The group will continue to work on the priority areas from the 10-year meeting, and Ms. Hand’s office will follow up with participants regarding the *Act in Time* campaign. She asked for any final comments or questions and reminded members that the next meeting would be held on May 22–23, 2003.*

Ms. Hand thanked everyone for attending and adjourned the meeting.

* Please note that the meeting has been moved to June 23–24, 2003.



National Heart Attack Alert Program

Executive Committee Meeting

**October 28–29, 2002
Bethesda, Maryland**

**NATIONAL HEART ATTACK ALERT PROGRAM
COORDINATING COMMITTEE
EXECUTIVE COMMITTEE**

**Meeting Summary
October 29, 2002**

Members

James M. Atkins, M.D., F.A.C.C. (Chair)
Christine Crumlish, Ph.D., R.N.
Charles L. Curry, M.D.
Bruce MacLeod, M.D., F.A.C.E.P
Mary Beth Michos, R.N.
Joseph P. Ornato, M.D., F.A.C.C.,
F.A.C.E.P.
Harry P. Selker, M.D., M.S.P.H.
David E. Simmons, Jr., M.S.N., R.N.
Robert J. Zalenski, M.D., M.A.

NHLBI Staff

Mary M. Hand, M.S.P.H., R.N.

Contractor Staff (Prospect Associates)

Jill K. Arvanitis, M.P.H., C.H.E.S.
Jo Lane Thomas, M.F.A.

WELCOME AND INTRODUCTIONS

Dr. Atkins welcomed participants and reminded them that they had a limited time for discussion of the issues on the agenda.

REPORTS ON SUBCOMMITTEE MEETINGS/SUBCOMMITTEE ISSUES

[Education Subcommittee Chairs]

Priority Area I: Widespread Dissemination and Implementation of “Act in Time to Heart Attack Signs” Campaign Materials by the NHAAP Coordinating Committee Member Organizations

- **Objective 1-a: Member Organizations:** *By the end of 2002, members of the NHAAP Coordinating Committee will cooperate with NHAAP staff to promote the Act in Time to Heart Attack Signs materials through their organizations’ communication channels to its members who can provide these materials to key public education target audiences.*
Dr. Crumlish reported that Mr. Win Morgan of Prospect Associates updated the subcommittee on the *Act in Time* activities and reported that NHAAP members had made great inroads in dissemination. One highly visible effort was Dr. Charles Curry’s satellite media tour. A total of 185 news organizations incorporated portions of or reported on *Act in Time*. Members of the NHAAP Coordinating Committee supported these social marketing efforts by bringing information to their organization’s program communications channels. Campaign information is transmitted to members of the organizations who can provide these materials to key target audiences. More than

286,000 materials have been disseminated, and the campaign has won seven national awards.

- **Objective 1-b: Other Professional Audiences:** *By the end of 2002, Act in Time materials will have been distributed to 100,000 health professionals and program managers who have the ability to promote Act in Time to Heart Attack Signs.* Materials have been distributed to more than 117,500 individuals, including 12,599 managers of employee health plans. An article on *Act in Time* will appear in the newsletter of the American Association of Occupational Health Nurses, and the project is in the process of developing a partnership opportunity with a fitness center management corporation.

Dr. Crumlish noted that Mr. Win Morgan of Prospect Associates is putting together a database of *Act in Time* activities and wants all members of the Coordinating Committee to notify him of any activities their institutions support. She noted that there would be additional Spanish products of *Act in Time*, which will be available by early 2003.

[Health Systems Subcommittee]

Priority Area 1: Emergency Medical Services (EMS) Systems Utilization

- **Objective 1-a:** *The NHAAP Health Systems Subcommittee and NHAAP staff will pull together data from all the Rapid Early Action for Coronary Treatment (REACT) papers/data and other sources for one publishable paper looking at the etiologies for underuse and optimal use of EMS for patients with possible acute cardiac symptoms.* Dr. Bruce MacLeod indicated that he would take the lead in this activity.
- **Objective 1-b:** *The NHAAP will hold a stakeholder meeting to problem solve issues (systems, education, etc.) related to the underuse and optimal use of EMS by patients with possible acute cardiac symptoms (as well as new approaches/methods) by February 2004.* Ms. Mary Beth Michos, Vice Chair, indicated that she would assume the lead role for this function, although she expressed her need for some direction in planning this event, which is most likely to occur in October 2004.

Priority Area 2: Evidence-Based Technologies

- **Objective 2-a:** *The NHAAP Health Systems Subcommittee will review the literature to identify technologies/strategies that positively affect the outcomes of patients with acute coronary syndromes (ACS) that are currently underutilized.* Dr. MacLeod reported that Dr. Lee Garvey from the subcommittee volunteered to take the lead in addressing this priority area. In the ensuing discussion, one of the participants inquired why systems don't change practice right away in the face of evidence-based guidelines. Like Ms. Michos, Dr. MacLeod said that he would like some guidance from experts regarding translation of evidence to practice, changing physician behavior, and strategies to do so. Dr. MacLeod pointed out that the bottom line of this committee's purpose: to change behavior. Another participant noted that there is a significant need to understand how people learn. The members of the Coordinating Committee agreed that it might be appropriate to bring someone from the field to discuss these issues. Dr. Selker suggested

that participants read a book entitled *Dissemination of Innovation* by Everett Rogers. He noted that in his opinion it was a good time to “reboot and think the science over.”

Priority Area 3: Quality Improvement

- **Objective 3-b:** *The NHAAP Health Systems Subcommittee will review performance quality measures and identify within those organizations, gaps that may exist in the care of patients with acute coronary syndromes.* The subcommittee noted that one of the most difficult challenges in this area is the implementation of evidence-based strategies. One approach to ensure quality care is to tie an understanding of the guidelines with accreditation. Although all agreed that “there needs to be some way to know how well we’re doing,” Ms. Hand noted that evaluation can be extremely costly and hard to design. Another participant noted that achieving a balance between the academic and the practical is essential—it is necessary to work with real numbers, which in this country are atrocious. For example, only 30 percent of hypertensives are aware that they are at risk of having a coronary episode. And, noted Dr. Atkins, REACT data indicate that when post myocardial infarction patients are asked how many times a health care professional had tried to explain what they should do in the event of a heart attack, only 5 percent had had this discussion with their caregivers.

The subcommittee agreed that a special presentation should be made to the NHAAP full committee in this area. Organization representatives should be encouraged to attend, and the Executive Committee recommended putting together a planning committee and developing specific objectives. One of the most critical topics for discussion in the group’s discussions would be how to address change and how to focus on systems change.

Ms. Hand noted that some of the guidelines have been institutionalized. The Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines (CRUSADE) project has developed quality improvement goals. **[NB: and the ACC’s Guidelines Applied in Practice and the AHA’s Get With the Guidelines are examples of acute myocardial infarction quality improvement programs.]** Dr. MacLeod noted that there was some distrust of the CRUSADE data because it is supported by the for-profit organizations, such as drug companies, that have the appearance of some secondary gain, and for this reason are the cause of some concern. Dr. Ornato said that an advantage to these types of research efforts is that they are independent of the cumbersome regulatory system and are better able to obtain funds for the research. Dr. Atkins added that the reason we do not see government leadership in national registries is because the cost of creating a critical infrastructure out in the field is prohibitive. Pharmaceutical companies already have the infrastructure and are “able to hit the ground running.” The National Institutes of Health (NIH) would need to create a system or partner with a workforce that was already out there. The introduction of a new drug costs \$800 million, and industry is often in the best position to invest these large sums in the research. The National Heart, Lung, and Blood Institute (NHLBI) supports basic, not applied, research.

Priority Area 4: Effect of Health Information Portability and Accountability Act (HIPAA)

- **Objective 4-a:** *NHAAP staff will arrange for a presentation to the NHAAP Coordinating Committee about HIPAA and its implications for health care systems and management of patients with acute coronary syndrome.* Dr. MacLeod reported that Mr. Alan Mertz, Chair of the Confidentiality Coalition of the Health Care Leadership Council, discussed with the subcommittee at some length the new HIPAA guidelines. Dr. MacLeod noted that Mr. Mertz focused more on what did not happen as the regulations were being written as opposed to discussing what are the effects of the relevant regulations. He reminded the subcommittee that this is now a 336,000-word regulation. Mr. Mertz cautioned about incidental contact in the treatment environment; and use of consultants who may be using the second, as opposed to the final draft which can result in misleading interpretations. Dr. MacLeod noted that Mr. Mertz is in essence a lobbyist for the health care industry, and his comments must thus be taken in this context.

[Science Base Subcommittee Chairs]

Dr. Joseph Ornato, Chair Science Base Subcommittee, reported on the subcommittee's discussion, including Priority Area #1 (identified at the 10-year meeting):

Priority 1: Technologies and Protocols for Management of Patients With Acute Coronary Syndromes (ACS)

- **Objective 1-a:** *The Science Base Subcommittee will review the literature based on an NHAAP literature search on important clinical trials and technologies for risk stratification of patients with ACS and identify implications and action for the NHAAP mission.*
- **Objective 1-b:** *The Science Base Subcommittee will review the literature based on an NHAAP literature search of important clinical trials and technologies to identify what interventions/strategies have a time dependence for ACS (diagnosis and treatment), as well as the implications and action for the NHAAP mission.*

Dr. Ornato discussed the subcommittee's discussion of the recommended timelines for the ST-segment elevation myocardial infarction (STEMI) guidelines, one starting with a realistic view of the onset of symptoms and the other from a prehospital triage and treatment perspective perspective, presented by Dr. Elliott Antman, current chair ACC/AHA STEMI Guidelines Committee. After much discussion, the subcommittee agreed upon the impracticality of implementing Dr. Antman's goals. Dr. Ornato noted that Dr. Antman is anxious for any input that members may have; members should contact Ms. Hand.

Other topics on the subcommittee's agenda were a redefinition of acute myocardial infarction and the issue of focusing more on prodromal symptoms. They agreed that it would be appropriate to ask the NHLBI if it would be willing to fund a workshop or a systematic literature search, as this would be an excellent time to review the science.

Dr. Atkins asked Executive Committee members to consider these issues in anticipation of a conference call sometime in the next month. He also asked Executive Committee members to review the proposed timeline for NHAAP activities. A tentative date of May 22–23 has been selected for the next meeting.



National Heart Attack Alert Program

Education Subcommittee Meeting

**October 28–29, 2002
Bethesda, Maryland**

**NATIONAL HEART ATTACK ALERT PROGRAM
EDUCATION SUBCOMMITTEE**

**Meeting Summary
October 28, 2002**

Subcommittee Members

Christine M. Crumlish, Ph.D., R.N.
(chair)
David E. Simmons, Jr., M.S.N., R.N.
(vice chair)
James M. Atkins, M.D., F.A.C.C.
Julie Bracken, R.N., M.S., C.E.N., A.P.N.
Dave Bryson
Diane Carroll, R.N., Ph.D.
M. Ray Holt, Pharm.D.
Kemlee White, R.N., C.O.H.N.-S.

NHLBI Staff

Mary M. Hand, M.S.P.H., R.N.

Contract Staff (Prospect Associates)

Jill K. Arvanitis, M.P.H., C.H.E.S.
Win Morgan, M.P.H., Ce.M.
Jo Lane Thomas, M.F.A.

**Other Coordinating Committee Members
Present**

Stephen V. Cantrill, M.D.
Lawrence D. Jones, M.D.
Bruce A. MacLeod, M.D., F.A.C.E.P.
Mary Beth Michos, R.N.
Harry P. Selker, M.D.

WELCOME AND INTRODUCTIONS [Dr. Christine Crumlish and Mr. David Simmons]

Dr. Christine Crumlish welcomed the Subcommittee members, along with the other Coordinating Committee members attending the meeting, and asked them to introduce themselves. She then presented a new Coordinating Committee member, Dr. Stephen Cantrill, who represented the American College of Emergency Physicians.

**REVIEW OF EDUCATION SUBCOMMITTEE PRIORITY AREAS
[Dr. Crumlish]**

Dr. Crumlish reviewed the Education Subcommittee's priority areas, or objectives, established in the last two meetings. Because the meeting folders contained a complete statement of the final priorities for the years 2002 through 2006, she felt that it was unnecessary to examine every item in detail. Instead, she gave the participants a few minutes to go over the handout on final priority areas/objectives prior to a more general discussion.

Dr. Crumlsh reminded the group that Mr. Win Morgan of Prospect Associates, Ltd., would be discussing the first major priority area, dissemination of the “Act in Time to Heart Attack Signs” campaign, later in the meeting.

Ms. Mary Hand updated the Subcommittee on the second major priority area—informatics projects, which are of interest to all the National Heart Attack Alert Program (NHAAP) Subcommittees. Of the six projects, a couple have already been completed, and a couple more are due to end late in 2003. According to Ms. Hand, the best time to present them would be in February 2004, perhaps during a special Coordinating Committee meeting.

REDUCING PREHOSPITAL TREATMENT-SEEKING DELAY IN PATIENTS WITH ACUTE CORONARY SYNDROMES AND STROKE: AMERICAN HEART ASSOCIATION WRITING GROUP

[Ms. Mary Hand, substituting for Dr. Angelo Alonzo]

The third Education Subcommittee priority area, “Conceptual Framework for Behavioral Change—A Research Initiative,” is intended to review the recommendations of the American Heart Association’s (AHA’s) January 2002 workshop on reducing treatment-seeking delay in patients with acute coronary syndrome (ACS) and stroke, and possibly to use these recommendations as a basis for research initiatives. Drs. Angelo Alonzo and James Atkins attended the workshop, cochaired by Drs. Debra Moser and Laura Kimble. As a product of this workshop, the AHA has convened a writing group to summarize the treatment-seeking delay literature for acute cardiovascular disease and to distill research recommendations for the field in this area. Dr. Alonzo was to have presented a brief report to the Education Subcommittee on this effort, titled “Reducing Prehospital Treatment Seeking Delay in Patients With Acute Coronary Syndromes and Stroke: American Heart Association Writing Group.” However, as he had a last-minute conflict, Ms. Hand spoke to the group on this special project.

According to Ms. Hand, the workshop and subsequent writing group were stimulated by:

- *The “failure” of the Rapid Early Action for Coronary Treatment (REACT) research program.* Thus, a major workshop objective was to consider additional research directions, particularly those that would address ways to educate patients both with and without current cardiovascular disease so that they would seek treatment in a timely manner.
- *The need to examine the problem of treatment-seeking delay for stroke symptoms.* Like patients with cardiovascular disease, those with ischemic stroke receive thrombolytic therapy, and in these cases too, time is of the essence.
- *The realization that appropriate symptom recognition and management are major problems across a variety of cardiovascular and cerebrovascular diseases.* Thus, future research directions must provide a unifying framework for practice and research.

The need to include heart failure on the writing group’s agenda was considered due to the large share of the health budget that this condition consumes. At present, there is little

agreement about how to promote appropriate symptom recognition and management among these patients; theirs is a complex compliance problem.

This group held a conference call in the fall and will put together a paper, producing a first draft by January 2003. Dr. Alonzo, Ms. Hand, Dr. Kathleen Dracup, and Dr. Julie Zerwic are among the members who will work on this project.

Dr. Moser has generated an outline, which will serve as a basis for the draft. The paper will contain eight major subjects, each with a number of subordinate topics.

The writing group will stress the importance of early treatment for optimal outcomes in ACS and stroke and the gains to be made by decreasing delay time, point out that the major impediment to early treatment is patient delay, and define “delay” as the time from the onset of symptoms to the arrival at the hospital. The writers also will divide treatment-seeking delay into four phases:

- The time when the patient first notices an abnormal symptom or symptoms
- The time when the patient recognizes this symptom or symptoms as in need of medical attention
- The time when these symptoms become severe enough for a patient or witness to seek treatment
- The time when the patient or witness seeks treatment

The paper will focus on all four phases, not just the last two, as most studies have done.

Finally, the writers will examine the extent of the problem of delay by examining data on delay times in ACS and stroke from national registries and large clinical trials and prehospital delay in sudden death or out-of-hospital cardiac deaths.

The writing group also will focus on the importance of early treatment in stroke, as well as in ACS, a direct result of recent recognition of stroke as another health problem for which prompt recognition and treatment can greatly reduce negative outcomes and promote optimal ones. Here too, the writers will point out the gains that patients can make by decreasing delay time and will note that the major impediment to early treatment is patient delay. The definition and four phases of treatment-seeking delay are the same for stroke as for ACS. To address the extent of the problem of delay here, too, the writers will look at data on delay times from national registries and large clinical trials.

The writing group will address the following concerns:

- *Factors associated with or predicting prehospital treatment-seeking delay in ACS.*
- Major categories of variables that affect delay of treatment: clinical, sociodemographic, cognitive, and emotional factors. To date, most studies have focused on the clinical and sociodemographic factors and largely ignored the social, cognitive, and emotional ones. The writers will review existing literature regarding the known categories of predictors of delay:

- Sociodemographic/clinical
 - Cultural/ethnic
 - Social
 - Cognitive and emotional, including knowledge
 - Health care provider (HCP) contribution to delay
- *Factors associated with or predicting prehospital treatment-seeking delay in stroke—the same ones as for ACS.*
 - *Differences between treatment-seeking delay in ACS and stroke.* Although there are common predictors across cardiovascular conditions, there also are differences among them. For example, the pathology of a stroke may render a patient cognitively incapable of making treatment-seeking decisions or physically unable to act.
 - *Interventions to reduce prehospital treatment-seeking delay in ACS.* The identified interventions will encompass community-based interventions, as well those focused on the individual patient and family.
 - *Interventions to reduce prehospital treatment-seeking delay in stroke, also encompassing community-based, patient-, and family-focused interventions.*
 - *Future directions.* The writing group will investigate:
 - Other relevant factors contributing to delay with a focus on potentially actionable ones
 - Novel interventions
 - Sudden death
 - New populations, particularly those who are most likely to delay treatment for symptoms of heart failure

Ms. Hand informed the meeting attendees that Dr. Moser would welcome any comments or suggestions regarding the writing group outline.

“ACT IN TIME TO HEART ATTACK SIGNS” CAMPAIGN: PROGRESS REPORT SINCE FEBRUARY 2002 AND DISCUSSION OF NEXT STEPS
[Mr. Win Morgan and Ms. Jill Arvanitis]

Mr. Morgan, Marketing Director for the National Heart, Lung, and Blood Institute Health Information Network, referring to the February 2002 Subcommittee meeting, reminded the group that its first priority area was the widespread dissemination and implementation of the “Act in Time to Heart Attack Signs” campaign materials—by the Subcommittee itself, by the Coordinating Committee as a whole, and by the individual member organizations of the Committee.

Now that the campaign had gotten under way, Mr. Morgan felt that it was time to bring the Subcommittee up-to-date on the campaign’s progress, to assess the feedback, and to talk about what the members could do to further promote the message and materials (see slides in

Attachment K). The first objective was for Committee members to distribute the campaign materials through their organizations' channels of communications and thus to provide these materials to key public education target audiences. Many groups have already achieved this goal. In fact, Mr. Morgan praised the various groups for having made the *Act in Time* campaign successful by getting the message out.

Dissemination by Partners

- The American Red Cross (ARC), for example, has provided sample materials and promotional flyers to all chapters nationwide, as well as small group discussion guides and lesson plans. Materials have gone out through ARC to the grass roots—to the people who need the information. Ms. Hand and Ms. Arvanitis attended a course given by Ms. Linda Burnett, manager of the wellness unit of the ARC national headquarters, for members at their worksite, with 30 men and women of mixed ethnic and racial backgrounds attending.
- AHA has integrated “Act in Time to Heart Attack Signs” materials into their Operation Heartbeat sites nationwide, distributing materials and using small-group discussion guides to get information out to people in the community.

One Subcommittee member, however, felt that there was not nearly as much enthusiasm for this campaign as there had been for the AIDS program. His feeling was that the benefit of the video would increase exponentially when showings were accompanied by a health professional to answer questions. Because busy working professionals wouldn't have the time to accompany the video to the numerous local sites, he suggested that retired physicians, nurses, and other health care workers might be willing and able to do the job. This idea was greeted with general approval among the Subcommittee members, many of whom then contributed ideas for getting in touch with these retired health care professionals: through retired physicians' associations, State contacts, local Red Cross chapters, State societies, AMA senior physicians' groups, ads in newsletters, and so forth.

Meanwhile, a number of additional organizations have already been busy helping to disseminate and promote the *Act in Time* campaign.

- The National Black Nurses Association has announced the campaign in its newsletter and thus sent the word out to 75 chapters throughout the country.
- Under the auspices of Dr. Atkins, the American College of Cardiology (ACC) has done an exemplary job of promoting the *Act in Time* campaign. In fact, the ACC was one of the first organizations to include an endorsement of the campaign on its home page and has also incorporated the campaign in its database of resource materials. Because ACC and other groups have put up links to the *Act in Time* Web site, the number of links has increased to more than 900.
- Dr. Charles Curry of the National Medical Association participated in a satellite media tour promoting the *Act in Time* campaign.

- Various organizations—among them the American College of Physicians Assistants (ACPA) and the American College of Preventive Medicine—have inserted *Act in Time* flyers into participants’ packets at conferences.
- The National Council on Aging has given a presentation at their conference, promoted the campaign on their Web site, strongly endorsed it at their chapter organizations, and printed a predisplay ad in their newsletter. (The display ad has since gone out electronically to Subcommittee members.)
- The Society of Chest Pain Centers and Providers (SCPCP) sent a cover letter with a promotional flyer to all the organization’s members. Also Dr. Lee Garvey, SCPCP representative, has, in partnership with the AHA, initiated a community outreach program, which has done very well.
- Mr. McGinnity of the American Academy of Physicians Assistants made a presentation at the academy’s annual meeting. Before the meeting, when the group sent out information packets to the participants, it included *Act in Time* promotional flyers.

A second campaign objective (1-b) was to get materials and promotional flyers to more than 100,000 health care professionals and facilities—patient educators, office-based cardiologists, and senior centers and services. Actually, the campaign surpassed its goals, reaching 117,000 since February 2002. The staff purchased, borrowed, and rented lists and mailed out promotional flyers; in addition, they went to a number of presentations or exhibits at conferences. Obstetricians/gynecologists and diabetologists were another campaign target (1-c), as these specialists often serve as the primary health care providers for women. The materials reached the Association of Women’s Health, Obstetric and Neonatal Nurses, which sent a promotional flyer with an endorsement cover letter to every member.

Less successful were requests to 185 editors of specialist journals and trade publications to publish drop-in articles, although some editors did agree to place free ads on a space-available basis. Mr. Morgan felt that the response might be better if the requests came directly from Subcommittee members.

NHAAP staff contacted the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) to place an announcement or article in its journal, to make a presentation at its national meeting (1-d), and also to contact directly more than 2,000 members by mail. In addition, the AACVPR put an announcement in its print and electronic publications.

The NHLBI worked with the American Association of Occupational Health Nurses (AAOHN) by direct mail and also with employers to reach nearly 13,000 managers of employee health-promotion programs. The AAOHN newsletter has published *A Matter of the Heart: What You Can Do To Educate Citizens About Heart Attacks*.

The AAOHN has initiated a partnership with Corporate Fitness Works, an organization running fitness programs for large companies; this partnership is reaching 250,000 employees with *Act in Time* materials.

A bonus objective was to persuade the major drugstore chains to distribute *Act in Time* wallet cards and, although less likely, possibly brochures. However, all the leads seemed to have gone cold, and Mr. Morgan requested help from the Subcommittee members in reaching the chains. One related suggestion was made to try to get in touch with the mail-order drug companies.

It was also suggested that the Public Broadcasting System (PBS) air the *Act in Time* video, then host call-in questions, and provide answers. PBS could syndicate the video, and it would thus reach even greater numbers of people.

In summary, more than a quarter million *Act in Time* materials have been distributed, including 110,000 wallet cards; 31,000 English-language brochures, back ordered, with 100,000 more recently printed and on their way into circulation; and 12,000 posters. The reference cards for physicians have not been in demand as much as the Subcommittee would like, and not many small group kits have gone out, but this is not very surprising, as people tend to use and reuse the kits many times. The patient action tablet, after a slow start, has generated more interest; hospitals particularly seem very interested in the tablet. And while only 750 videos have circulated by themselves, they also have gone out as part of the small group kits.

A total of 117,567 flyers have reached the public through various promotions; in addition, the Palm operating system program, on various shareware Internet sites, had been downloaded more than 4,000 times at the time of the meeting, with the numbers steadily increasing. The Palm program is a physician's quick reference guide for talking to patients about how to recognize heart attack signs and what to do about them, but patients also are downloading the program and using it to talk to their physicians. The program links back to the NHLBI Web site (<http://www.nhlbi.nih.gov>), to the *Act in Time* campaign.

Awards

All the above-mentioned educational materials have earned for the *Act in Time* campaign a number of communications awards, which Ms. Jill Arvanitis enumerated for the group:

- The Communicator Award for outstanding work in the communications field
- The Crystal Award of Excellence in the category of Marketing and Promotion for the overall campaign
- The Award of Distinction for the small group session kit
- The APEX 2002 Award in the category of Training and Information Campaigns and Programs for the small group session kit; and in the Special Purpose category for the patient action tablet. The purpose of the APEX awards is to recognize excellence in graphic design, editorial content, and the ability to achieve overall communications excellence
- The Silver Inkwell Award of Excellence for the overall campaign and a second award for the video, presented by the Washington, DC, Chapter of the International Association of

Business Communicators, with special thanks to Dr. Bruce MacLeod for his time serving as expert advisor on the video

- The 2002 National Health Information Silver Award for the overall campaign
- The National Institutes of Health Plain Language Award for the core brochure

The Partner Contribution Database and Other Electronic Materials

Mr. Morgan told Committee members that they would soon be receiving various *Act in Time* materials as e-mail attachments; these materials will include ready-to-publish drop-in articles, a PowerPoint presentation in a self-extracting Zip file, and a camera-ready public service announcement (PSA). Members may also request link text and banners if they wish. All these materials can be invaluable in disseminating the *Act in Time* message. Members can take the articles to the editors of their newsletters, the PSAs to their marketing directors, and the links and banners to their Web experts. Because of people's general reluctance to open e-mail attachments for fear of computer viruses, Mr. Morgan assured the Committee members that the e-mail attachments coming from his office would be screened for viruses.

Mr. Morgan also informed the group that he had set up a database to keep a record of what people have done to advocate for the *Act in Time* campaign. He asked Subcommittee members to reply to the e-mails and inform him of what they have done as individuals, committees, or organizations.

The group agreed that it would be beneficial to find out what impact the materials are having, through followup, but of course, funds for impact evaluations would be an issue.

NEW "ACT IN TIME TO HEART ATTACK SIGNS" MATERIALS [Ms. Hand and Ms. Arvanitis]

Spanish Small Group Lesson Kit

The campaign has put together a Spanish-language version of the video, using a Spanish-speaking physician and some Spanish-speaking actors portraying patients, along with a 1-hour lesson plan. Either a layperson or a health professional can give the lesson in any of a variety of settings—a church, a hospital, or some other suitable space.

The lesson can serve as an add-on chapter to augment a nine-lesson Spanish heart-health program given by *promotores* or lay health educators. The first nine lessons are on heart disease prevention. This tenth lesson, on heart attacks, was pilot-tested at the *promotores* network meeting in Texas in August. NHLBI staff member Matilda Alvarado took the lesson plan to the meeting, and two seasoned instructors delivered it. The *promotores* were very excited about it, and they will be working with the ARC, which wants to get into the Hispanic community.

Easy-To-Read Brochure

The main brochure containing the symptom and action messages, along with the risk factors, will be adapted to accommodate the interventions used in the REACT program in an

easy-to-read format. The investigators surrendered the copyright of materials, and *Act in Time* brochure writers looked at the findings and debunked the myth of the Hollywood heart attack. Although the REACT program did not reduce delay time, it did increase the use of 9-1-1, a secondary outcome measure, and it did point to educational needs.

Women's Brochure

The NHAAP plans to develop a brochure specifically for women about their potential heart attack symptoms because of the widespread perception that they are completely different from men's. Dr. George Sopko's workshop on Women and Ischemia Syndrome Evaluation (WISE), held by the NHLBI, addressed this issue. As a part of the workshop, Dr. Selker, Ms. Terry Long, and Ms. Mary Hand and several others, examined the research to see how different women's acute symptoms were from men's. The bottom line, according to large databases, is that there is a great deal of overlap in major presenting symptoms, including chest pain, although there were some differences in the proportion of women who had shortness of breath, for example. Women also tend to be more likely to have comorbid conditions and to be somewhat older than men when presenting with symptoms.

The women's brochure will summarize these findings and the NHLBI will be doing some other activities relating to the message in this program and in the NHLBI women's campaign, *The Heart Truth*. *The Heart Truth* is a strong, aggressive campaign aimed at women between the ages of 40 and 60. The objective is to give them a wakeup call at a time in their lives when their risk starts to increase—to talk to them seriously about their risk and tell them what they can do about it. This message would seem ideal for both campaigns.

A participant noted that heart disease seems to have become a far greater problem over the last 30 years. Last year, more than 460,000 women died of heart disease. However, only 20,000 were under the age of 65. In the 1960s, the average life expectancy was a mere 66; now it is in the mid-to-late seventies. The population age distribution has shifted, and now heart disease is affecting more women. The participant noted that we are seeing more heart disease in women as they are living longer.

Ms. Hand commented that many women see breast cancer as the disease that will "get" them, even though they have only a 1 chance in 9 of dying from it. But while women have a 1-in-3 chance of dying from heart disease, they simply don't see themselves as heart attack victims. When Ms. Terry Long conducted some focus groups for the women's campaign, she learned that women really didn't think the presence of risk factors—smoking, hypertension, and diabetes, for example—meant that they could have a heart attack; so when they did have symptoms, they did not see a heart attack as a possibility.

The Subcommittee expressed concerns about preparing healthy women for later recognition of serious symptoms. Often women in their thirties, forties, and fifties present with chest pain and show no evidence of disease when they are young. Could these pains relate to chest pain later in life when these women do have heart disease? Telling them not to worry may not be the best way to handle the situation, since they may at a later date have similar pains that have real significance.

Some focus group participants from the Rapid Early Action for Coronary Treatment Research Program reported that their doctors also spoke of the naïve belief that bypass surgery can “fix” heart disease. Thoracic surgeons play into these misassumptions by telling patients that they are fine after surgery, when in reality they have only taken care of one set of problems.

The Subcommittee agreed that physicians should try to give patients a list of all the things that would reduce their risk of heart attack and discuss strategies that would reduce angina. Patients need to know that obstructive coronary artery disease and death from infarction are two different things. Doctors should warn high-risk patients of their risk of a future cardiovascular event—such as people with preexisting coronary disease or angina, those who are postprocedure, or those with diabetes. Obesity is another risk factor, and it is a serious problem in this country; 65 percent of the population is overweight or obese.

ADJOURNMENT [Dr. Crumlish]

There being no further discussion, Dr. Crumlish thanked the members and adjourned the meeting.



National Heart Attack Alert Program

Health Systems Subcommittee Meeting

**October 28–29, 2002
Bethesda, Maryland**

**NATIONAL HEART ATTACK ALERT PROGRAM
HEALTH SYSTEMS SUBCOMMITTEE**

**Meeting Summary
October 28, 2002**

Subcommittee Members

Bruce MacLeod, M.D., F.A.C.E.P. (Chair)
Mary Beth Michos, R.N. (Vice Chair)
George K. Anderson, M.D., M.P.H., F.A.C.P.M.
J. Lee Garvey, M.D.
Wayne H. Giles, M.D., M.S.
Lawrence D. Jones, M.D.
Jay Merchant, M.H.A.
John Moore (Substitute for Lori Moore, M.P.H.,
E.M.T.-P.)
Jimm Murray
Daniel Stryer, M.D.
Thomas M. Wiley, LTC, M.C., U.S.A

Other Coordinating Committee Members

James M. Atkins, M.D., F.A.C.C.
Stephen Cantrill, M.D.
Diane Carroll, R.N., Ph.D.
Robert H. Christenson, Ph.D.
John G. McGinnity, M.S., P.A.-C.
Harry P. Selker, M.D., M.S.P.H.

NHLBI Staff

Mary M. Hand, M.S.P.H., R.N.

Contract Staff

Jill K. Arvanitis, M.P.H., C.H.E.S.
JoLane Thomas, M.F.A.

Guest

Alan Mertz

WELCOME AND INTRODUCTIONS [Dr. MacLeod and Ms. Michos]

Dr. MacLeod welcomed the group and introduced Mr. Alan Mertz, Executive Vice President of the Healthcare Leadership Council, Washington, DC (see page 9 in Coordinating Committee summary).

**The Effect of the Health Information Portability and Accountability Act
(Priority Area 4) [Mr. Alan Mertz]**

Mr. Alan Mertz began the discussion of how the Health Insurance Portability and Accountability Act (HIPAA) would affect access to care. The HIPAA regulations have progressed through three phases: law writing, regulation writing, and the current compliance phase. The compliance phase has been complicated by the fundamental structure of the original law. Mr. Mertz indicated that two approaches were possible for the construction of these regulations. The first option would have exempted from regulation, activities considered under the umbrella term of “health care operations,” in initial drafts of this legislation. The second option stated that every use and disclosure of health care information would be prohibited unless it was specifically listed in the HIPAA regulations. However, the number of consent

requirements necessitated by this approach was excessive. Yet this option was adopted by the Department of Health and Human Services (HHS), resulting in a 366,000-word document of allowable disclosure situations that has intimidated and confused most providers who have to use it. Those who provide immediate and/or emergency care (a group that includes many who provide care for people experiencing heart attacks) are especially concerned.

Hard-won modifications to the exclusionary options have resulted in more reasonable criteria: Health providers are now allowed to share information with other providers and pharmacists without obtaining prior consent, and information used for research purposes is exempt from HIPAA regulation if specific identifying factors have been removed.

Execution of some sections of the regulation will still present difficulties. First, the notification and recordkeeping requirements are complex. All information disclosed for research purposes must first receive a waiver from an Institutional Review Board (IRB) or another privacy board. Second, health care professionals affected by this regulation need additional information in order to comply properly. Finally, some Congresspersons favor a return to the original consent requirement format. In addition, it is always possible that the HHS could change the regulation in any particular year.

Mr. Mertz invited discussion concerning the compliance difficulties encountered by those who work in the field. A participant asked what the penalties were for noncompliance. Penalties are quite severe—up to \$250,000 in fines and 10 years in prison for intentional, willful disclosure and willful harm—and are enforced by the HHS and its Civil Rights Office. However, providers cannot be sued in State court for unlimited punitive damages. Mr. Mertz noted that the legal system and self-proclaimed HIPAA consultants have alarmed providers by underscoring HIPAA requirements based on the original exclusionary law.

Mr. Mertz said the reality is that the HHS currently is not equipped to monitor compliance. Although the HHS is training several hundred people in its regional Civil Rights offices to enforce the regulation, it is probably more likely to target larger institutions, hospitals, and insurance agencies than after individuals.

Dr. MacLeod asked which part of the health care system would be most affected by the cost of implementation. Mr. Mertz stated that only three entities are covered under the law: health plans, providers, and clearinghouses. Providers will be the most affected. In addition, the HHS has identified a category called “business associates,” which includes any individual hired by a provider to perform a function on his or her behalf. The provider is responsible for the use of identifiable information by any business associates. Providers must have a legal contract with each associate and are liable for any penalties incurred. Some providers, such as large hospitals, may have as many as 600 to 700 business associates with whom they are required to contract in this manner.

Dr. Harry Selker (who participated as an observer at the meeting) inquired about the relationship of the regulations to entities in the public domain, such as emergency medical services (EMS) and 9-1-1 operations, which often identify patients. In his view, HIPAA may be in conflict with the Open Records Act. Mr. Mertz responded that it was this exact situation that led to the creation of a category of excluded communications referred to as “inadvertent

disclosure.” Originally, the HIPAA regulation covered not only written communications but also oral communications (including radio transmissions). Therefore, under this regulation, notifying a paramedic or an ambulance service that a patient needed services would involve an illegal disclosure of information. The establishment of “inadvertent disclosure” allows the use of personal information in the course of treating the patient, when the disclosure is incidental.

Mr. Mertz explained that the inadvertent disclosure statute covers a multitude of communications that occur within the treatment setting. This statute alleviated many concerns that the regulation would interfere with daily operations and thus with patient care and patient safety. A participant confirmed concerns about patient safety, relating the situation of a hospital removing identifying names from patients’ rooms and monitors, which compromised patient safety and resulted in incorrect medications being given to three different patients.

The Subcommittee discussed the problem of open records requests by the news media in the context of the new HIPAA guidelines. The Open Records Act gives the news media the right to know the actions taken by a Government entity. Although some information is made public (i.e., fire department logs published in small-town weekly papers), it is unclear how HIPAA regulations relate to the Open Records Act. Mr. Mertz agreed that this area needed additional investigation.

A participant raised the question of information sharing that falls within the purview of public health. Mr. Mertz responded that any kind of reporting to a Government body (i.e., required reporting to the Centers for Disease Control and Prevention or a public health department) is a permissible disclosure. Also, any information relevant to outcomes, epidemiology, or disease tracking is exempt, and any voluntary reporting of adverse events resulting from any kind of device or pharmaceutical product or equipment is allowed. The original regulation stated that information could be disclosed only to the manufacturer if it was mandated or required by the Food and Drug Administration. Because adverse event reporting is generally voluntary, the regulation was changed to accommodate this situation. A participant asked about State-mandated police notification of gunshot wounds, child and elder abuse, or assaults. Mr. Mertz said that any kind of law enforcement reporting or disclosure is allowed, but it is advisable for providers to keep accurate records of these disclosures.

Dr. Selker raised a question concerning the development of an EMS registry for the City of Boston. The program follows patients from hospital to hospital to see where cardiac catheterizations are being performed and records the response times from the streets to each hospital. A central database exists and is necessary for quality improvement (QI) and public health purposes. The individual IRBs consider this a QI project and, therefore, exempt, although identifiable information is included. Mr. Mertz responded that this appeared to be quality outcomes research in health care operations and thus fell under the exempt category. Registries specifically are allowed to include identifiable disclosures. However, any type of clinical research (i.e., a clinical trial) requires informed consent. This is why, as a rule, clinical trial consent forms include an authorization to use the information. Not all types of trials are amenable to waivers of consent, and these situations must be evaluated by individual IRBs, who have four criteria to consider. Mr. Mertz indicated that he would provide this information at the full meeting the following day.

Mr. Mertz asked for suggestions regarding possible recommendations to the HHS to educate providers and dispel myths regarding HIPAA. A participant related that little help had been offered by the Federal Government, forcing providers to hire HIPAA consultants to ensure compliance. No focus exists at the Federal level to provide information for various types of medical services. Mr. Mertz replied that the HHS is planning to have a checklist for providers available on its Web site in time for the April compliance date, and this is expected to improve the situation.

Participants inquired about what would happen if compliance is not possible by the April date. Could the first year be considered an “education phase,” without penalties? Mr. Mertz responded that this possibility had been suggested to the HHS but was rejected. The HHS will continue to educate providers but will not consider a moratorium on penalties.

A question was raised concerning registries held by and for the advantage of private corporations, such as pharmaceutical companies. Participants agreed that the information residing in private registries is important. Mr. Mertz stated that private registries were allowed and, in fact, had been instrumental in helping persuade the HHS that revision of the regulation was necessary. In particular, the Genentech registry was instrumental in convincing the HHS that waiving the authorization requirement allowed pharmaceutical companies to contact and treat patients with advanced disease when new treatment modalities were identified.

REVIEW OF REVISED HEALTH SYSTEMS SUBCOMMITTEE PRIORITY AREAS [Dr. MacLeod and Ms. Michos]

Dr. MacLeod reviewed the four quality-improvement priority areas that have been identified for the Health System Subcommittee (see slides in Attachment L). Priority area 1 is EMS utilization. Objectives include:

- Identifying the inappropriate barriers to accessing EMS and recommending, evaluating, and improving the system
- Assembling the Rapid Early Action for Coronary Treatment EMS publications by June 2003
- Convening a stakeholders’ meeting to engage in problem solving activities related to underuse and optimal use of EMS by patients with possible acute cardiac symptoms
- Research and demonstration projects based on the first two subgoals

Priority area 2 is the use of evidence-based technologies by the health care system. Objectives include conducting a literature review to identify technologies and strategies that positively affect the outcomes of patients with acute coronary syndromes (ACS) and that are currently underutilized (was due October 2002) and producing a best systems practice paper by June 2003.

The third priority area is QI, and its objectives include reviewing and shaping national quality-improvement efforts related to the management of patients with ACS. Activities will include contacting three quality-improvement organizations to propose quality measures for the care of ACS patients. The second objective involves identifying gaps that may exist in the care of patients with ACS through the completion of the first objective by June 2003.

Other objectives relevant to this priority area are:

- Including existing initiatives (i.e., CRUSADE, American Heart Association's (AHA's) Get With the Guidelines (GWTG), American College of Cardiology's (ACC's) Guidelines Applied in Practice (GAP), and others) to promote quality-improvement measures
- Including race, ethnicity, socioeconomic status, and gender analyses
- Developing a minimum of one new quality measure based on the second objective by June 2003

The fourth priority area is a review of HIPAA regulations.

Objective 2a, which refers to reviewing the literature to identify technologies or strategies that positively affect outcomes of patients with ACS, was due in October 2002 and mirrors the technology review completed by Dr. Joseph Lau and the Science Base Subcommittee earlier this year. Dr. MacLeod noted that this effort entailed a review of the accuracy of technologies for diagnosing patients with acute cardiac ischemia in the emergency department (ED) and their clinical impact when used in this setting. The Health Systems Subcommittee will attempt to assess the extent to which technologies with the strongest evidence base are underutilized. A white paper on this issue will be completed by June 2003; the Subcommittee is looking for an individual to take the lead in organizing a writing group to develop a first draft of the white paper. Dr. MacLeod summarized the objectives that are due to be achieved and reported on by June 2003:

- 1a. Written overview on barriers to the use of EMS by patients with acute cardiac ischemia.
2. Summary of evidence-based technologies positively affecting the outcomes of patients with ACS.
- 3b. Completion of contact with three quality-improvement organizations to propose quality measures for care of patients with ACS. Following this, the subcommittee will identify gaps in the care of patients with ACS.

Additionally, 1b, the stakeholders' meeting, is slated for October 2003 or February 2004 and is in need of an individual to assume leadership of the task by June 2003. Following the stakeholders' meeting, recommendations will be made about the need for possible demonstration projects. The primary challenge for the Health Systems Subcommittee is to maintain momentum towards accomplishing objectives between subcommittee meetings and to identify volunteers to staff the efforts.

QUALITY IMPROVEMENT (*Priority Area 3*)

CRUSADE: A National Quality-Improvement Initiative [Dr. Robert Christenson]

Dr. Christenson of the American Association of Clinical Chemistry began the discussion of this priority area with a presentation about CRUSADE: Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines? (See slides in Attachment M.)

Between 1975 and 1997, the inhospital mortality rate for patients with ST-segment elevation had been almost halved, from 24 percent to about 14 percent. However, the ACS mortality rate has remained about the same. The objectives of CRUSADE are:

- To determine the current state of awareness and adherence to evidence-based guidelines that were developed for non-ST-segment elevation myocardial infarction (NSTEMI) patients
- To implement quality-improvement initiatives to promote these recommendations
- To improve clinical outcomes for NSTEMI patients via early risk stratification and implementation of evidence-based care

The CRUSADE initiative is national in scope (including more than 400 hospitals) and has as its overarching goal the fostering of relationships between emergency medicine, cardiology, hospital quality-improvement initiatives, academia, and industry to encourage the use of AHA/ACC guidelines by clinicians. Most importantly, CRUSADE is a quality-improvement initiative to optimize risk stratification for the NSTEMI group.

Patients are first evaluated for inclusion into the high-risk NSTEMI group. A patient qualifies for inclusion if he or she has experienced ischemic symptoms lasting more than 10 minutes and less than 24 hours, with at least one of the following:

- Cardiac markers—creatinine kinase-myocardial band (CK-MB) or troponin assay (TnI/TnT) above upper limit of normal (ULN) or positive bedside troponin assay
- Dynamic ST-segment electrocardiogram (ECG) changes (ST-segment depression greater than 0.5 mm or transient ST-segment elevation of 0.6 to 1.0 mm lasting less than 10 minutes)
- If a transfer patient, arrival at a CRUSADE-participating hospital within 24 hours of onset of symptoms

Data collection involves the use of a concise, three-page form that obtains retrospective information (patient risk factors and presenting symptoms, use of medications, use of invasive procedures, and inhospital clinical outcomes) and includes a payment of \$21 per form returned. This form should not require informed consent and should be viewed by the local IRB as a quality-improvement initiative. However, each IRB should make its own determination.

The primary endpoints considered are the effectiveness of quality-improvement initiatives as measured by changes in adherence to AHA/ACC treatment guidelines. Experts agree that these treatments help patients, but in many cases they are not utilized appropriately. Identified endpoints include:

- Early discharge/aspirin and clopidogrel use
- Early discharge/beta blocker use
- Discharge/ACE-inhibitor and statin use
- Glycoprotein IIb/IIIa inhibitors/early use and during percutaneous coronary intervention (PCI)
- Early invasive management (use of catheterization/PCI/coronary artery bypass grafting (CABG))

- Appropriate secondary prevention measures, including smoking cessation and cardiac rehabilitation

Several patient-identification strategies have been suggested. In EDs, these include prospective identification of patients, including cooperation with research coordinators who are in search of patients to enroll in clinical trials, and review of daily admission logs. Screening also should be done after hospital admission through review of coronary care unit (CCU) or telemetry floor admission logs and daily catheterization laboratory schedules. It is important to develop triggers for CCU/telemetry floor nurses to identify patients for CRUSADE. Finally, screening after discharge should include review of the discharge diagnosis for chest pain and review of all patients with elevated cardiac marker levels from laboratory records. The goal is to reach the largest spectrum of patients available.

Additional quality-improvement initiatives include regional education meetings to examine the ACC/AHA guidelines and review the QI initiative and site surveys to assess site beliefs and practice environment. A Department of Veterans Affairs Medical Center will be different from a community hospital in these areas, but similarities also can be identified, especially among ST-segment elevation patients and what are considered appropriate treatments. The development of educational QI materials has included an ED risk stratification algorithm and sample orders, guideline posters and pocket cards, and discharge doctor and patient checklists. Also, the development of a Web site and a toolkit for use at individual sites has been suggested.

Perhaps the most important component of the project design is the quarterly feedback reports. These reports enable sites to compare themselves to other similarly sized and typed institutions and identify areas for improvement. Feedback for physicians is considered an effective way of changing behaviors and obtaining improved adherence to the guidelines.

The emergency medicine and cardiology physicians at each site act as advocates for CRUSADE. They must develop new strategies to identify high-risk NSTEMI patients early during hospitalization and to implement QI tools to promote the ACC/AHA guidelines. The toolbox includes acute care performance indicators and a discharge form with the question, "Do you know the warning signs and symptoms of a heart attack and the actions to take if they occur?" Certainly, the cooperation of QI nurses and research coordinators will be essential for the completion of case report forms and assistance in educational efforts.

The CRUSADE project will provide a great deal of information about why current AHA/ACC treatment guidelines for ACS are not followed. Why is it that the evidence for the success of these measures is so strong, and yet practitioners are not following them? What initiatives can improve adherence, and how can emergency medicine/cardiology collaborations be promoted? Initial findings from CRUSADE data have been interesting. At discharge, 40 percent of patients with low ejection fraction, diabetes mellitus, or hypertension failed to receive an ACE inhibitor; 23 percent of patients with hyperlipidemia failed to receive a lipid-lowering drug; 10 percent of patients failed to receive aspirin, and 42 percent of current smokers did not receive smoking cessation counseling. These findings underscore the need for this project.

This study also lends itself to followup of laboratory turnaround times for biochemical markers. There is evidence that earlier treatment will benefit these patients, and the National Heart Attack Alert Program (NHAAP) has set a laboratory turnaround time goal of 30 minutes for ACS patients in its “4 Ds”—door-to-patient presentation, data (ECG), decision (about treatment), and drug therapy—guidelines. Identification of the usual laboratory turnaround times through the use of a simple time-record sheet may clarify areas for improvement. Serial sampling is also important, so patients do not become victims of kinetics.

In summary, the CRUSADE program collects data as part of this registry, views the results, implements the interventions and education, monitors progress, and provides staff with feedback on that progress. It is hoped that the outcome will be a drop in patient mortality. Dr. Christenson invited conference participants to visit the CRUSADE Web site (www.crusadeqi.com).

TECHNOLOGIES AND PROTOCOLS FOR MANAGEMENT OF PATIENTS WITH ACS (*Priority Area 1*)

[Subcommittee Discussion]

As the discussion began, a participant observed that it is one thing to educate practitioners, but it is quite another thing to get them to act on their new knowledge. Dr. Christenson observed that the GWTG group and CRUSADE are working together to address this problem.

Another participant stated that although there was evidence that the use of biochemical markers improves care, there was little evidence that the use of these markers to identify patients in the ED would be successful. In fact, the reliance on a negative troponin laboratory finding is misleading. Patients with low troponin may be sent home, even though it is possible that they are having a heart attack. Thus, the use of biochemical markers could lessen the quality of care and even cause deaths. Dr. Selker suggested that troponin testing be delayed until the decision has been made to admit the patient to the hospital. Dr. Christenson agreed that troponin levels are not standardized throughout the country. A positive result at one institution is not necessarily considered positive at another. Much more needs to be learned about the relationship of troponin levels to ACS. However, CRUSADE is focused on the unstable ACS patient, for whom the data on diagnosis is clearer.

Ms. Hand was asked if, with the emphasis of the National Heart, Lung, and Blood Institute (NHLBI) on the translation of information that is known to provide useful results, there were resources that the Institute might offer on how to address this issue. She replied that this dilemma was much of what this Committee was about: looking at evidence for use of this test and its appropriate utilization. However, the question remains: Can clinical implementation be encouraged once guidelines are issued and a report produced? CRUSADE offers a more comprehensive approach to the institutionalization of best practices. The NHLBI’s Division of Epidemiology and Clinical Applications is concerned with research and its translation. A participant suggested the Cochran synthesis of the evidence on interventions to improve practice as a resource. The third version of the Preventive Services Task Force has also struggled with this problem. Another participant suggested that a discussion with experts on this topic might be

considered for future meetings. In general, participants agreed that providing tools for feedback to physicians is the most effective way to encourage new technology for implementation and to reduce implementation time. The use of a risk management approach to encourage implementation can be effective, but it is slow and is dependent on the many variables and personalities involved. The Centers for Medicare and Medicaid Services has taken this route, utilizing State peer review organizations and then providing feedback to risk management personnel.

Additionally, the challenge of sustaining behavioral change must be addressed. Whenever a system of delivery is involved, more pressure is needed to maintain the behavioral change. At the institutional level, required checklists improve compliance. This has been demonstrated in the aviation industry, which has mandatory behavioral guidelines. This guideline infrastructure has produced geometric, downward statistics that are sustainable. What instituted this structure, however, was mandatory legislative mandates for behavioral change. Medicine does not have legislated protective measures that allow for disclosure of mishaps without punitive measures placed on the people involved. This is significantly different from the Federal Aviation Administration or National Transportation Safety Board models.

Members of the panel agreed that checklists are a positive method for standardizing care. A strict “cookbook” approach is not the aim; rather, a system that allows the user to augment, change, or adapt treatment based on knowledge and experience is preferred. However, it is unnecessary for every institution to devise its own checklist. Checklists for representative clinical pathways are available, as demonstrated on Dr. Christopher Cannon’s Web site. Although new research data often render guidelines obsolete, it is possible to provide practitioners with data that are, for example, up-to-date for the past month. These materials need to be widely disseminated to the average physician who may be unaware of the most current clinical recommendations.

A participant noted the existence of extensive literature assessing the impact of clinical guidelines on practice, and in general, it has been found that they have no impact. It is important to be realistic about what really works. The programs that do work are focused on very small areas, such as the NHAAP. The NHLBI has recently funded eight studies on implementation strategies, which may provide important information in the future. However, enough data currently exist to determine what works and what does not. Acquisition of a speaker familiar with this topic was suggested for a future meeting.

A major challenge is obtaining institutional buy-in to a program of change. CRUSADE or any other program will be only as effective as the institution’s reaction to it. Many people will be reflective about new measures, but if the audit and feedback are removed, the changed behaviors will backslide. It is imperative for the institution to systematize the change. Another participant volunteered that physicians are often very suspicious of studies that are supported (either overtly or covertly) by drug companies. It is vital that physicians respect the data that they receive, and consider them without bias. This is another challenging aspect for achieving compliance.

REPORT ON THE HEALTH PLAN EMPLOYER DATA AND INFORMATION SET CARDIOVASCULAR MEASURES [Dr. MacLeod and Ms. Hand]

Dr. MacLeod stated that a possible strategy to achieve system change is to implement measurement in some way. He asked Ms. Hand to update the Committee on the National Committee for Quality Assurance (NCQA) and the Health Plan Employer Data and Information Set (HEDIS) group.

Ms. Hand informed participants that she and Dr. MacLeod had recently spoken with Dr. Joachim Roski, Assistant Vice President of Quality Measurement and Research for the NCQA. One of the NHAAP's objectives is to revisit whether this Subcommittee can get a HEDIS measure that will help improve some aspect of patient care related to patients presenting with ACS. Three measures from this Subcommittee were submitted to the NCQA in 1998, but they were turned down. The NCQA did not believe that those measures, which included ED admissions and followup of patients discharged from the ED, were within their purview. Dr. Roski reviewed some of the NCQA's current cardiovascular measures, which address hypertension management, appropriate low-density lipoprotein screening and levels, beta blocker treatment following a heart attack, smoking cessation advice, and a variety of diabetes-related measures. The NCQA is currently field-testing a measure for beta blockers for patients discharged with congestive heart failure and one looking at the quality of anticoagulant management. A Measurement Advisory Panel will convene soon to deal with cardiovascular measures. The first phase of this panel will deal with ready-made, tried-and-true measures, and the second phase will consider measures that are less easily quantified and involve development. This second set of measures will have to be meaningful and feasible to collect in terms of importance and cost.

Dr. Roski emphasized that HEDIS focuses on accountability in the health care system and attempts to determine to what extent the system is achieving it. One indicator that the Subcommittee had previously submitted, involving counseling high-risk patients about heart attack symptoms and action steps in the managed care setting, was revisited with Dr. Roski. However, no data exist that show this intervention with patients is effective (in terms of outcomes), so the measure did not meet NCQA criteria.

Dr. Roski discussed with Ms. Hand and Dr. MacLeod a voluntary program called the Heart and Stroke Recognition Program, in which physicians can receive recognition for superior cardiovascular care. Providers in this program measure performance for 8 to 10 measures, and if they exceed performance standards, they receive an award. The measurement criteria are similar to HEDIS measures. Dr. Roski was asked whether minimum standards could be set to encourage physicians or health care providers to apply these measures. This was not considered an option. He was also asked whether administrative data could be reviewed (e.g., emergency room visits, primary care physician visits) to determine situations in which access to care was available, but the proper diagnosis or treatment was not made in a timely manner. Dr. Roski stated that because HEDIS is mainly focused on the non-CMS population, the statistical power might not be sufficient in this suggested administrative approach. He was open to future discussions, however.

Dr. MacLeod requested input from the Subcommittee regarding the need for a measure and regarding what such a measure should be. The question was raised as to whether the measure must be evidence-based and actionable, in that the intervention will actually improve survival rates. A provider may have a given rate, and the system may have a higher rate; the goal would be to bring them both within the norm. However, there may be qualities of the system that affect the rate that cannot be changed. Will it still be possible to change the rate? The NCQA will not adopt a measure until this question has been addressed.

If the rate is an aggregate of many different factors, these factors may require breakdown into their subelements in order to determine what, why, and how rates are being affected. Ultimately, NHAAP measures are different from HEDIS in that they involve quality management. Thus, NHAAP data sets may be more difficult, but not impossible, for application of HEDIS-determined measures.

A participant noted that each year 26,000 people presenting at the physician's office or hospital with heart attack symptoms are sent home without the correct diagnosis. This is a significant number, even though the percentage rates are small, ranging from 1 or 2 to 10 or 11 percent per hospital. It may be difficult to reduce a 2-percent level, but 11 percent is a different story. It is also disturbing—because research has shown that they are twice as likely to die if they are sent home—that younger women, African-Americans, and people with more scripted presentations were more likely to be sent home. In addition, the cost to the hospitals in terms of malpractice awards is significant.

The panel agreed that the problem is a data-collection issue. What is the rate of missed heart attacks? It is possible that the health insurance plans have a system that can find the people that were missed. The insurance companies have the capacity to conduct followup to determine whether the person was seen in the emergency room and whether the person was later hospitalized or died. What data would be important? Suggestions were an ED visit with death or rehospitalization within 30 days or collection of information from the point 72 hours prior to the death or rehospitalization. It is unclear what the minimally acceptable interval would be. However, it is clearly important to reduce the 10- or 11-percent rates that some hospitals are reporting.



National Heart Attack Alert Program

**Science Base
Subcommittee Meeting**

**October 28–29, 2002
Bethesda, Maryland**

**NATIONAL HEART ATTACK ALERT PROGRAM
SCIENCE BASE SUBCOMMITTEE**

**Meeting Summary
October 28, 2002**

Subcommittee Members

Joseph P. Ornato, M.D., F.A.C.C.,
F.A.C.E.P. (chair)
Robert J. Zalenski, M.D., M.A. (vice chair)
Stephen V. Cantrill, M.D.
Arthur A. Ciarkowski, M.S.E., M.B.A.,
M.P.A.
Robert H. Christenson, Ph.D.
Charles L. Curry, M.D.
Gerald DeVaughn, M.D., F.A.C.P.
Bruce A. MacLeod, M.D., F.A.C.E.P.
John G. McGinnity, M.S., P.A.-C.
Robert A. McNutt, M.D., F.A.C.P.

Harry P. Selker, M.D., M.S.P.H.
Pamela Steele, M.D., M.P.H.
Daniel Stryer, M.D.

NHLBI Staff

Mary M. Hand, M.S.P.H., R.N.

Contract Staff (Prospect Center)

Jill K. Arvanitis, M.P.H., C.H.E.S.
Jo Lane Thomas, M.F.A.

WELCOME AND INTRODUCTIONS [Dr. Joseph Ornato and Dr. Robert Zalenski]

Dr. Ornato welcomed the participants and asked them to introduce themselves. He informed the Subcommittee that Dr. Elliott Antman, Director of the Coronary Care Unit at Brigham and Women's Hospital in Boston and Chair of the Writing Committee to Develop New American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (MI), would be joining the meeting via conference call.

**REVIEW OF THE SCIENCE BASE SUBCOMMITTEE PRIORITY AREAS
[Drs. Ornato and Zalenski]**

Dr. Ornato began the review of the Science Base Subcommittee priority areas by reminding the Committee that although tentative timelines had been set, these timelines were flexible (see slides in Attachment N). The work on several of the priority areas is progressing as planned; the proposed work for others appears to have been somewhat ambitious.

The first priority area has as its goal the identification of technologies and protocols that assist in risk stratification, diagnosis, and early treatment of acute coronary syndrome (ACS) patients, especially those who have non-ST-elevation MI. The first objective under this priority area is a review of the literature relevant to important clinical trials and technologies for risk stratification of patients with ACS and the identification by October 2002 of implications and actions for the National Heart Attack Alert Program (NHAAP) mission. This literature search is in its final stages and should be ready for distribution shortly. The second objective is a review

of the literature regarding important clinical trials and technologies to identify interventions or strategies that are time-dependent for ACS diagnosis and treatment, as well as implications and actions for the NHAAP mission. This review also is progressing.

Priority area 2 is the application of current strategies and new technologies in order to empower patients with patient-based/provider-supported solutions to recognize and respond to heart attack/ACS symptoms. In essence, this issue is the early recognition of ACS. Originally, the National Library of Medicine (NLM) and the NHAAP Coordinating Committee, including the Department of Veterans Affairs, planned to sponsor a meeting by October 2002 or as soon as the NHAAP informatics contracts projects are finished, so that they could be incorporated into one review to be discussed at a meeting dedicated to the field of patient-based decision-support aids. Currently, the NLM–Heart Attack Alert contracts will be featured at an NHAAP Coordinating Committee meeting in early 2004. There is no activity to report on this priority area.

Priority area 3 is the establishment of an ACS patient surveillance database in the 4,200 Emergency Departments (EDs) in the United States to capture real-time acute cardiac-related, symptom-specific data and outcomes. This database will be superimposed on a planned public-health surveillance system that will monitor cases associated with exposure to biological, chemical, and nuclear weapons of mass destruction and that is expected to be in place by 2004. NHAAP staff and selected members of the Science Base Subcommittee would participate in this initiative by conducting an environmental scan of existing disease surveillance initiatives in the Government by 2002, to provide information on possible NHAAP actions to promote the ACS ED surveillance database. The Subcommittee expressed for the record its hope that Dr. Daniel Pollack, the Centers for Disease Control and Prevention (CDC) contact for this project, would attend the next meeting.

The final priority area is Sudden Cardiac Death, which is intended to monitor and support the Post-Resuscitation and Initial Utility in Life-Saving Efforts (PULSE) effort, translate and disseminate the Public Access Defibrillation (PAD) trial results, and develop priorities for future cardiac-arrest research. One of the goals of this priority area is to identify liaison representatives from both the PULSE Steering Committee to the NHAAP Science Base Subcommittee and from the Science Base Subcommittee to the PULSE Steering Committee. A liaison still needs to be identified; any interested subcommittee members were urged to contact Dr. Ornato or Dr. Zalenski. The PAD trial is still ongoing and is likely to continue until September 2003. One interim analysis has already occurred, and an extension was granted based on accrual and survival data.

TIME-TO-TREATMENT RECOMMENDATIONS FOR THE INITIATION OF REPERFUSION TREATMENT: DISCUSSION ABOUT THE FRAMEWORK OF THE ACC/AHA GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH ST-ELEVATION MI (STEMI) [Subcommittee]

Dr. Antman joined the subcommittee meeting via teleconference to discuss the American College of Cardiology (ACC) and the AHA Guidelines for the Management of Patients with ST-Elevation MI, specifically the draft time-to-treatment recommendations (see slides in Appendix O). He first reviewed the evolution of guidelines for ACS. In 1990, guidelines for

acute myocardial infarction (AMI) did not distinguish between ST elevation and non-ST elevation MI. By 2000, the ACC and AHA had divided STEMI and non-ST-elevation MI (the latter including unstable angina) into two separate guidelines. The 2000 effort was recently updated (2002), and a summary article on non-ST-elevation MI has been published. (See “Evolution of Guidelines for Acute Coronary Syndromes—slide 1.)

Dr. Antman next discussed the current time-to-treatment strategies and timeframes in the current STEMI draft guidelines. He explained that it is important to identify the timeframe in which the provider interacts with the patient. The guidelines include sections that acknowledge the importance of primary and secondary prevention; however, the greatest concern of those in the field is the problem of delay to treatment, including patient delay, prehospital delay, and ED/hospital/transfer delay. (See slide 2.) Much reference has been made to “the golden hour”: the importance of timing with respect to symptom onset and initiation of reperfusion treatment. For the majority of patients, this timeframe more realistically is 90 minutes or less. However, with the advent of new technology and the opportunity for transmission of the electrocardiogram (ECG) by emergency medical services systems, the administration of therapy in a prehospital setting is a realistic possibility. Prehospital treatment has the potential of moving the field closer and closer to the time at which the event actually occurs.

From various clinical trials (slide 3), Dr. Antman reviewed the composite endpoints that illustrate differences between thrombolytic treatment versus transfer for percutaneous coronary intervention (PCI). Data that favor fibrinolytic reperfusion methods (lowered rate and reduction of recurrent MI) are seen in contemporary trials, such as the Assessment and Safety Efficacy of New Thrombolytics (ASSENT III) (2.7-percent recurrence) and the Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO V) (3.5-percent recurrence). Much of the benefit that is observed for reperfusion is from comparing the higher recurrence rates found with the use of other methods (6.3 percent for the Danish Multicenter Randomized Study on Thrombolytic Versus Acute Coronary Angioplasty in Acute Myocardial Infarction-2 (DANAMI-2) and 8.8 percent for the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) (which examined thrombolytic therapy versus primary percutaneous coronary intervention for MI in patients presenting to hospitals without onsite cardiac surgery) and bringing them into the lower ranges reported in trials with straight pharmacologic reperfusion. The rate of urgent PCI is lower in some trials than in others; this may be due to the randomization of patients to other types of treatment, such as fibrinolytic therapy.

Dr. Antman told the Subcommittee that four areas are assessed when a reperfusion pathway for ST-elevation MI is developed. First, how much time has passed since the onset of symptoms? Second, what is the risk from MI that the patient is experiencing (i.e., size and location of the infarction)? Third, what is the risk of administering lytic therapy to this patient? Fourth, how long will it take to deliver the patient to a skilled PCI center and initiate treatment? After answering these questions, one of two treatment arms is selected. (See slide 4.) The first arm, fibrinolysis, is immediately followed by noninvasive risk stratification, including a 12-lead ECG. Patients treated with fibrinolysis whose symptoms are not resolved are crossed over to the second treatment arm (“rescue”), mechanical revascularization at a PCI center. Also, ischemia-driven symptoms would necessitate a crossover to the PCI arm. Finally, crossover to mechanical revascularization later in the timeframe also is a possibility. This option, which is labeled “routine” and may occur early or late in the timeline, is still considered investigational. If PCI is

the treatment of choice following evaluation of the questions, transport delay to the PCI center must be taken into account. The ideal timeframe is considered 60 minutes from the onset of symptoms for thrombolytic treatment and 90 minutes from the onset of symptoms to PCI. However, all four areas must be considered before deciding on a treatment arm, even if a patient has delayed contact with the emergency medical system from the time of onset of his or her symptoms.

The guidelines are intentionally vague regarding whether the thrombolytic treatment can be administered in the field or should be administered only in the ED. First, the timeframe, including the time from the onset of symptoms and the time to ED, must be considered. Second, the skill needed to administer these treatments in the field (including the ability to complete and transmit an ECG to a medical center) is an important factor. Dosing requirements and inappropriate administration of the thrombolytic treatment to patients who are not having an MI raise concerns. In addition, the mortality risk of each patient will determine the risks and benefits of the particular interventions.

Is it possible to create a set of criteria for a prehospital, licensed thrombolytic system? Dr. Antman proposed that three criteria be met before the answer can be affirmative: (1) an emergency medical services (EMS) team that has undergone training in prehospital thrombolytics, (2) the capability of transmitting an ECG to a medical center, and (3) a medical control review (online medical command) that can authorize the thrombolytic administration in the field. These criteria were successfully used in a previous clinical trial; it was possible to implement them, save time, and ensure a reasonable safety factor.

Dr. Bruce MacLeod considered these requirements a satisfactory minimum baseline consideration but was concerned with cost-effectiveness and risk/benefits. Hospital medical directors may be reluctant to embrace this system. However, it is important to see whether adequate experience and expertise levels in the field to accomplish this system are possible.

Dr. Arthur Ciarkowski questioned the logistics of storing thrombolytics in EMS units. Most thrombolytics have an expiration date of at least a month, and EMS personnel are required to check their drug boxes on a regular basis to make sure that medications have not expired. Will there be enough prevalence of disease so that the medications will be used in a month's timeframe? This is an additional question to consider.

Dr. Antman discussed the Comparison of Angioplasty and Prehospital Thrombolysis In Acute Myocardial Infarction (CAPTIM) trial. The CAPTIM trial evaluated prehospital thrombolysis versus referral for PCI. All of the other trials mentioned have involved in-hospital thrombolysis versus PCI. The mortality rate at American sites was lower for the prehospital thrombolysis group compared to the PCI group. However, the CAPTIM report was accompanied by a strongly worded editorial by Dr. Gregg Stone, who argued that it was quite clear that the preferred treatment path was primary PCI, with the recommendation that patients with ST-elevation MI should receive pharmacologic treatment (e.g., aspirin or other medications) and be entered on a transfer pathway to PCI. The window for enrollment in the CAPTIM trial for PCI was 180 minutes, although most patients received treatment before this. On the basis of this study, Dr. Antman put forward the notion that this timeline of 3 hours might be adapted for the guidelines; 60 and 90 minutes are "ideal" but may be overly aggressive.

Dr. Cantrill addressed the change in the group's philosophy regarding thrombolytic treatment. In the past, this Subcommittee has been strongly pro-lytic; there now appears to be a preference for PCI. Dr. Antman responded that it was an integrated decision, involving the specific medical condition of the patient, the availability of trained EMS personnel, and the time factor. The decision tree is not strictly adherent to predetermined times or pathways, due to the complexity of each situation.

Dr. Cantrill also emphasized that the timeline proposed in the guidelines should be supported by the data; otherwise, the credibility of the guidelines will be suspect. Dr. Antman said that there were strong data supporting a 60-minute timeline for thrombolytic therapy. The 90-minute timeline for PCI is more questionable, although data exist that have not yet been published from the DANAMI-2 study to support the 90-minute PCI time limit. Dr. McNutt offered that there was an unpublished review available that considered the timelines for various reperfusion trials that indicated that many organizations had difficulty getting patients to treatment within the desired time. Therefore, any timeline also must reflect realistic situations. Dr. Antman expressed interest in reviewing these data.

Dr. Antman emphasized that the centerpiece of the guidelines would be a discussion of how to select the reperfusion strategy. The guidelines also should reflect the differences in delay time and tradeoffs that pertain to overall mortality. The Subcommittee was asked to submit any additional comments or suggestions to Dr. Antman in writing.

PRODROMAL SYMPTOMS AND MI: THE USE OF THE RAPID EARLY ACTION FOR CORONARY TREATMENT DATABASE TO REFINE THE EVIDENCE BASE [Dr. Robert Christenson]

The Subcommittee discussed problems associated with changes in the defined levels of the biochemical marker troponin to identify patients with ACS. Lower levels of troponin are now considered positive indicators of ACS, and this has important implications for the monitoring of trends in large data sets. Hospitals have incorporated the redefinition of ACS into their diagnostic charting, resulting in a 15- to 30-percent increase in reported MIs. Patients who would have been coded as secondary MIs previously (due to elevated troponin levels from other varied medical, surgical, or traumatic problems) are now being coded as MIs. It, therefore, has become problematic to look at secular trends over time. Additional problems in standardization of troponin measurements across different sites further complicate the problem. The National Institute of Standards and Technology (NIST) has attempted to develop a standardized troponin methodology and set of values. However, clinicians push current troponin assays to the extreme low ends of their capabilities and change from one assay to another, making standardization difficult. Additionally, patients who have other comorbid illnesses also may have comparatively high assay levels, yet their high mortality rates are driven by other diseases. More realistic criteria would be an elevated troponin plus a clinical syndrome consistent with the diagnosis.

Dr. Christenson presented information regarding a proposal to use the Rapid Early Action for Coronary Treatment (REACT) database to identify prodromal symptoms for MI (see slides in Attachment P). As background, Dr. Christenson reported that patients with episodes of antecedent angina, especially within 24 to 28 hours of an MI, have better left-ventricular

functional outcomes and prognoses than those without these episodes. Several physiological mechanisms may contribute to this improved outcome, including:

- Opening of coronary collaterals, due to the increased pressure resulting from subtotal occlusion
- Ischemic preconditioning of the myocardium, brief episodes of ischemia prior to a sustained occlusion, stimulating A₁-adenosine receptors, and reducing the cellular influx of calcium
- The formation of thrombi that are less resistant to fibrinolysis

The REACT study and database include a geographically diverse cross section of moderate-sized communities, containing 20 pair-matched intervention and control community groups and unique patient populations. The proposal is made up of three sections. The first considers triage strategies (Principal Investigator: Dr. Jerris Hedges, hypotheses 1 and 2); the second looks at community mortality rates (Principal Investigators: Drs. Harry Selker and David Kent, hypotheses 3 and 4); and the third looks at prodromal symptoms (hypotheses 5, 6, and 7).

Dr. Christenson is spearheading this proposed third area. The goal of the aim is to analyze biochemical marker data in the groups with prodromal versus abrupt onset of symptoms, in order to determine the association between symptom type and hospital and postdischarge outcome. A secondary aim is to examine the proportion of patients who experience preinfarction angina (prodromal symptoms) in the week prior to admission for evaluation of possible AMI, and to determine whether the profiles of patients experiencing prodromal symptoms varies according to age, gender, and race.

Dr. Christenson reviewed the hypotheses relevant to his aim. Hypothesis 5 states that (a) patients with prodromal symptoms will have a significantly lower extent of biochemical marker release compared to patients with abrupt onset of symptoms, and (b) prodromal symptoms and lower biochemical-marker release independently will predict lower 1- and 5-year mortality in patients discharged after AMI, compared with abrupt-onset-symptom patients.

Hypothesis 6 states that (a) there will be no significant differences in the ability of the biochemical markers to predict in-hospital, 30-day, and 1-year mortality between genders in both age-adjusted and age-specific analyses; and (b) there will be no significant difference in the ability of the biochemical markers to predict in-hospital, 30-day, and 1-year mortality between racial groups for age-adjusted and age-specific analyses.

Hypothesis 7 states that (a) the proportion of patients in a community setting who have prodromal symptoms prior to hospitalization for International Classification of Diseases (ICD)-9 code 410 (AMI) or 411 (unstable angina) will be between 40 and 60 percent; (b) the prehospital delay from onset of symptoms until time of treatment for patients having prodromal symptoms will be significantly longer compared to patients having abrupt onset of symptoms; and (c) there will be no significant age, gender, or racial differences between patients with prodromal presentation versus those with abrupt onset of symptoms.

The REACT database will be analyzed for all of these instances of prodromal symptoms, including biochemical markers, the size of the infarction, and age-adjusted gender and race differences. Tools will include a telephone survey, medical records abstract forms, and the National Death Index. Inpatient inclusion criteria will be admittance to the hospital with chest pain and discharge with a diagnosis of AMI or unstable angina. The followup telephone survey will provide information about the number of patients who experienced prodromal symptoms in the week prior to the ED visit, the number and type of symptoms that they experienced, and what they believed was the cause of the chest pain. The REACT Medical Record Abstract forms will provide information on ED presentation and admission, including prehospital delay times and biochemical-marker release data, as well as demographic characteristics and patient medical history. Finally, the National Death Index will be used to analyze the association of biochemical-marker release and coronary heart disease-related deaths among patients. In conclusion, REACT offers a unique opportunity to examine these important issues in a community setting and add to a prodromal evidence base.

The Subcommittee agreed that there is much to learn about the prodromal syndrome. A Subcommittee member questioned the lack of a control group in the REACT study. An abrupt-onset group (versus those with prodromal symptoms) has been identified, but no control group. Another participant asked how the study was defining prodromal symptoms, stating that the issue of prodromal symptoms also had been studied in a trial of congestive heart failure. At first, patients reported experiencing symptoms 3 days prior to the MI. When a time-back calendar technique was used in 100 consecutive patients, the patients were able to extend their symptoms back 16 days. Therefore, the measurement tools (e.g., the time-back calendar technique) are exceedingly important. Additionally, a control group was vital to the analysis, because a significant portion of the control group had similar symptom complexes, going back over time, due to other medical issues.

Dr. Ornato asked whether the National Death Index was searchable. It is a publicly searchable database, by Social Security number. The index is computerized in some States; in other States, a written request must be made. The use of this index is a standard epidemiological approach.

The prodromal issue presents a potential action item for the Subcommittee. It has been reported that approximately half of those who have a heart attack experience prodromal symptoms. Possible courses of action include increasing provider education strategies, a literature review, or a workshop. The Subcommittee agreed that a serious study is warranted in this area; the issue is important and timely and should be acted on in the near-term future. The NHAAP has the ability to budget this as a special project. The Subcommittee has the responsibility to review evolving science, although this is an extremely difficult subject to study.

The Subcommittee members raised several questions. Methodologically, it is very precarious to gather data from living adults; there is a risk of diffusing the abilities of the organization, which still has much work to do on AMI, in which 60 minutes is “the head of the pin.” The evaluation of prodromal symptoms may be premature. However, the Subcommittee agreed that the NHAAP has a history of carefully considering topics before moving forward. The charge of the Science Base Subcommittee is to monitor problem areas, and this is a good example.

SCIENCE BASE LITERATURE REVIEW [Subcommittee]

Individual members of the Subcommittee were assigned various topics to review. Each Subcommittee member reported on his or her topic, highlighting one or two papers. Dr. Ornato suggested that participants go around the room, rather than follow the phase I through IV order presented in the *Literature Review January 1, 2000–June 30, 2002* that was mailed prior to the meeting.

Phase I: Patient Bystander Aspects and Actions

Part E. Prodromal Symptoms (page 50): Dr. Christenson observed that the literature is very diverse on this subject. Some say that the prodromal symptoms are valid, and others point out that certain populations, such as diabetics, will not experience prodromal presentations. Other papers, using a multivariable analysis, indicate that the presence of diabetes is important in that it may prevent ischemic preconditioning.

Phase IV: General/Crosscutting Aspects and Actions

Part K. New Information Technologies (page 497): Much information technology literature is political in strategy or oriented in policy. A general theme of many of the papers is the precarious nature of databases, including the electronic medical records databases. In one instance, practitioners were not able to identify 60 percent of people with ischemic heart disease by looking at medical records through such measures as a two-variable search on nitroglycerin use and diagnosis. The difficulty of information processing in this advancing area is sobering, and the articles included in the section were considered weak. It was not clear whether the problem existed in the processing of the data in a search or in the way the databases were set up. It may be necessary to look at new ways of warehousing data.

Phase III: Hospital Aspects and Actions

Part F. AMI Management and Treatment in the Emergency Room (page 222): The strict use of criteria or an algorithm to decide where to admit patients was a highly successful approach in one study. In another study, a 90-minute accelerated critical pathway for chest-pain evaluation dropped Coronary Care Unit (CCU) admissions by 40 percent and did not miss any MIs. The pathway utilized clinical history, electrocardiographic findings, and triple cardiac marker testing (cardiac troponin I, myoglobin, and creatine kinase (CK)-MB). In another paper, researchers were able to decrease the length of hospital stays from 6.9 to 3.5 days in low-risk MI populations, with no increase in readmissions or adverse events, and 25 percent fewer invasive cardiac procedures. Another study was able to identify a subset of chest-pain patients that did not need telemetry monitoring upon admission (page 101). For some institutions, this is significant because of the chronic shortage of telemetry beds.

Phase I: Patient/Bystander Aspects and Actions

Part A. Variables Associated With Patient Delay: A review of variables associated with patient delay emphasized the significant role of psychological processes in patient decisionmaking and the lack of information available regarding why patients deny that they have significant symptoms or delay seeking treatment after the onset of symptoms. This is an area of

potential intervention. The field is approaching the realm of diminishing returns on how to shave another minute off treatment after medical contact has been made. The most advances will be made when decreases in patient delay can be actualized.

Phase III: Hospital Aspects and Actions

Part D. Primary Percutaneous Transluminal Coronary Angioplasty (PTCA): Dr. Steele noted the study abstracted on page 157, by Dauerman et al., “Outcome of Patients With Acute Myocardial Infarction Who Are Ineligible for Primary Angioplasty Trials.” She found the study very interesting and noted that it did not fit in with some of the other concepts in this section.

Phase IV: General/Crosscutting Aspects and Actions

Part I: Demographic and Cultural Considerations (Age, Race, Gender, and Socioeconomic Considerations) as Factors in AMI Interpretation, Presentation, and Treatment: Dr. Curry reported that many papers were being published on this subject. Given the same symptoms, it is important to determine whether different treatment courses are followed for women and minorities. Dr. Curry asked for a definition of the “lifestick device” for resuscitation. This device performs a triple-cadence cardiopulmonary resuscitation (CPR). Suction occurs with each downstroke, so on the upstroke, one is actually pushing down on the abdomen, causing counterpulsation. Some studies suggest that using this device may be much more effective than traditional CPR.

Phase II: Prehospital Aspects and Actions

Parts B, C, and D: Emergency Medical Dispatching, Emergency Medical Services Configuration, and Prehospital Thrombolytic Therapy: One study reported increased survival resulting from dispatcher-assisted CPR. Another study looked into whether the use of lights and sirens had any clinical benefit and found that lights and sirens reduced ambulance response times by an average of 1 minute 46 seconds. Although statistically significant, this time saving is likely to be clinically relevant in only a few cases. Yet another study emphasized the importance of a good medical contact system for first responders in early identification of patients with ACS. Another study asked whether in-hospital nurses should be using automatic external defibrillators as first responders to improve outcomes from cardiac arrest; this would require a change in nursing philosophy. In a prehospital thrombolysis study, it was found that early administration of thrombolytics before the patient arrived at the hospital decreased both the time to thrombolysis and all-cause mortality, although the definition and relevance of all-cause mortality was not clarified. In a prehospital thrombolytic study (page 76, number 6), a trial demonstrated higher patency of the infarct-related artery and decreased mortality in patients with AMI when heparin was initiated in the ambulance. This may be a much more feasible place to start, rather than the use of thrombolytics in the ambulance. This result was encouraging for early treatment advocacy.

A member of the Subcommittee asked whether the Subcommittee should take a position on PCI versus thrombolysis treatment and make a commitment as to its recommendations regarding triage. Dr. Antman is dealing with this issue in developing guidelines for the PCI/thrombolytic therapy timeline. In the NHAAP Coordinating Committee’s community planning paper, this was advocated for on a regional or local basis.

Phase III: Hospital Aspects and Actions

Part A. New and Current Diagnostic Technologies and Tests (Including Standards for Performance Testing for AMI and Acute Ischemic Syndromes): A study highlighted the lack of usefulness of biomarkers in EDs. The study suggested that biomarkers have very low sensitivity to diagnose ACI. A mortality rate study used Internet figures to show that mortality did have some relationship to quality of care but did not really discriminate between individuals. An article to determine hospital cost guidelines based on computer-based systems, which also attempted to teach cost-containment strategies by this system, found this approach to be unsuccessful. These articles are important because many methods used to improve care are very much works in progress.

Phase III: Hospital Aspects and Actions

Part A. New and Current Diagnostic Technologies and Tests (Including Standards for Performance Testing for AMI and ACI): A randomized controlled trial on cardiac biomarkers (article 16, Dagnone et al., “Chest Pain With Nondiagnostic ECG in the Emergency Department: A Randomized Controlled Trial of Two Cardiac Marker Regimes”) showed no difference among CK, CK–MB, and troponin levels in diagnostic outcomes. In another trial (article 46, Limkakeng et al., “Combination of Goldman Risk and Initial Cardiac Troponin I for Emergency Department Chest Pain Patient Risk Stratification”), doctors were given two negative predictors (a Goldman risk score that was low and a negative troponin). The study followed those patients admitted to the hospital and found that 5 percent eventually had MIs or vascular procedures. The doctors rightly did not trust the negative markers, and the combination of the two risk stratification modalities did not identify a subgroup of patients at less than 1-percent risk for death, AMI, or revascularization within 30 days.

Phase IV: General/Crosscutting Aspects and Actions

Part K. New Information Technologies (Telehealth, Telecommunication, Diagnostic Decision Support, Databases, and Medical Records): A medical records study (article 3, McManus et al., “Comparison of Estimates and Calculations of Risk of Coronary Heart Disease by Doctors and Nurses Using Different Calculation Tools in General Practice”) highlighted the inability of clinicians to discriminate risk using clinical findings. Nurses and doctors were given multiple risk calculators, but they were able to evaluate the risk of coronary heart disease with limited accuracy. The Subcommittee’s literature review package described 22 different measures that were still being tested to diagnose acute cardiac ischemia. Multiple combinations of factors, most in very poor, prospective small study designs, did not offer the ability for appropriate analysis.

Phase II: Prehospital Aspects and Actions

Part G. Prehospital Diagnostic Strategies: A Case Study: This study (article 3, Nagao et al., “Cardiopulmonary Cerebral Resuscitation Using Emergency Cardiopulmonary Bypass, Coronary Reperfusion Therapy, and Mild Hypothermia in Patients With Cardiac Arrest Outside the Hospital”) of hypothermia induced in 23 patients showed neurological recovery in 12 of them. This result encourages further testing of this strategy, preferably in randomized trials.

Austrian and Australian studies both have previously demonstrated improved survival using this technique. In fact, several U.S. hospitals have already adopted the technique, which reduces the core temperature of cardiac arrest survivors who remained comatose following resuscitation in ED to a modest degree, with the goal of maintaining the lowered temperature for 24 to 48 hours and then allowing patients to passively rewarm. Hypothermia is also being studied in the treatment of AMI. The technique has been shown in animals to reduce infarct size.

Phase III: Hospital Aspects and Actions

Part B. Chest Pain Centers: Throughout these articles, it was apparent that cardiac markers are used effectively in these centers, even though an NHAAP technology report deemphasized the use of markers. Clinically, however, this is the leading approach in the diagnosis of ACS and in the selection of therapy. It might be worthwhile for the NHAAP to refocus on the use of cardiac markers. Trials (both randomized and before-and-after designs) already show that they work very effectively.

Phase III: Hospital Aspects and Actions

Part G: Unstable Angina Treatment and Non-Q Wave MI, and Part H: Anticoagulants: New anticoagulant and antiplatelet therapies, e.g., Clopidogril and oxyparin show promise and support the strategy of early invasive treatment. Also, it is important to note that huge advances have been made in the treatment of non-ST-elevation MIs, a category that is included in the 10-year NHAAP objectives. Much of the recent focus has been on decreasing time to treatment, little of which applies to non-ST-elevation MI. However, increased implementation of proven therapies for non-ST-elevation MI would have an impact on patient survival. At least half of MIs fall into this category, and there is a need to refocus attention on this area. Even in the United States, proven strategies for non-ST-elevation MI are underutilized.

Finally, it was suggested that priority area 2 of the “Act in Time to Heart Attack Signs” measures be incorporated as a performance measure. It is obviously important to advise patients with cardiac disease of the need to act quickly if symptoms occur; there is also a need to provide smoking cessation education for these patients. The creation of performance measures has the potential to drive change, particularly in the hospital environment. Additionally, the National Committee for Quality Assurance (NCQA) is now actively considering new measures and might be open to this idea. It is certainly within the goal of disseminating the “Act in Time to Heart Attack Signs” message.

ADJOURNMENT [Dr. Ornato]

Dr. Ornato thanked the Subcommittee members for their participation and adjourned the meeting.



National Heart Attack Alert Program

Attachments

**October 28–29, 2002
Bethesda, Maryland**

ATTACHMENT A
LIST OF ATTENDEES

**NATIONAL HEART ATTACK ALERT PROGRAM
COORDINATING COMMITTEE MEETING**

Participants

October 29, 2002

Organization	Representative
Agency for Healthcare Research and Quality	Daniel Stryer, M.D.
American Academy of Insurance Medicine	Lawrence D. Jones, M.D.
American Association for Clinical Chemistry, Inc.	Robert H. Christenson, Ph.D.
American Association of Clinical Care Nurses	Diane L. Carroll, R.N., Ph.D.
American Association of Occupational Health Nurses	Kemlee K. White, R.N., COHN-S
American College of Cardiology	James M. Atkins, M.D., F.A.C.C.
American College of Emergency Physicians	Stephen V. Cantrill, M.D.
American College of Occupational and Environmental Medicine	Emmett B. Ferguson, M.D.
American College of Preventive Medicine	George K. Anderson, M.D., M.P.H. F.A.C.P.M.
American Heart Association	Joseph P. Ornato, M.D., F.A.C.C., F.A.C.E.P.
American College of Physicians	Robert A. McNutt, M.D.
American National Red Cross	Pat Bonifer-Tiedt, Sc.M., M.S.
American Nurses Association, Inc.	Christine M. Crumlish, Ph.D., R.N.
American Pharmaceutical Association	M. Ray Holt, Pharm.D.
Association of Black Cardiologists	Gerald DeVaughn, M.D., F.A.C.C.
Centers for Disease Control and Prevention	Wayne H. Giles, M.D., M.P.H.
Centers for Medicare and Medicaid Services	Jay Merchant, M.H.A.
Department of Defense, Health Affairs	
Department of Veterans Affairs	Pamela Steele, M.D., M.P.H.
Emergency Nurses Association	Julie Bracken, R.N., M.S., C.E.N., A.P.N.
Food and Drug Administration	Arthur A. Ciarkowski, M.S.E., M.B.A., M.P.A.
Health Resources and Services Administration	David B. Snyder, R.Ph., D.D.S.
International Association of Fire Chiefs	Mary Beth Michos, R.N.

International Association of Fire Fighters
National Association of EMS Physicians
National Association of State Emergency
Medical Services Directors
National Black Nurses Association
National Center for Health Statistics
National Highway Traffic Safety
Administration
National Medical Association
Society for Academic Emergency Medicine
Society of General Internal Medicine

Lori Morre, M.P.H., N.R.E.M.T.-P.
Bruce MacLeod, M.D., F.A.C.E.P.
Jimm Murray
David E. Simmons, Jr., M.S.N., R.N.
Richard Gillum, M.D., F.A.C.C.
David W. Bryson
Charles L. Curry, M.D.
Robert J. Zalenski, M.D.
Harry P. Selker, M.D., M.S.P.H.

[Absent]

American College of Chest Physicians
National Association of Emergency Medical
Technicians
National Heart, Lung, and Blood Institute
The American Association of Health Plans

Samuel Goldhaber, M.D.
Christopher Cebollero, M.S., N.R.E.M.T.-P.
Claude Lenfant, M.D.
Arthur Dresdale, M.D.

[Vacant]

American Hospital Association
American Medical Association
American Public Health Association

Invited Speakers

Eva Marie Grace
Alan Mertz

American College of Cardiology
Healthcare Leadership Council

NIH and NHLBI Staff

Brandy N. Airall, M.P.H.
Suzanne Goldberg, R.N., M.S.N.
Jeanette Guyton-Krishnan, Ph.D., M.S.
Mary M. Hand, M.S.P.H., R.N.

Nancy A. Hart, M.A.

Terry Long

Emily A. Lozano, M.D.

Marcel E. Salive, M.D., M.P.H.

Elanor Schron, R.N., M.S.

Guests

Patricia Enright Kaplan

Robert J. McNellis, M.P.H., PA-C

Deanna Simmons

Ogilvy Public Relations

American Academy of Physician Assistants

National Black Nurses Association

Contract Staff (Prospect Associates)

Jill K. Arvanitis, M.P.H., C.H.E.S.

Win Morgan, M.P.H., Ce.M.

Josephine Thomas, M.A.

ATTACHMENT B
COORDINATING COMMITTEE AGENDA

**NATIONAL HEART ATTACK ALERT PROGRAM (NHAAP)
COORDINATING COMMITTEE**

**Bethesda Marriott Hotel
5151 Pooks Hill Road
Bethesda, Maryland 20814**

Salons 1 and 2

**Tuesday, October 29, 2002
9:00 a.m.–1:00 p.m.**

Meeting Agenda

9:00 a.m.	Welcome and Introductions	Ms. Mary Hand
9:15	Executive Committee/Subcommittee Reports Education Subcommittee Health Systems Subcommittee Science Base Subcommittee	Dr. James Atkins, Chair Executive Committee Dr. Christine Crumlish, Chair Dr. Bruce MacLeod, Chair Dr. Joseph Ornato, Chair
9:45	National Cardiovascular Health Conference Conference Report Media Events Related to the NHAAP	Dr. Gerald DeVaughn Ms. Terry Long
10:00	Health Insurance Portability and Accountability Act (HIPAA)	Mr. Alan Mertz Health Care Leadership Council
10:45	BREAK	
11:00	Healthy People 2010 Data Sources: Update	Dr. Jeanette Guyton-Krishnan Dr. Wayne Giles
11:15	“Act in Time to Heart Attack Signs” Progress Report Overview of Progress Since February 2002 Campaign Partners: Dissemination Update <ul style="list-style-type: none">• American Red Cross• American College of Cardiology• Society of Chest Pain Centers & Providers• Other Coordinating Committee Organizations	Ms. Hand Ms. Long Ms. Long Ms. Patricia Bonifer-Tiedt Ms. Eva Grace Dr. Lee Garvey Committee

Tuesday, October 29, 2002 (continued)

12:15 p.m. Women's Heart Health

Women and Ischemia Syndrome Evaluation
Workshop: Recommendations

Dr. George Sopko

Acute Symptom Message

Dr. Harry Selker

**12:30 When the Family Becomes the Patient:
Caring for the *Survivors* of Patients Who
Have Sudden Death from Cardiovascular
Causes**

Dr. Robert Zalenski

12:45 Other Organization Reports

Cardiac Arrhythmia PORT
Agency for Health Care Quality & Research

Dr. Daniel Stryer

National EMS Research Agenda

Dr. Jeffrey Michael

Others

1:00 Final Comments/Adjournment

Ms. Hand

ATTACHMENT C

DR. DEVAUGHN'S PRESENTATION SLIDES

ATTACHMENT D

MS. LONG'S MEDIA EVENTS PRESENTATION SLIDES

ATTACHMENT E

MR. METZ'S PRESENTATION SLIDES

ATTACHMENT F

DR. GUYTON-KRISHNAN'S PRESENTATION SLIDES

ATTACHMENT G

MS. LONG'S AIT PROGRESS REPORT PRESENTATION SLIDES

ATTACHMENT H

DR. GARVEY'S PRESENTATION SLIDES

ATTACHMENT I

DR. SELKER'S PRESENTATION SLIDES

ATTACHMENT J

DR. ZALENSKI'S PRESENTATION SLIDES

ATTACHMENT K

MR. MORGAN'S PRESENTATION SLIDES

ATTACHMENT L

DR. MACLEOD'S PRESENTATION SLIDES

ATTACHMENT M

DR. CHRISTENSON'S CRUSADE PRESENTATION SLIDES

ATTACHMENT N

DR. ORNATO'S PRESENTATION SLIDES

ATTACHMENT O

DR. ANTMAN'S PRESENTATION SLIDES

ATTACHMENT P

**DR. CHRISTENSON'S PRODROMAL SYMPTOMS AND MI
PRESENTATION SLIDES**