

National Heart Attack Alert Program Coordinating Committee and Subcommittees

## MEETING SUMMARY REPORTS



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#### NATIONAL HEART, LUNG, AND BLOOD INSTITUTE NATIONAL HEART ATTACK ALERT PROGRAM COORDINATING COMMITTEE

#### HIGHLIGHTS

#### March 23, 2004 Bethesda, Maryland

Dr. Barbara Alving, Acting Director, National Heart, Lung, and Blood Institute, (NHLBI) welcomed the participants and introduced Dr. George Mensah, the new representative of the Centers for Disease Control and Prevention (CDC) on the Coordinating Committee. Dr. Mensah is the Chief, Cardiovascular Health Branch, of the National Center for Chronic Disease Prevention and Health Promotion's Adult and Community Health Division at CDC. Dr. Alving also welcomed several substitute representatives.

- The focus of the meeting was on National Heart Attack Alert Program (NHAAP) Informatics Technology projects that were funded by the NHLBI and the National Library of Medicine. Reports on these projects were presented in three areas:
  - Phase I (patient delay). Dr. Thomas Aversano described the Patient-Initiated Emergency Response System (PIERS) project; Dr. Rita Kukafka described the MI-HEART project that examined the impact of tailored, Web-based health information; and Mr. Ransom Weaver described the Heart Sense video game to reduce heart attack prehospitalization delay.
  - Phase II (prehospital delay). Dr. Helmuth Orthner described Integrated Information Technologies for Emergency Medical Care, a project using upgraded voice/data communication in the emergency medical services (EMS) environment. Dr. Harry Selker described two pilot trials that used predictive instruments—one trial using a computerized electrocardiogram and another trial of the feasibility of using glucose, insulin, and potassium—in the prehospital setting to reduce mortality from acute coronary syndrome.
  - Phase III (hospital delay). Dr. Octo Barnett reviewed "Chest Pain: The First 60 Minutes," a package of Web-based simulated patient cases and pre/post tests.
- After discussions of the presentations, Dr. Angelo Alonzo, Professor, Department of Sociology, The Ohio State University, Columbus, Ohio, reflected on the promise of informatics to promote early recognition and response to heart attack patients.

- Dr. James Atkins, Chair of the Executive Committee, reported on the Executive Committee meeting that was held earlier in the day and then introduced the subcommittee chairs for their reports on the subcommittee meetings that took place the previous day.
  - Mr. David Simmons, Vice Chair of the Education Subcommittee, reported on the Education Subcommittee meeting from the previous day that largely focused on progress and implementation of the "Act in Time to Heart Attack Signs" campaign through the Coordinating Committee organizations and in minority communities:
    - ▶ Ms. Terry Long, Senior Manager, Health Communications and Information Science, within the Office of Prevention, Education, and Control (OPEC) at NHLBI, gave a review and progress report on the "Act in Time to Heart Attack Signs" campaign.
    - ▶ Ms. Janet Kelly, Nutrition Education Specialist, OPEC, NHLBI, described her and others' work implementing the "Act in Time to Heart Attack Signs" small group session kit with American Indian and Alaska Native groups.
    - ▶ Ms. Lenee Simon, Community Health Specialist, OPEC, NHLBI, presented an overview of a pilot project with the Housing Authority of Baltimore City, which introduced the "Act in Time to Heart Attack Signs" small group session to the public housing community.
  - Dr. Bruce MacLeod, Chair of the Health Systems Subcommittee, reported on the meeting that took place the previous day. The subcommittee discussed the following issues:
    - ► The Subcommittee discussed a revised paper on "Use of EMS by Patients with Acute Coronary Syndromes (ACS)" that will be used as a background paper for the October 2004 meeting and has been submitted for publication.
    - ▶ Ms. Mary Beth Michos, Subcommittee Vice Chair, reviewed the draft agenda for the October 2004 meeting for EMS Stakeholders, to problem-solve around issues related to improving EMS utilization by ACS patients.
    - ▶ Dr. J. Lee Garvey, representative of the Society of Chest Pain Centers and Health Systems Subcommittee member, presented a draft paper for Subcommittee discussion entitled "Prehospital 12-Lead Electrocardiography—A Call for Implementation in EMS Systems Providing Advanced Life Support."
    - ▶ Dr. MacLeod reported on his and the NHAAP Coordinator's interim discussions with the National Committee for Quality Assurance, about a quality indicator for ACS patients related to utilization of EMS.

- Dr. Joseph Ornato, Chair of the Science Base Subcommittee, reported on the Science Base Subcommittee meeting from the previous day:
  - ► The Science Base Subcommittee reported on their (every other meeting) review of the Literature in four broad areas: Phase I, Patient/Bystander Aspects and Actions; Phase II, Prehospital Aspects and Actions; Phase III, Hospital Aspects and Actions; and Phase IV, General/Crosscutting Aspects and Actions.
  - ► For each topic within the areas, they considered: the state-of-the-science; any apparent trends; recent groundbreaking studies that warrant discussion by the Science Base Subcommittee; and the topic's impact on the efforts of the NHAAP.
  - ► Then Ms. Mary Hand, NHAAP Coordinator, and Dr. Teri Manolio, Director, Epidemiology and Biometry Program, Division of Epidemiology and Clinical Applications, NHLBI, gave an update on their efforts to address the Science Base Subcommittee priority area of the establishment of an ACS patient surveillance system.
  - ▶ Dr. Robert Christenson, representative of the American Association for Clinical Chemistry, Inc., reported on the work of the National Association of Clinical Biochemistry Committee to update the Laboratory Medicine Practice Guidelines for Biochemical Markers for ACS, and on the May 2004 Beckman Conference, the forum in which the draft guidelines will be discussed. NHAAP professional organizations were invited in late 2003 to designate a representative to the guidelines development process.
  - ► Finally, Dr. Joseph Ornato presented an update on the Public Access Defibrillation (PAD) study, as part of his report.
- Mr. Drew Dawson, representative of the National Highway Traffic Safety Administration (NHTSA), provided an update on an Institute of Medicine report on the future of emergency care in the U.S. health system, which will be expanded, with the help of the NHTSA, to include prehospital EMS.



#### **National Heart Attack Alert Program**

# Coordinating Committee Meeting

#### NATIONAL HEART, LUNG, AND BLOOD INSTITUTE NATIONAL HEART ATTACK ALERT PROGRAM COORDINATING COMMITTEE

Special Focus: Informatics Technology for the NHAAP

Meeting Summary March 23, 2004

## WELCOME AND INTRODUCTIONS (Dr. Barbara Alving)

Dr. Alving welcomed the Coordinating Committee members, noting that she has served as Acting Director of the National Heart, Lung, and Blood Institute (NHLBI) since last August when Dr. Claude Lenfant retired after 22 years of service. Dr. Alving introduced a new Coordinating Committee member, Dr. George Mensah, representing the Centers for Disease Control and Prevention (CDC) and replacing Dr. Wayne Giles. Substitutes standing in for regular members at today's meeting include Ms. Pamela Hirsch, representing the American Association of Occupational Health Nurses; Dr. Ijaz Kahn, representing the American College of Chest Physicians; Dr. Carol Bickford, representing the American Nurses Association; Mr. Donald Vardell, representing the American Red Cross; and Mr. Jonathan Moore, representing the International Association of Fire Fighters.

Dr. Alving then reviewed the day's agenda, noting that the majority of the meeting will be devoted to hearing presentations on the Informatics Technology (IT) projects that had their roots in the 1998 symposium entitled "New Information Technology and the NHAAP: Setting a 5-Year Agenda," which was cosponsored by the NHLBI, the National Library of Medicine (NLM), and the Agency for Health Care Policy and Research (AHCPR). Dr. Alving recognized the contributions of Dr. Mark Smith (who represented the American College of Emergency Physicians at that time) for spearheading the symposium. A major premise at the time of the symposium (and upon which the NHAAP was started) was that early artery-opening treatment with thrombolytic therapy for patients with ST-elevation myocardial infarction (STEMI) saved lives and heart muscle. Percutaneous transluminal coronary angioplasty (PTCA) was considered an alternate treatment approach. Goals were to shorten access time, ensure correct care, and measure outcomes of interventions.

Dr. Alving reviewed how the acute cardiac care field has advanced since the 1998 symposium. She said that primary angioplasty, including the use of stents, is widely being used and has been shown in many reports to surpass fibrinolytic therapy, especially in centers that do a high volume of these procedures. Reports indicate that time to treatment may not be as critical because primary angioplasty yields higher rates of reperfusion of the infarct-related artery in patients presenting later. There are now sensitive and specific biomarkers, such as troponin, to diagnose acute myocardial infarction (AMI). Automated external defibrillators (AEDs) are more widely available, and the Public Access Defibrillation (PAD) trial report showed that survival from cardiac arrest can be improved by the use of AEDs by nontraditional responders. The NHAAP moved ahead with its goal of reaching the public through its "Act in Time to Heart

Attack Signs" campaign, which is based on lessons learned from the Rapid Early Action for Coronary Treatment (REACT) study. In addition, it has been shown that lives are saved when hospitals follow heart attack guidelines.

Dr. Alving noted that despite these advances, the challenges that gave rise to the 1998 symposium remain largely unchanged. A report by DeLuca et al., concluded that although primary angioplasty may guarantee a higher rate of reperfusion in patients presenting later compared with thromobolysis, it cannot prevent myocardial necrosis, which is related to the duration of the occlusion, particularly in higher risk patients. The risk of 1-year mortality increases by 7.5 percent for each 30-minute delay. REACT found that patient delay is difficult to affect and has remained largely unchanged over the past decade. Fewer than half of chest pain patients access emergency medical services (EMS) that can ensure earlier treatment once they arrive at the hospital and can offer technology such as an AED and the option of triage to an angioplasty-capable hospital in some communities. Too may patients die from cardiac arrest before reaching the hospital. We need to learn more about getting patients to call 9–1–1 earlier. Health care systems are still far from seamless in recognizing and responding to patients who present with acute symptoms. Information technology approaches are needed to realize optimal and early recognition and treatment for all heart attack patients.

Finally, Dr. Alving explained that the featured presentations on informatics for the NHAAP were organized according to the phases conceptualized by the NHAAP, in which actions by others can either contribute to or reduce delay: Phase I involves actions by patients and those around them; Phase II comprises actions associated with patient transport, whether by EMS or someone else; Phase III entails actions by hospital providers leading to diagnosis and treatment. Dr. Alving noted that after each set of presentations there would be panel discussion, facilitated by selected NHAAP Coordinating Committee members who have been identified in advance.

#### INFORMATICS TECHNOLOGY FOR THE NHAAP—PROJECT PRESENTATIONS

## **Introduction to NHAAP Informatics Technology Projects** (Dr. Donald Lindberg and Dr. Milton Corn)

To begin, Drs. Lindberg and Corn of the NLM introduced the presentations on IT projects. Dr. Lindberg identified several issues that must be addressed: getting people to dial 9–1–1, getting them to the hospital quickly, examining delays in the emergency department (ED), and choosing and implementing the right therapy. Dr. Lindberg said that he is grateful to Dr. Lenfant for inviting IT experts to address these problems.

Dr. Corn explained that contracts for the Informatics Technology projects were awarded in two phases. First, 14 successful applicants received funding for feasibility demonstrations, and seven of these were funded a larger contract. Two-thirds of the funding was from the NHLBI and one-third from the NLM. In the second phase, the value of the projects was demonstrated. Dr. Corn noted that changing the behavior of patients, physicians, and EMS staff is one of the goals of the IT projects, and it was hoped that the projects will lead to ways to change behavior that can be applied to areas beyond heart disease.

The IT project directors proceeded to describe their projects' goals, key activities, and results, and discussed results and recommendations for future directions.

#### Patient Delay (Phase I Projects)

Patient-Initiated Emergency Response System (PIERS) (Dr. Thomas Aversano)

Dr. Aversano described the PIERS project, a collaboration of the Johns Hopkins Medical School, the Johns Hopkins Applied Physics Laboratory, and the Maryland Emergency Medical System (see slides, attachment C). The PIERS system addresses the entire range of the pathophysiology of coronary artery disease (CAD)—from stable angina to progressive angina, plaque rupture, unstable angina, and AMI.

Dr. Aversano noted progress in AMI care, including the advent of the cardiac care unit, which offers defibrillation and beta-blockers and reduced mortality from 30 percent to 15 percent. Mortality in patients with STEMI is typically 9–10 percent, but the advent of thrombolytic therapy reduced that figure to 6–7 percent; today, with PTCA done promptly and appropriately, the rate is 3 percent. However, prehospital mortality is still a high 30 percent.

Barriers to patient care exist at all phases: Phase I (patient/bystanders), Phase II (EMS) and Phase III (in-hospital). In Phase IA, chronic monitoring of CAD can prevent patients from advancing to the acute phase in Stage IB. PIERS aims to reduce treatment delays in all three phases and also to reduce the number of admissions for acute coronary syndrome (ACS) in Phase IB.

A solution already exists: the patient-initiated emergency response system, in which the patient calls 9–1–1 and the EMS dispatcher calls for an ambulance. However, this system does not always work—the average symptom-to-treatment time is more than 120 minutes. Reasons for delay in Phase I include denial, uncertainty (embarrassment), attempts to contact a physician/loved one, and being single. In Phase II, delays are EMS related, such as trying to obtain an electrocardiogram (ECG) in the field. Phase III delays include failure to obtain an ECG and difficulties reviewing the ECG, getting a consultation, and recruiting a treatment team.

The concept behind PIERS is to bring elements of the ED critical to making an ACS diagnosis of ACS *to* the patient. PIERS is designed to be easy to use and is based on ubiquitous, robust technology that patients and physicians would want to use. It is also designed to be inexpensive and cost-effective, provide built-in quality and error management, have a flexible configuration, and evolve with automation. An important concern was to ensure that the system itself cannot become a source of delay. It is designed to be part of the overall EMS system. The PIERS system provides for teleconsultant training, information, and routing solutions, and data storage and retrieval.

In the PIERS system, the patient takes home a special 12-lead ECG harness. The ECG is transmitted by a wireless system that connects the patient to a "teleconsultant," who can review the ECG and talk to the patient by telephone. The information, along with the patient's baseline ECG, is stored in a central server and can be routed to the EMS, ED, and the patient's physician. During a call for AMI, the baseline and current ECG are displayed simultaneously. The central server can also gather information from the patient by voice responses.

The ECG harness is the system's weakest link because the system fails if the patient does not wear it correctly. The electrode leads do not require adhesives; they are embedded in shoulder, chest, and waistline components of the harness. The patient personal monitor (PPM) is a hand-held pocket personal computer that includes an ECG acquisition system that a patient can talk on. Patients receive a training manual to help them learn how to use the harness and PPM.

The goal of PIERS is to catch patients while their angina is progressing, but the system can also be used during an acute episode. Diagnosis of ACS is based on historical information (risk factor profile, past medical history, current history) as well as comparison of current and baseline ECGs. PIERS has three modes of operation: (1) setup and testing, (2) monitoring of chronic CAD, and (3) acute ACS event. In Mode 2, the patient regularly hooks up to the harness and calls the system every month to transmit a 12-lead ECG to the central server. The patient undergoes an automated inquiry (the Seattle Angina Questionnaire), and the angina score and the ECG are sent to the patient's physician. If there are disturbing trends, the physician is alerted. Some of the questions may lead the patient to a heart failure class. The ECGs are examined for new Q-waves or ST-segment changes.

During an ACS event (Mode 3), the patient is immediately connected to the teleconsultant, who questions the patient by phone. If it is determined that the patient is having an AMI, EMS is dispatched. EMS has the patient's 12-lead ECG in hand, and the information is also sent to the receiving ED.

PIERS can reduce time-to-treatment for the following reasons: (1) because patient contact is direct, uncertainty and shame/embarrassment are reduced; (2) data are forwarded to EMS prior to pickup, with no need to obtain a field ECG; (3) uncertainty is reduced and the EMS will not take the patient to the wrong hospital; (4) data are forwarded to the ED prior to arrival, which aids identification; and (5) the ECG obtained pre-EMS allows the ED to call in an angioplasty team if necessary.

Dr. Aversano said that the PIERS system is now fully functional, and the system is ready for a Phase III clinical trial. He noted that there are similar systems but none have been tested clinically.

**Discussion.** In leading the discussion of the PIERS project, Dr. Joseph Ornato, American Heart Association representative on the NHAAP Coordinating Committee, noted that the Shahal project in Israel and a newer one in Germany have provided ECG platforms to patients with known cardiac disease. There is limited ability to identify persons in the general population who will have cardiac arrest. Dr. Aversano raised the following issues:

• Persons in the Shahal program are clients—not patients—who pay to take home a 12-lead device, transmit their ECG, and connect to a cardiac teleconsultant. Shahal also owns the ambulance system used to transmit clients to the ED. The clients are a select group of motivated people; about 20 percent have no known disease. No clinical trial has shown that Shahal is effective. The clients' time-to-treatment is 44 minutes, but this has no meaning. A randomized controlled trial (RCT) is needed to test the system and determine if it actually might increase time-to-treatment. A

company in the United States is selling 12-lead ECG devices but does not offer ambulance service.

- This type of system should not be client-based but should be part of an integrated system of care for generalized disease management that would monitor patients chronically and reduce hospital admissions. PIERS could be one part of this type of system.
- A clinical trial is needed in a high-risk group (e.g., persons with known coronary disease, stroke, or peripheral vascular disease). The rate of recurrent MIs (approximately 6 percent) would require about 800 patients in each of the two study arms to demonstrate a 30 percent reduction in time-to-treatment. Another measure would be a reduction in the number of AMI visits to the hospital.
- PIERS includes only ECGs, but it does have the capability to transmit QT changes and to send the information to the physician, who would need to interpret the data. Only a small population of persons will need implantable cardioverter defibrillators, even among the group at high risk of sudden death.

Dr. Ornato noted that the wearable AED device has an application to the torso that is similar to the device used in the PIERS project. The few hospitals that have adopted this technology provide intriguing anecdotal data indicating that the device (with noise filtering) records clear heart rhythm. A potential use is for patients who come to the hospital with ACS and end up staying 1–3 days; instead, the patient could be sent home with a wearable AED.

The Reynolds Foundation has awarded the Johns Hopkins School of Medicine \$24 million to establish a multidisciplinary center focused on decreasing the rate of sudden cardiac death. This study will randomize survivors of AMI (both STEMI and non-STEMI) with low ejection fractions to going home with/without an AED (not the wearable AED, which costs \$25,000).

MI-HEART: The Impact of Tailored, Web-Based Health Information (Dr. Rita Kukafka)

Dr. Kukafka presented the final report on the MI-HEART project (she had presented an interim report several years ago) (see slides, attachment D). The project was conducted by the Department of Biomedical Informatics at Columbia University with Dr. James Cimino as principal investigator. The primary objective of MI-HEART was to determine whether a clinical information system can favorably influence the appropriateness and rapidity of decisionmaking in patients suffering from AMI symptoms. Outcomes are the likelihood of action (seeking help in response to symptoms) as reported by patients, and changes in attitudes and beliefs associated with patient delay. The hypothesis is that tailored educational tools are more effective than nontailored tools in favorably influencing study outcomes.

MI-HEART used data-driven and highly personalized messages that were tailored to provide specific information matched to the characteristics of an individual. RCTs have shown that tailored communications tend to hold people's attention and are more effective in promoting behavior change than generic communications. The five-step MI-HEART tailoring process

(1) determined which variables are most important, (2) developed a tailoring questionnaire and data file, (3) constructed messages and developed a message file, (4) wrote algorithms and matched them to the message file, and (5) automated the tailoring process.

The project has published a paper on a model of patient response to AMI (Kukafka et al., 1999), identifying the variables leading to action and transport to the ED. These variables are related to the patient's symptom phase (somatic and emotional awareness), interpretation phase (expectation of symptoms and perceived threat), and decision phase (cost efficacy; response efficacy; and the symptom context, which includes indirect variables such as clinical status, health history, and sociodemographics). The study recruited participants from physicians' offices, advertisements, online resources, and promotional materials such as brochures. Participants were required to provide their consent as well as consent from their physicians, who confirmed patient eligibility—being at high risk for AMI. Followup was conducted at 1 and 3 months.

The clinical trial randomized patients to three groups: (1) the <u>tailored group</u> received Web-based messages tailored to demographic data, health history, and modifiable factors associated with patient delay; (2) the <u>nontailored experimental group</u> received Web-based messages that were not tailored; and (3) the <u>control group</u> received print messages that were not tailored. All three groups completed an online baseline questionnaire that included rating of present health, past and present health conditions, health care utilization, and intention to respond to AMI symptoms under a number of different scenarios. The sample population (n=94) was mostly male (71 percent), married (77 percent), and Caucasian (89 percent). Mean age was 57 years, and 35 percent had annual incomes greater than \$75,000.

Dr. Kukafka reviewed some of the baseline findings regarding health history and what participants said they would do if they had symptoms. On a scale of 1–10 (with 10 the best), self-efficacy was rated 5.65 for symptoms, 6.74 for action, and 6.44 for cognitive (managing negative emotions at outset of pain). For outcome expectation—calling 9–1–1, ratings were only 2.79 for improved survival and 3.23 for reduced damage.

Dr. Kukafka noted that psychologist Dr. Albert Bandura defined self-efficacy as the *belief* in one's capabilities to organize and execute the sources of action required to manage prospective situations. He felt that beliefs are critical to behavior change. A belief is an individual's representation of reality that has enough personal validity and credibility to guide behavior and thought.

The MI-HEART study assessed three dimensions: (1) high levels of anxiety arousal (symptom labeling), (2) the need for a coping strategy (taking action), and (3) the need for cognitive control of intrusive negative thinking in a threatening situation (controlling negative emotions). The strength of the subjects' belief in their ability to execute the requisite activities was rated and recorded on a scale of 10-unit intervals, and a summary score was calculated for each dimension. The tailored group showed significant improvement in self-efficacy in all three dimensions. This group viewed the communications more than the nontailored experimental group, considered the system more user friendly, and found the system easy to understand. However, there was no change in the measure of intention (to call 9–1–1).

Study limitations were the small sample size (due to difficulty in recruitment of subjects, attrition, and lack of incentives). Possible solutions are to offer incentives and bring users into incidental contact with the intervention (e.g., in waiting rooms, the supermarket, etc.). Another limitation was that participants were primarily Caucasian, male, and well educated. Solutions are to consider social and cultural issues and to plan and develop the intervention component directed at implementation issues.

Dr. Kukafka concluded that the project was encouraged by the results that favor the tailored group's significant improvement in key cognitive variables. Change in these variables is a good sign—a pathway to behavior change. Further study is needed with a larger sample and perhaps a higher intervention dose to determine if changes in the mediating cognitive variables will lead to significant improvement in dependent measures (intention to act) and, more specifically, actual changes in patients' behavior when responding to AMI symptoms.

**Discussion.** Ms. Nancy Foster, American Hospital Association representative on the NHAAP Coordinating Committee, led the discussion of the MI-HEART project. She noted opportunities to use computer-assisted learning and asked how this education could be embedded in the lives of diverse populations so that people can learn how to respond if they or a loved one have symptoms of a heart attack. Dr. Kukafka made the following points during the discussion:

- Web-based interventions aimed at people who are not ill must reach people where
  they are (e.g., in waiting rooms, at malls). Kiosks can be placed everywhere—like
  automated teller machines. The entire population needs to be aware of the need to
  respond to AMI symptoms.
- We need to think about social and cultural barriers to technology use and add an IT implementation intervention to clinical trials to address these barriers. Web-based technology should also include a social marketing campaign at the community level to promote the importance of using the Internet to obtain health information. This campaign should match the social norms and attitudes of the audience in order to develop appropriate messages.
- Stages-of-change models that used computer programs were not encouraging until they were coupled with the health care provider. Electronic medical records could provide tailored messages at provider visits. This would be hard to study in an RCT, however.
- Dr. Kukafka is working on other interventions that incorporate tailored communication at the point of care, such as giving patients a printed handout to reinforce provider counseling. The provider continues to be the most credible source of information.
- There are no data on how many patients who suffer a heart attack have routine physician visits that would allow for the provision of tailored information. Multilevel interventions are most effective.

Mr. Weaver described the Heart Sense project, which was conducted by the University of Pennsylvania's Department of Systems Engineering, with Dr. Barry Silverman serving as the principal investigator (see slides, attachment E). This project developed a narrative fiction video game that at-risk persons view while in the physician's waiting room or on the Internet as part of an assigned health intervention. The goal of the game is to get people to understand the behavioral issues related to delay so that they call 9–1–1 immediately when they have symptoms. The viewer interacts with the characters in the video to lead them to make the correct decisions, which affect the outcome of the game. Playing video games is the most popular entertainment activity in the United States.

After a prototype game was tried in 17 high-risk persons from a clinic who were predominantly African American, about 60 years of age, and not very computer savvy, the narrative and dramatic aspects of the game were fleshed out. Characters in the story include those having a heart attack, a hero who needs to help them (but can hurt them if he acts irresponsibly), a romantic interest, and an "evil brother" who has kidnapped the hero's mentor. The hero must make choices that determine the narrative outcome. Users are asked to direct what the hero does. By creating their own story or learning experience, users have a vested (tailored) interest in what is happening. The game goes through processes based on the Heart Sense patient behavior change theory, which includes recognizing symptoms and overcoming attitudes, norms, and self-efficacy issues to result in behavior change.

A clinical trial was developed to assess the drama game. Subjects 45–75 years of age were assigned to one of four arms: (1) the baseline arm received no intervention, (2) the pamphlet arm received generic information (a pamphlet on heart attacks), (3) the movie arm viewed the game with the interactive feature disabled, and (4) the full game arm received game play training. Several hypotheses were tested. One hypothesis was that learning by game play versus standard learning tools (such as pamphlets) will lead to higher intent to call 9–1–1 in the event that participants are confronted with heart attack symptoms (their own or in another person) in real-life situations. Another hypothesis was that learning by game play will lead to greater rehearsal and more chance to work out any delay issues ahead of time, and hence, will also lead to higher readiness/transfer and less delay. A third hypothesis was that learning by game play will provide a more vivid experience and greater retention of the information and therefore will affect followup.

Data from the study include the choices made by the video viewers and data from assessment instruments given before and after playing the game. The project attempted to assess the theory that intention to call 9–1–1 will lead to actual calling. In addition, users were given the choice of giving back some of the fee for participating in the study if they could give a friend a pager that would summon 9–1–1. After the study was completed, they were told that this choice was part of the study.

Mr. Weaver said that the project is now completing the clinical trial and will start the analysis soon. He noted that the development team included persons in the fields of cardiology, digital media design, medical informatics, acting, writing, game programming, sound engineering, music, and production.

**Discussion.** During the discussion of Heart Sense, led by Dr. Diane Carroll, American Association of Critical Care Nurses representative, Mr. Weaver said that the effectiveness of the game will be measured by the questionnaires given before and after the game to identify obstacles to taking action when a person has heart attack symptoms.

Asked to comment on the cultural diversity issue, Mr. Weaver said there are different audiences at different levels of sophistication. The cartoon approach was well received across demographic groups. The message was not complex.

Future implementation will involve using the game in a number of platforms such as a link on a Web site, on a kiosk or personal computer (PC) at a doctor's office, and on a CD–ROM. We need to get people to play the game. Dr. Alving added that the game could be a family affair, one that grandparents can play with younger generations, thus helping to explain diseases to the family.

Mr. Weaver recommended looking at the papers in the meeting packet that cover the design process. The prototype game design editor can be used to develop games for other purposes (e.g., a game for diabetes), using existing characters and media elements.

#### Prehospital Delay (Phase II Projects)

Integrated Information Technologies for Emergency Medical Care (Dr. Helmuth Orthner)

Dr. Orthner described an IT project conducted at the University of Alabama at Birmingham that was concerned with improving clinical communication with upgraded voice/data communication in the EMS environment (see slides, attachment F). The objectives were to examine the potential of an enhanced information infrastructure in prehospital EMS environments to avoid delays in the transportation phase, improve clinical data acquisition and documentation, improve clinical communication between emergency medical technicians (EMTs) in the field and physicians in the ED, and speed up and improve clinical decisionmaking.

In this project, EMS providers stabilize the patient and acquire data using wireless devices, communicate with the control physician (using voice data messaging), and transmit data to the regional EMS patient database. The patient is transported to the best destination using the Birmingham Regional EMS System (BREMSS) TraumaNet (now called LifeTrac), and clinical resources at the receiving hospital are reserved. At the ED, the chest pain team is mobilized, the patient is examined, data received from the EMS team are validated, and diagnostic tests are performed. The ED physician accesses patient data from the EMS patient database via the Web. These data are integrated with data from the hospital, and the cardiologist is notified. After continued observation and diagnostic testing, the patient is admitted to the hospital or treatment facility or sent home with instructions.

Dr. Orthner reviewed a proposed workflow model for EMS data transmission and identified several challenges, including overlapping organizations and command structures; competing EMS (private and public ambulance companies, separate/combined fire and medical services); competing health care organizations that are reluctant to share data; and failure to use clinical information standards even if they are available.

Technology assumptions include enhanced prehospital and in-hospital infrastructure, including wireless local area networks and cellular wide area networks; hand-held devices such as personal digital assistants (PDAs) and tablet PCs; wearable computers; and mobile clinical instruments. There are questions about whether regional EMS patient databases can reliably identify patients and whether patient data are safe and secure.

Usability assumptions include bringing clinical knowledge to the point of care using telemedicine, computerized EMS protocols, and improved education in the field. The usability of digital devices in the field depends on user interface (PDA vs. tablet PCs), power requirements that may not yet be adequate, the safety and security of patient information, and reliability against shock and vibrations.

**Discussion.** Dr. George Anderson, American College of Preventive Medicine representative, facilitated the discussion of Dr. Orthner's presentation. He asked what priorities Dr. Orthner would recommend for the NHAAP's action plan. Dr. Orthner made the following suggestions:

- Establish an infrastructure to enhance the prehospital environment (e.g., voice/data communication).
- Identify patients at risk and provide access to their records. This would lead to an EMS database that is based in a neutral place (such as the State Health Department). These data would be useful for treatment for AMI, stroke, and trauma (conditions where treatment in the first hour is critical).
- Simplify what EMTs are asked to do (e.g., capture data only).

During the discussion, the following points were raised:

- In Europe, expert clinicians are present in the ambulance, but this is unlikely to happen in the United States.
- Privacy requirements of the Health Insurance Portability and Accountability Act
  would have to be addressed from political standpoint. If the data are in a hospital, the
  Joint Commission on Accreditation of Healthcare Organizations would also present
  challenges. It was suggested that patient data could be put on a "smart card" that is
  owned by the patient.
- We must show that IT can make a difference to patient outcomes. Studies should not lump together the range of prehospital care providers but look at the characteristics of each system. The EMS community recognizes that it can give better care if it has more information about patients.

EMS Clinical Trial of ECG-Based Predictive Instruments (TIPI-5-EMS) (Dr. Harry Selker)

Dr. Selker described the first of two projects at the Center for Cardiovascular Health Services Research at Tufts-New England Medical Center that focused on the use of computerized ECG decision support in the form of cardiac predictive instruments. These

instruments are used to make critical clinical decisions and decisions about the use of expensive resources—e.g., triage for possible acute cardiac ischemia (ACI) and AMI, and coronary reperfusion therapy for AMI. Dr. Selker noted the need for clinical research and intervention clinical trials in the EMS setting, as well as difficulties in conducting research and the challenges of RCTs in this setting.

The Boston TIPI-5-EMS pilot trial demonstrated the infrastructure, procedures, operations, and execution for ECGs in an entire city's prehospital EMS setting using a time-insensitive predictive instrument (TIPI). A goal was to demonstrate EMS use of ACI-TIPI and thrombolytic predictive instrument (TPI)-capable computerized ECGs as a way to automate patient entry, randomization, and data collection. The TIPI is valid both for real time clinical use and for retrospective review of care. The computerized ECG is used to automatically collect data.

The TPI instrument identifies patients likely to benefit from percutaneous coronary intervention. In an earlier study funded by the Agency for Healthcare Research and Quality (AHRQ), a clinical trial in 10 hospital EDs with almost 11,000 patients found that predictive instruments improve decisionmaking, especially in more rural hospitals and for patients with less obvious disease. The investigators developed a 5-part TPI component predictive instrument to predict the likely outcomes of patients with STEMI, including 30-day mortality with and without reperfusion; 1-year mortality; and likelihood of cardiac arrest, thrombolysis-related intracranial hemorrhage, and thrombolysis-related major bleed. The TPI Trial (published in 2002) found that the instrument had minimal effect in patients with high baseline reperfusion rates, but it increased the use and timeliness of reperfusion in often missed groups and when involved physicians were offsite.

Dr. Selker then provided details about the Boston TIPI-5-EMS pilot trial (see slides, attachment G). This trial included 399 EMS runs for patients with symptoms suggestive of ACS and screened for inclusion. Patients were enrolled from January through March 2002, and 165 patients gave written consent. The study findings confirmed the feasibility of an electronically randomized EMS trial using a computerized ECG. Dr. Selker described study subject consent, inclusion procedures, participation of paramedics, practical randomization in the EMS setting, and successful randomization and collection of electronic and conventional data. The next steps are to demonstrate use of the methods in an RCT of EMS acute pharmacological intervention with ACS with decision support by ECG-based ACI-TIPI and TPI predictions.

Glucose-Insulin-Potassium (GIK Study: Immediate Myocardial Metabolic Enhancement During Assessment and Treatment Via EMS (IMMEDIATE) Trial (TIPI-6-IMMEDIATE) (Dr. Selker)

Dr. Selker then discussed a second trial, the TIPI-6-IMMEDIATE pilot trial, which was conducted by Tufts-New England Medical Center and the Emerson Hospital EMS in suburban Concord, MA. This study examined the feasibility of using glucose, insulin, and potassium (GIK) in a prehospital EMS system with relatively wide transport areas and with patient transfer for invasive cardiac procedures. Research suggests that inexpensive treatment with GIK may reduce ACS mortality by 50 percent by reducing infarctions and ventricular arrhythmias and by lengthening the time window for benefit from reperfusion therapy.

The TIPI-6-IMMEDIATE RCT was an "effectiveness trial" instead of an "efficacy trial." It was conducted from August through October 2002 and enrolled 29 patients of the 115 patients screened. Dr. Selker described details of the study (see slides, attachment H), including inclusion and exclusion criteria, patient characteristics, the subjects' presenting clinical characteristics, prehospital treatments given by EMS, elapsed times to treatment, ED triage disposition, hospital survival and in-hospital revascularization procedures, study infusion (and incidence and reasons for early discontinuation of infusion), and levels of potassium and glucose during infusion. He noted that the paramedics asked for patient consent in real time, and this worked well for both paramedics and patients. The intervention and control groups were comparable in size and diagnosis.

Results of the pilot trial confirmed the feasibility of an EMS trial and demonstrated readiness to conduct a national trial. Overall, 91 percent of the patients who received full infusion had ACS. Time from symptom onset to EMS arrival was 39 minutes, and infusion was started within an additional 19 minutes. Most patients survived, and many had catheterization and reperfusion. GIK may have an important effect in preventing arrhythmias, and it is crucial to treat arrhythmias before arrival at the hospital. Levels of potassium and glucose were not dangerously high, though a few patients had to have the infusion stopped because of hyperglycemia.

Dr. Selker noted that the trial also randomized the use of ACI-TIPI/TPIs. When these instruments were used, less people needed to have inappropriate treatment stopped by the ED physicians. The instruments also predicted a higher proportion of AMIs.

The next step is to hold a multicenter national clinical trial. A proposed study in Massachusetts, Texas, and Wisconsin will include 15,435 subjects. The primary endpoint is to show that GIK reduce all-cause mortality at 30 days and 1 year.

**Discussion.** Facilitating discussion of Dr. Selker's presentations, Dr. Robert McNutt, American College of Physicians representative, asked what the NHAAP could do to eliminate barriers to incorporating the use of predictive instruments such as the TIPI in the prehospital setting. The following comments were made:

- Market forces are important; if there is no money to be made from a device or
  protocol, its adoption is stifled. ACI-TIPI is in the public domain, and there has been
  evidence of the usefulness of GIK for two decades. However, predictive instruments
  have been incorporated in ECGs worldwide and will probably be dominant with time.
  Good data does not necessarily support the adoption of technology.
- Predictive instruments are especially important for low-probability patients without obvious AMI. We need clinical trials to see if the instruments make a difference.
- Trials in the ED have shown that predictive instruments improve recognition and treatment of STEMI, and data support their use in the prehospital setting. The question is what they add to the standard ECG. The ED-based TIPI trial showed that the instruments are particularly useful when less expertise is available.

• The idea of using these instruments should be promoted to the Centers for Medicare & Medicaid Services since inappropriate 1-day admissions for chest pain is a problem nationwide.

#### Hospital Delay (Phase III) Project

Chest Pain: The First 60 Minutes (Dr. Octo Barnett)

Dr. Barnett reviewed the development of "Chest Pain: The First 60 Minutes," an interactive educational package developed by Massachusetts General Hospital with funding from the NLM and the NHAAP. The package consists of Web-based simulated patient cases simulations and pre/post-tests with 10 questions. The tests are available at the following Web site: http://nhaap.mgh.harvard.edu/nhaaptest.

The objectives of the project were to develop Web-based case simulations, distribute them over the Internet, demonstrate that physician/nurses would use the program, and show that it improves knowledge and changes behavior in the ED.

For the research study group, ED directors of 12 community hospitals in Massachusetts were contacted and 6 hospitals agreed to participate. A nurse coordinator visited the hospitals weekly. Computer terminals were not readily available in the EDs; the EDs had interest and enthusiasm but not much follow through.

The program also offered "ad-lib" use of the package on the Internet. Through an e-mail list from the Association of American Medical Colleges, students were notified that they could access the program on the Internet for a 3-month period. Optional access was also offered to 15,000 physicians who used a decision support system known as Dxplain. Scoring was done via pre/posttests.

Dr. Barnett displayed sample pages from the Internet version for physicians (see slides, attachment I); a different version is available for nurses. Users were asked to consider the case studies as real patients. The scenarios include sections on case presentation, current illness followup, prior medical history, physical exam, ECG review, therapy, case review, disposition choices, ECG interpretation, and case critique (mandatory and optional items and disposition). A brief tutorial on AMI is also offered, with links to abstracts.

Dr. Barnett reviewed results of an analysis of the study group users and ad-lib users who completed the program. These results include improved scores and changes in behavior after completion of the program and after the tutorial. The project demonstrated that a fair number of physicians and nurses would use the package and that its use would improve knowledge. It also showed that use changed behavior in the ED. Distribution over the Internet was easy and inexpensive.

Dr. Barnett added that it would require updating to keep the package current, and that getting ED staff to use it is a challenge. It was suggested that the package be promoted by professional societies and be part of accreditation. Faculty could promote student use of the package, which might be a useful tool to incorporate into the medical school curriculum, perhaps as part of resident training.

**Discussion.** Dr. Stephen Cantrill, American College of Emergency Physicians' representative on the NHAAP Coordinating Committee, facilitated discussion of Dr. Barnett's presentation. The following points were raised during the discussion:

- Most of the persons who developed the program were cardiologists; five were ED physicians.
- Most of the participants took the test because they were asked to do so—they did not choose on their own to take it. ED physician staff were not in the cohort. ED physicians know what to do. Delay is not in knowing *what* to do but in knowing *how* to do it.
- The next step is to keep the program up to date. Dr. Barnett welcomes input.

Reflections: The Promise of Informatics to Change the Behavior of Patients, Providers, and Health Care Systems for Early recognition and Response to Heart Attack Patients (Dr. Angelo Alonzo)

Dr. Alonzo, Professor, Department of Sociology, The Ohio State University, noted the 1998 informatics symposium charge to the NHAAP: to promote improved access, improve decisionmaking, and improve outcome measurements. This meeting's presentations indicate that there has been progress in all three areas in terms of the use of informatics and computers (see slides, attachment J). There has been progress in the ED and EMS in terms of reducing time-to-treatment and evaluating therapeutic interventions. But patient delay is still a problem.

Dr. Alonzo focused on patient/bystander delay and action as an area that needs further work. He proposed the following:

- Develop a Web-based, tailored, health information and decision support intervention for the patient. Predict the likelihood of a person delaying.
- Focus on a "Just in Case" educational intervention instead of a "Just in Time" intervention. Get people prepared and able to assess the symptoms they are experiencing.
- Move to multidimensional tailored intervention strategies rather than the "one size fits all" approach. "Act in Time" is becoming tailored.
- Use the Web to educate the public. A recent study showed that 75 percent or 204.3 million Americans have Web access at home. People also have access at work, school, and libraries. The Web gets 40.6 million health hits daily; the "Act in Time" site had 30,363 hits in February.
- Attract people who may have risk factors through multimedia—print, television, takehome cards, the Web, etc.
- Identify the audiences you want to attract. Assess who they are so you can tailor and deliver the messages to them, and continue to reassess their knowledge.

Dr. Alonzo said that the basis of tailoring is to identify known and emerging risk factors for ACS and patient delay. Clinical risk factors include high blood pressure, diabetes, lipids, obesity, CVD history, C-reactive protein (CRP), family history, and emerging ones. Social/psychological/cultural risk factors include age, race/ethnicity, low socioeconomic status (SES), low education level, gender, complex information about a person's life, social situations (location, day of week, time of day, others present). Psychological risk factors are self-efficacy, somatic awareness, anger/hostility, and depression. Cognitive risk factors include learning style, problem-solving skills, attentional resources, and memory. Health/illness experiences and knowledge risk factors include health history, ACS knowledge and expectations, ED/EMS/hospital experiences, and cumulative adversity and post-traumatic stress disorder. We should identify which risk factors are more of a problem than others, based on science-based evidence.

Multimedia tailored systems can include "walk-throughs" with a selection of successful choices. For example, "Heart Sense" and "Chest Pain: The First 60 Minutes" have the potential to be tailored to specific target audiences. We also need to reeducate people about the "Hollywood Heart Attack."

Dr. Alonzo listed the following challenges: (1) the low cost of mass media versus the high cost of tailored interventions; (2) the need to make interfaces more user-friendly to reach the technology-challenged/deprived audiences; (3) dealing with the variability of Web browsers—some of which cannot download complex files; and (4) the general complexity of intervention development.

Dr. Alonzo summarized his advice as follows: Develop a Web-based "Just in case" educational intervention that is individually tailored to promote improved access, strengthen patients' decisionmaking skills, and give them the opportunity to prepare. This is complex and expensive. "The technology is there," he said, "so grab it and run."

## **EXECUTIVE COMMITTEE AND SUBCOMMITTEE REPORTS** (Dr. James Atkins, Executive Committee Chair)

Dr. Atkins announced the tentative date for the next meeting: October 25–26, 2004. He noted that Mr. Jimm Murray, representative of the National Association of State EMS Directors for over 10 years, will be leaving the Coordinating Committee and will receive a certificate of appreciation to recognize his many contributions.

#### **Education Subcommittee (Mr. David Simmons, Jr., Vice Chair)**

Mr. Simmons, substituting for Dr. Christine Crumlish, reported on the presentations at the Education Subcommittee's meeting. Several staff members from NHLBI presented at the Education Subcommittee meeting, their report summaries are described below. Ms. Terry Long, Senior Manager, Health Communications and Information Science, OPEC, provided an update on the "Act in Time to Heart Attack Signs" campaign, which targets high-risk groups but includes the public. Ms. Janet Kelly, Nutrition Education Specialist, OPEC, described a 1-hour small group session kit on "Act to Heart Attack Signs" targeting American Indians and Alaska Natives. (This was based on a similar small group session targeting the Hispanic population that

was described at the last meeting.) Ms. Lenee Simon, Community Health Specialist, OPEC, described how the original "Act in Time to Heart Attack Signs" small group session (in English) has also been adapted for the public housing community in Baltimore.

One of the Education Subcommittee priority areas is to monitor the NHAAP/NLM informatics projects for application outside the research setting. This information was reported at the Coordinating Committee meeting.

The "Act in Time" materials have been mailed to almost 10,000 primary care physicians in 30 counties with the highest rates of cardiovascular mortality. This was done in conjunction with the Society of General Internal Medicine and the American College of Physicians. Ms. Hand asked members to fill out the 1-page "Act in Time To Do List" for disseminating "Act in Time" campaign materials. This will reflect the wish list of activities for making member organizations aware of "Act in Time" materials.

#### Health Systems Subcommittee (Dr. Bruce MacLeod, Chair)

Dr. MacLeod discussed two papers being developed by the Subcommittee. "Use of Emergency Medical Services (EMS) by Patients With Acute Coronary Syndromes (ACS): Overview and Future Directions" describes the current state of prehospital care for ACS and will serve as the basis for the Stakeholders' Meeting on EMS Utilization to be held in October 2004. "Prehospital 12-lead Electrocardiography—A Call for Implementation in Emergency Medical Service Systems Providing Advanced Life Support," calls for use of the prehospital 12-lead ECG by all advanced life support (ALS) services with AMI patients. Suggestions and comments on these papers will be submitted within 1 month, followed by a conference call, distribution to the Coordinating Committee, and submission for publication.

Efforts are continuing with the National Committee for Quality Assurance to add a cardiovascular measure to the Health Plan Employer Data and Information Set (HEDIS). This measure would monitor the proportion of patients brought to the ED by ambulance.

The group also discussed the proliferation of electron beam computed tomography (EBCT) scanning to detect a calcium score for CAD. The American College of Cardiology (ACC) has published a position paper that does *not* recommend the use of EBCT. This paper will be distributed to Coordinating Committee members.

Ms. Mary Beth Michos told the group about the Stakeholders' Meeting on EMS utilization to be held in October 2004. The meeting's goal is to review the current state of prehospital EMS utilization for patients with ACS and to identify where it should be in the future. The meeting will define strategies to reach goals, action plans, and monitoring and evaluation. Ms. Michos reviewed the agenda for the 2-day meeting, and she asked members to send her suggestions for speakers.

#### Science Base Subcommittee (Dr. Ornato, Chair)

Dr. Ornato said that the Science Base Subcommittee focused on the periodic literature search, identifying the need to focus more on prehospital deaths, issues related to reperfusion strategies (percutaneous coronary intervention vs. thrombolysis), and the challenge to improve

cardiovascular research and learn from the example of oncology research. He reported that Dr. Teri Manolio, Director, Epidemiology and Biometry Program, Division of Epidemiology and Clinical Applications, NHLBI, presented a progress report on the development of a patient surveillance system for ACS, and Dr Robert Christenson, American Association for Clinical Chemistry, Inc. representative, discussed the May Beckman conference in Boston to update guidelines for biomarkers for ACS and heart failure.

## **Public Access Defibrillation (PAD) Trial Update** (**Dr. Ornato**)

Dr. Ornato presented an update on the PAD trial and lessons learned from the trial following his report on the Science Base Subcommittee meeting (see slides, attachment K). The prospective RCT was conducted in 24 North American cities; 193 units were randomized into two groups. Both groups trained lay, volunteer-based, out-of-hospital cardiac arrest rescuers on recognizing signs and symptoms of possible cardiac arrest in adults. One group was educated to call 9–1–1 quickly and perform cardiopulmonary resuscitation (CPR) while waiting for EMS to arrive; the other group received the same training but was also trained and equipped to use AED.

The trial's primary endpoint was not the percent of survivors but the *number* of survivors to discharge from the hospital in each group. This endpoint was selected because statisticians predicted an ascertainment bias—a greater likelihood of ascertaining cardiac events in the AED arm of the study.

The study took place at 193 large public access units that included a significant number of individuals above age 50, including sites at recreation, shopping, and entertainment areas; community centers; office buildings; and a few large apartment complexes. The sites were randomized to result in roughly the same number of at-risk individuals.

The trial trained almost 20,000 lay rescuers; their average age was 40, half were male, and one third had less than a high school education. The group had 20 percent turnover in 1 year. Having lay person teams trained and equipped to use an AED quickly (in addition to calling 9–1–1 and doing CPR) doubled the number of survivors, compared to the CPR and 9–1–1 group. Neurologic outcomes of survivors in both groups were comparable (93 percent in CPR only; 90 percent in CPR plus AED). There were only 35 adverse events, including the theft of 19 AEDs and psychological effects of lay persons' involvement in unsuccessful resuscitation. The AEDs did what they were designed to do in the hands of rescuers; there were no cases of an AED failing to shock a person with a shockable rhythm, or an AED shocking someone who lacked a shockable rhythm.

Dr. Ornato concluded that the PAD strategy is safe and doubles the number of lives saved when used by trained rescuers. The majority of benefit was in public places; the residential locales in the study accounted for very few survivors in both study arms. The problem with the study strategy is that most cardiac arrests occur in the home. The public venues, even with a large number of people at risk, represent only 20 percent of cardiac arrests; widespread use of PAD will save only an additional 2,000–4,000 lives per year. This is significant but pales in light of the estimated 460,000 out-of-hospital cardiac arrests per year. A substudy of the trial is looking at cost–benefit; results should be available in the next few months. The home AED trial,

which is just starting, will address the question of whether a single lay person covering 1 or 2 individuals in the home environment will yield better results and whether this will be cost effective.

Dr. Ornato said that a formula was available to determine how many cardiac arrests would occur in the study; this was slightly overestimated, but survival was underestimated, and the two canceled each other out. With 2 years of study in the 993 public locations, there were 230 events and 45 survivors. These are small numbers relative to the large population at risk. A PAD strategy by itself will not solve the problem of out-of-hospital cardiac arrests.

The following comments were made during the discussion:

- Another challenge in the home is whether the event is really witnessed.
- Currently, not enough is known about where AEDs should be located; the study
  analyses may shed light on this soon. A study in Seattle found great variation of the
  event rate by site; the important factor was where people age 55 and older were likely
  to be. Office buildings are low-event places, while senior centers are likely to have
  more events. In Dallas, AEDs will be used more frequently in certain places.
- In Fort Lauderdale, AEDs were put in place 18 months ago in Disney Cruise terminals (which include a relatively young population) and in the casino boat that caters to a smaller but older high-risk population. There was only 1 AED use in the terminal versus 10–11 uses in the casino boat.

## REPORT FROM THE NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION (NHTSA)

(Mr. Drew Dawson)

Mr. Dawson provided an update on the Institute of Medicine (IOM) report titled "The Future of Emergency Care in the U.S. Health System." This report has focused predominantly on ED care. A collaboration between the IOM, the Health Resources and Services Administration, and the NHTSA will expand the report to include prehospital EMS. The first meeting of the expanded committee will take place in June. The IOM is accepting nominations for persons to serve on the committee.

## FINAL COMMENTS AND ADJOURNMENT (Ms. Hand)

Ms. Hand thanked the Coordinating Committee members and speakers for their participation and adjourned the meeting.



#### **National Heart Attack Alert Program**

## **Executive Committee Meeting**

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

#### **Meeting Summary** March 23, 2004

#### **Subcommittee Members**

#### **NHLBI Staff**

James M. Atkins, M.D., F.A.C.C. (Chair) Charles L. Curry, M.D. Bruce A. MacLeod, M.D., F.A.C.E.P. Mary Beth Michos, R.N. Joseph P. Ornato, M.D., F.A.C.P., 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., C.N.N.

Robert J. Zalenski, M.D., M.A.

Mary M. Hand, M.S.P.H., R.N. George Sopko, M.D.

#### **Contract Staff**

Judith Estrin, M.A.

#### WELCOME AND INTRODUCTIONS (Dr. James Atkins, Chair)

Dr. Atkins welcomed the members of the Executive Committee meeting.

#### REVIEW OF NATIONAL HEART ATTACK ALERT PROGRAM (NHAAP) COORDINATING COMMITTEE AGENDA (Ms. Mary Hand)

Ms. Hand reviewed the agenda for the NHAAP Coordinating Committee meeting, noting that the meeting's special focus on informatics projects would include presentations and panel discussions.

#### **NEXT MEETING DATE/OTHER NOTES** (Ms. Hand)

The group discussed potential dates for the next meeting in October 2004 and decided on Monday and Tuesday, October 25–26.

Ms. Hand reported that Mr. Jimm Murray, who has represented the National Association of State Emergency Services Directors, is rotating off the Coordinating Committee and will receive a certificate of recognition for his contributions.

## **REPORTS ON SUCOMMITTEE MEETINGS AND ISSUES** (Chairs/Vice Chairs)

#### **Education Subcommittee (Mr. David Simmons, Jr., Vice Chair)**

Mr. Simmons (substituting for Dr. Cristine Crumlish, Chair) gave a report on the Education Subcommittee meeting.

- Several members of the NHLBI's Office of Prevention, Education, and Control (OPEC) presented information about the NHAAP's "Act in Time to Heart Attack Signs" campaign. First, Ms. Terry Long, Senior Manager, Health Communications and Information Science, NHLBI, presented a progress report on the campaign. Then Ms. Janet Kelly, Nutrition Education Specialist, NHLBI, described a program tailored for the American Indians and Alaska Natives, and Ms. Lenee Simon, Community Health Specialist, NHLBI, described a program tailored for the public housing community in Baltimore. Both of these programs were based on the "Your Heart, Your Life" program that was developed for the Hispanic community.
- Ms. Hand reviewed the Education Subcommittee's Priority 2 area, which focuses on the informatics projects that would be presented to the Coordinating Committee that day. In the Priority 3 area, an update on an American Heart Association (AHA) paper reviewing patient delay will be presented at the next NHAAP Coordinating Committee meeting.
- NHAAP has mailed "Act in Time" materials to almost 10,000 primary care physicians (PCPs) in 30 U.S. counties with the highest mortality from cardiovascular disease (CVD). This project was a collaboration with the Society of General Internal Medicine and the American College of Physicians.

Dr. Harry Selker suggested that NHAAP conduct an evaluation of the mailing to PCPs and offered to help with this. The evaluation could be accomplished by sampling recipients or by looking at CVD mortality rates in the 30 targeted counties.

Ms. Hand reviewed the "To Do" checklist in the meeting packet, noting that when members indicate what activities they would like to do, they will be sent the appropriate materials and tools. "Act in Time" has been a prime activity for the Education Subcommittee; there will be three more meetings before the next 5-year review.

#### Health Systems Subcommittee (Dr. Bruce MacLeod, Chair)

Dr. MacLeod reported that the Health Systems Subcommittee discussed two papers that are in progress.

• "Use of Emergency Medical Services (EMS) by Patients With Acute Coronary Syndromes (ACS): Overview and Future Directions" describes the current state of EMS use for ACS and will serve as the basis for the Stakeholders' Meeting on EMS Utilization to be held in October 2004. This paper will end with a concise call to

action. The Subcommittee would like to publish this paper in a generalist journal, such as the *Journal of the American Medical Association*.

• "Prehospital 12-lead Electrocardiography—A Call for Implementation in Emergency Medical Service Systems Providing Advanced Life Support," calls for prehospital 12-lead electrocardiogram (ECG) programs in all advanced life support services. This will be published as an editorial in a journal such as *Circulation*.

Subcommittee members will make suggestions for revisions to both papers within 1 month, followed by conference calls. The papers will then go to the full Coordinating Committee for review. Ms. Hand will send copies of both papers to the Executive Committee.

Ms. Mary Beth Michos discussed plans for the Stakeholders' Meeting on EMS Utilization that will problem solve in the area of prehospital EMS utilization. The meeting will be held in conjunction with the October NHAAP Coordinating Committee meeting. It will start by identifying the current state of prehospital EMS utilization and goals for improvement. Breakout sessions will define strategies to reach these goals, action plans, and monitoring and evaluation. Ms. Michos has asked for suggestions for speakers. One suggestion is Mr. Drew Dawson, representing the National Highway Traffic Safety Administration.

Dr. MacLeod reported that the National Committee for Quality Assurance (NCQA) was asked to advise on a measure that would monitor the proportion of patients brought to the emergency department (ED) by ambulance, which is now about 40 percent. The NCQA's Measurement Advisory Panel (Dr. Tom Lee, Chair) rejected this measure for several reasons: its importance relative to other CVD measures, cost effectiveness, and health plan accountability. The group noted that measures established by the Health Plan Employer Data and Information Set (HEDIS) drive what health plans do. Health plans prefer to use measures other than EMS because of cost. Dr. Selker offered to participate in a conference call with Dr. Lee to discuss this issue.

It was noted that there is only anecdotal evidence for the benefit of ambulance transport to the ED. Some papers suggest a benefit, but these are not high-quality studies. Another problem is that few cardiologists know much about EMS.

The Executive Committee discussed whether the NHAAP should address the use of electron beam computed tomography (EBCT) to screen for coronary artery disease (CAD). The American College of Cardiology (ACC) reviewed the literature and has stated that this test is not worth doing on a routine basis because it does not add more to the standard risk factor profile. Dr. Atkins noted that half of the people age 50 and older have a positive EBCT calcium score, and that asymptomatic patients with a positive score would receive the same treatment they would receive for other risk factors. Furthermore, a high calcium score means CAD, which would make a person uninsurable. The group decided to distribute the ACC's position paper on EBCT to the Coordinating Committee.

#### Science Base Subcommittee (Dr. Joseph Ornato, Chair)

Dr. Ornato said the Science Base Subcommittee's discussion of the literature search raised several issues. First, the focus on prehospital deaths (the majority of which result from AMI) raises the reperfusion dilemma and the question of using percutaneous coronary intervention versus fibrinolytic therapy. Another issue was Dr. Robert McNutt's challenge to compare CVD research with oncology research, which he argued was more organized and directed. This is debatable but provocative; we need to look at what cardiovascular research has achieved and where it can go from here. Finally, Dr. Teri Manolio discussed opportunities to help achieve an ACS patient surveillance system.

The Executive Committee's discussion raised the following points:

- The National Institutes of Health (NIH) supports strong bench research on CVD but does not emphasize clinical research. The NHAAP should support NIH Director Dr. Elias Zerhouni's efforts to strengthen clinical research. The NHAAP can recommend directions to promote clinical research (including a systematic approach and standard reporting) and promote the use of data to reinforce the clinical research roadmap.
- Much clinical research in cardiology is aimed at drugs or devices. Many
  pharmaceutical companies require that researchers sign a binding contract that
  restricts control of the project and the information that can be presented (negative
  studies may not get reported). Councils of drug manufacturers support some
  nonprofit organizations, and their funding determines which projects are promoted.
  We need to partner with industry and get more clinicians involved in research.
- The ACC and the AHA tend to focus on single diseases/single projects, but clinical research should focus on CVD overall. Another problem is that clinical cardiology does not have advocacy behind it.
- General Clinical Research Centers (GCRC), a consortium of clinical research organizations, will hold meetings in 2004 and 2005. Dr. Selker offered to contact this group to see if there is interest in strengthening clinical research on CVD.

#### **ADJOURNMENT**

Dr. Atkins thanked the participants and adjourned the meeting.



#### **National Heart Attack Alert Program**

## **Education Subcommittee Meeting**

## NATIONAL HEART ATTACK ALERT PROGRAM EDUCATION SUBCOMMITTEE

#### Meeting Summary March 22, 2004

#### **Subcommittee Members**

David E. Simmons, Jr., M.S.N., R.N., C.N.N. (Vice Chair)
James M. Atkins, M.D., F.A.C.C.
Julie Bracken, M.S., R.N., C.E.N., A.P.N.
Diane L. Carroll, R.N., Ph.D.
Emmett B. Ferguson, M.D., M.P.H.
Pamela Hirsch, M.S., M.Ed., R.N.-C
(Substitute for Carol Cunningham Base, M.S., B.S.N., C.O.H.N.-S)
Don Vardell, M.S. (Substitute for Pat Bonifer-Tiedt, Sc.M., M.S.)

#### Advisor

Angelo A. Alonzo, Ph.D.

#### **Other Coordinating Committee Members**

Bruce A. MacLeod

#### **NHLBI Staff**

Jeanette Guyton-Krishnan, Ph.D., M.S. Mary M. Hand, M.S.P.H., R.N. (National Heart Attack Alert Program [NHAAP] Coordinator) Janet Kelly, M.S., R.D. Terry Long Lenee Simon, M.P.H.

#### **Contract Staff**

Judith Estrin, M.A.

## WELCOME AND INTRODUCTIONS (Mr. David Simmons, Jr., Vice Chair)

Mr. Simmons, standing in from Dr. Christine Crumlish, welcomed the members of the Education Subcommittee and asked them to introduce themselves.

## "ACT IN TIME TO HEART ATTACK SIGNS" CAMPAIGN REVIEW AND PROGRESS REPORT

(Ms. Mary Hand and Ms. Terry Long)

Ms. Hand noted that the Education Subcommittee identified the "Act in Time to Heart Attack Signs" campaign as a major priority at the NHAAP's June 2001 10-year meeting. Following the results of the Rapid Early Action for Coronary Treatment (REACT) research program, the Coordinating Committee recommended moving forward with the campaign and targeting minorities, older Americans, and women. Planning is done at 5-year intervals; the next planning meeting is slated for October 2006, at which time the NHAAP will assess the "Act in Time" dissemination effort. There should be three NHAAP Coordinating Committee meetings between now and then.

Ms. Hand asked Subcommittee members to fill out the "Act in Time To Do List" in the meeting packet and return it to her by the end of the meeting. The completed forms will indicate which activities the member organizations have either done or plan to do and help to identify gaps. Ms. Hand also called attention to "Ideas for 'Advocating Act in Time," a handout that gives examples of how member organizations have promoted the "Act in Time" campaign by publishing articles or advertising materials in their publications or Web sites, linking to the "Act in Time" site, giving talks, or distributing materials.

Ms. Long, Senior Manager, Health Communications and Information Science, NHLBI, provided a progress report on the "Act in Time to Heart Attack Signs." Campaign (see slides, attachment L). She began by reviewing the rationale and objectives for the campaign and then described the process, as follows:

- **Situation analysis** was based on REACT, a 4-year NHLBI-funded study in 10 communities and the first large-scale study to evaluate the effects of community education on patient delay time.
- **Message development** led to the design of a clear action message that called on health care professionals to give their patients three messages: (1) learn the heart attack warning signs; (2) call 9–1–1 immediately if a heart attack is suspected; (3) and be prepared with a heart attack survival plan.
- Materials development resulted in a complete product line for materials for health care professionals, patients, and the public. The "Act in Time" products have won seven awards to date. Four new products include an easy-to-read handout in English or Spanish, a discussion kit for Spanish speakers, and "Honor Your Heart" materials for American Indians and Alaskan Natives.
- **Dissemination and Promotion** have resulted in the distribution of 300,000 materials to date and more than 14,500 downloads of the "Act in Time" PalmOS program. A special focus on primary care physicians (PCPs) led to the distribution of materials to 9,446 PCPs in 30 U.S. counties with the highest cardiovascular mortality. Information is being added to a database documenting dissemination and promotion activities. Next steps include increased focus on minorities, including dissemination of new Spanish-language materials and materials for American Indians/Alaskan Natives, and collaboration with the NHLBI's "Heart Truth" campaign.
- **Monitoring and evaluation** is where the campaign is now.

Ms. Long provided examples of how member organizations have promoted the "Act in Time" campaign. For example, the American Red Cross provides a speakers' kit with sample materials and Web site promotion. The American Heart Association's (AHA's) Operation Heart Beat has integrated "Act in Time" materials. The National Council on the Aging pledged to give the "Act in Time" course in 1,000 senior centers in 1 year. The National Medical Association provided a satellite media tour. A goal is to increase campaign visibility through the use of tools such as the drop-in article and announcement, camera-ready public service announcement,

ready-made Web link text and buttons and banners, HTML and text e-mail templates, and PowerPoint slides.

Ms. Long noted that "Act in Time" is number one on the Google search engine when "heart attack" is the search term. Users can access or order all "Act in Time" materials from the NHAAP Web site. Most inquiries come via the Web; this is where many Americans obtain health information. There was discussion about resending the advocacy package with the electronic tools for promoting "Act in Time" through member organizations. Subcommittee members suggested that because universities may not allow downloading of large ZIP files, it would be best to send member organizations an e-mail with a link to the NHAAP Web page from which information can be downloaded. Another suggestion was to link the "Act in Time" Web site to other NIH Web sites (e.g., for high blood pressure, diabetes, aging, and cholesterol). NHAAP will ask MEDLINE if it can link to the "Act in Time" Web site. NHAAP cannot link to Web sites for drugs (such as statins), but these sites might be able to link with NHAAP.

## ENHANCING AMERICAN INDIAN/ALASKA NATIVE (AI/AN) COMMUNITY OUTREACH WITH "ACT IN TIME TO HEART ATTACK SIGNS" MESSAGES (Ms. Janet Kelly)

Ms. Kelly, Nutrition Education Specialist, Office of Prevention, Education, and Control (OPEC), NHLBI, described an "Act in Time" outreach program targeting AI/ANs (see slides, attachment M). The program's goals are (1) increased awareness of cardiovascular disease (CVD) and strategies to adopt both personal and community heart health behaviors; (2) a shared vision within the community to maintain a capacity to address heart health issues; (3) and the development of an outreach module that can be shared with AI/AN communities. The program was adapted from the "Salud para su Corazón" program targeting the Hispanic community and incorporates its train-the-trainer model. In this model, a group of key community educators (nurses, nutritionists, community health representatives) are trained, and they then conduct train-the-trainer sessions for community educators. The trained community educators proceed to train individuals, families, patients, and the community.

Phase I (1998–2000) of the AI/AN program included a background report, selection of tribal communities, formative research to identify community needs, and the development of brochures and a video. Communities were selected on the basis of a high occurrence of three or more risk factors, low socioeconomic status (SES), limited access to care, and poor dietary practices. Other selection factors such as need for health education materials were also considered. Three CVD-based community outreach projects were established in Bristol Bay, AK; Laguna, NM; and Ponca, OK.

Phase II focused on orientation and community readiness. The Mobilizing AI/AN Communities Workshop on Improving Cardiovascular Health was held in May 2001. Training and implementation of education and outreach activities followed, and a draft manual was produced. The next steps were integrating the program into community life and evaluating the links between strategies with outcomes. The training provides basic CVD education to heart health teams in the three communities—providing knowledge about heart-health behaviors, practice, and skills; and empowering and motivating the teams to take the messages back to their communities.

Honoring the Gift of Heart Health is a nine-session manual on topics such as heart disease risk factors, physical activity, and healthy eating. PowerPoint visuals go along with the manual. Handouts include those on heart attack warning signs; calling 9–1–1; roleplaying at work, home, or the office; and 6 Steps to Survival. The training features practical and fun-filled, hands-on learning, skills development, demonstrations/practice, simulations/roleplaying, discussion/sharing, and incentives (such as food). Community involvement includes theme days and traditional games. Graduation activities include the "Eagle and Buffalo Dance" and a heart healthy traditional lunch.

An evaluation component will connect the strategies with outcomes. The next step is to work with the Indian Health Service (IHS) to expand the training nationally.

In response to questions, Ms. Kelly made the following comments:

- Cultural differences include diet. The program encourages the communities to eat traditional foods that are healthy and available (e.g., moose stew, caribou).
- IHS clinics are spread out and often too small. The program will work with the clinics to provide heart health information.
- Good telephone service is often lacking in AI/AN communities; 9–1–1 is still not universal. A person's street and house number may be needed for 9–1–1 to work, but some mail is addressed to intersections in the these communities.
- The program targets both urban and rural AI/AN communities. The AI tribes are diverse, and communities are asked to personalize the manual.

## HEALTHY HEARTS IN PUBLIC HOUSING: A PROJECT OF THE HOUSING AUTHORITY OF BALTIMORE CITY (Ms. Lenee Simon)

Ms. Simon, Community Health Specialist, OPEC, NHLBI, described a heart health outreach program focusing on the public housing population in Baltimore (see slides, attachment N). The project is funded by a 3-year (2002–2005) contract from the NHLBI in collaboration with the Housing Authority of Baltimore City, Morgan State University, the Department of Housing and Urban Development in Baltimore, and the Baltimore City Department of Recreation and Parks. Baltimore's Public Housing Authority is the Nation's fifth largest, with 40 public housing developments and 60,000 residents (92 percent African American).

The project has two core components: (1) community health worker (CHW) training and outreach, and (2) heart healthy lifestyle adoption and maintenance—the "Heart Healthy Clubs." The first component recruits, interviews, and selects public housing residents; provides intensive 2-month training; and hires, supports, and supervises CHWs as integral program implementers. The training is college credited and delivered by Baltimore City Community College. Training areas include core CHW competencies (e.g., communication skills, community education), the American Heart Association's Cardiopulmonary Resuscitation (CPR) Heart Saver training, blood

pressure measurement certification, and the NHLBI Heart Health Lay Health Training curriculum, which includes core content from the Latino-targeted *Your Heart, Your Life* training manual revised for cultural appeal and relevancy to African Americans. The training includes eight sessions on heart disease risk factors and one session on "Act in Time to Heart Attack Signs."

The evaluation component includes pre-/post-tests on knowledge, attitudes, and behavior. A "stages of change" assessment includes self-report of intentions and practice, and process evaluations are conducted. Graduation day is an opportunity to celebrate the completion of the training program and to inform public housing residents about their work. (It was suggested that the number of referrals for cardiovascular care would be a good outcome.)

CVD risk reduction programs are being implemented at (1) public housing sites, including graphical and engaging presentations by CHWs to raise awareness and knowledge about CVD risk factors and acute events; (2) health fairs and other special events; (3) ongoing heart health lifestyles clubs targeting seniors, youth, and families; (4) and dissemination of "Act in Time" materials for the public and providers, as well as other NHLBI materials.

During the discussion, Ms. Simon added that the 20 CHWs are 18–76 years of age, and 2 are male. The program has reached more than 1,000 housing residents so far. The educational materials have been adjusted to be relevant to the African-American community by including photos of this population and revising statistics on heart disease and smoking. Plans for ongoing training include updating training on blood pressure measurement and refreshing CPR certification skills and CVD content.

### NATIONAL LIBRARY OF MEDICINE (NLM)/NHLBI INFORMATICS FOR THE NHAAP: PROJECTS WITH AN EDUCATIONAL COMPONENT (Ms. Hand)

Ms. Hand turned attention to the Education Subcommittee's Priority Area 2, which focuses on informatics projects to promote the use of evidence-based technologies by health care systems. These projects resulted from the 1998 Symposium with support from the NLM and Agency for Health Care Policy and Research (now called the Agency for Healthcare Research and Quality, or AHRQ). The Subcommittee's goal was to monitor informatics projects for their use and application outside of research studies. Directors of the informatics projects will present reports on six of the seven informatics projects at NHAAP's Coordinating Committee meeting (one project director was unable to attend). Ms. Hand described three of the most relevant projects to the Education Subcommittee:

- MI-HEART: This project, conducted by Columbia University, studies the use of electronic medical records coupled to a Web-based delivery system to deliver customized patient education materials related to recognition and response to heart attack symptoms. Dr. Rita Kukafka will present the final report.
- "Chest Pain: The First 60 Minutes:" This project, conducted by Massachusetts General Hospital, is a Web-based interactive educational package covering emergency department (ED) management of patients with chest pain. It includes a pretest, simulated patient-management problems, a posttest, and an online tutorial

summarizing current best practices. After each case, users receive extensive critiques of their decisions as well as references and abstracts to support the decisions. Dr. Octo Barnett will present this project; he has provided a Web link to the test, http://nhaap.mgh.harvard.edu/nlm. (Users can enter their name when asked for a password.) The test takes about 1 hour to complete.

• Heart Sense—A Game for Heart Attack Prehospitalization Delay Reduction: This project was developed by the University of Pennsylvania. The target audience is the U.S. population at risk for a first myocardial infarction (MI) (e.g., elderly, female, African American, and low SES). In developing the video game, four treatments were studied: basic standard of care, a multimedia program with a soap-opera type story, basic standard of care with a coaching character, and story and content without multimedia. Mr. Ransom Weaver will make this presentation.

Ms. Hand added that the Subcommittee also established A Conceptual Framework for Behavioral Change—A Research Initiative for Priority Area 3. These are two efforts that relate to this priority area. The Education Subcommittee is tracking a paper titled "Reducing Treatment—Seeking Delay in Acute Coronary Syndrome and Stroke," which has its origins in an AHA symposium held in January 2002. Dr. Deborah Moser leads the workgroup developing the paper, and Ms. Hand will check with her on its progress. Ms. Hand also noted that the Executive Committee meeting in June 2003 included a discussion about an extension of the REACT study that would have potential relevance to Priority Area 3. Interest in a second generation REACT study was stimulated by Ms. Hand's proposal that the NHAAP prepare a paper providing an update on critical Program issues and their status, including patient delay, calling 9–1–1, and treatment post-REACT. A conference call was recently held with representatives from the NHAAP Executive Committee and Science Base Subcommittee, and Dr. Lawton Cooper, NHLBI REACT Project Officer, to discuss the prospects for this initiative.

Ms. Hand reminded members to fill out the "To Do" list. She said that her office stands by ready to help members implement their plans for disseminating the "Act in Time to Heart Attack Signs" campaign.

#### **ADJOURNMENT**

Mr. Simmons thanked the speakers and Subcommittee members and adjourned the meeting.



### **National Heart Attack Alert Program**

# Health Systems Subcommittee Meeting

### NATIONAL HEART ATTACK ALERT PROGRAM HEALTH SYSTEMS SUBCOMMITTEE

#### Meeting Summary March 22, 2004

#### **Subcommittee Members**

Bruce A. 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.

Drew E. Dawson Nancy E. Foster J. Lee Garvey, M.D. Andrea G. Gelzer, M.D. Lawrence D. Jones, M.D. Jay Merchant, M.H.A.

George Mensah, M.D. (replacing Wayne Giles, M.D., M.S.)

Jonathan Moore, EMT-P (Substitute for Lori Moore, Dr.P.H., M.P.H., E.M.T.-P.)

Jimm Murray

#### **Other Coordinating Committee Members**

James A. Atkins, M.D., F.A.C.C. Stephen Cantrill, M.D., F.A.C.E.P. Diane L. Carroll, Ph.D., R.N. Emmett Ferguson, M.D., M.P.H. Patricia Hirsch, M.S., M.Ed., R.N.-C Robert L. Jesse, M.D., Ph.D. Robert A. McNutt, M.D., F.A.C.P.

#### Guests

Angelo Alonzo, Ph.D. Gamunu Wijetunge, EMT-P

#### **NHLBI Staff**

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#### **Contract Staff**

Jill K. Arvanitis, M.P.H., C.H.E.S. Judith Estrin, M.A.

### WELCOME AND INTRODUCTION (Dr. Bruce MacLeod and Ms. Mary Beth Michos)

Dr. MacLeod welcomed the Subcommittee members and asked them to introduce themselves.

Dr. Lawrence Jones raised an issue that was not on the agenda—freestanding health providers that give electron beam computed tomography (EBCT). He stated that radio ads have been saying, "One in five myocardial infarctions (MIs) do not show up on electrocardiograms (ECGs)—therefore, come to us if you think you may have a heart attack, even if you need to drive farther." Dr. Jones wondered whether the National Heart Attack Alert Program (NHAAP) should address whether a need exists to ensure that the ads are responsible and lead to people getting the appropriate care. Ms. Hand pointed out that it sounded as if there is no distinction between symptoms of new onset (i.e., stable ischemic) heart disease versus acute ischemic (e.g., heart attack) symptoms in the ads. Ms. Nancy Foster added that the American Hospital Association has expressed concern about specialty or "boutique" hospitals because they are undermining the financial stability of community hospitals.

The following additional comments were made:

- Positive EBCT scans lead to nuclear perfusion scans to rule out coronary artery disease (CAD).
- Screening would be warranted in asymptomatic persons if there were an intervention, but there is no intervention for calcified arteries. About 85 percent of persons age 50 and older have CAD but may not have symptoms because their disease is not obstructive. A positive EBCT scan can make a person uninsurable by labeling them as having CAD.
- Studies have shown that EBCT is not sensitive or specific. The only valid use of EBCT at present is for epidemiological research. As the technology evolves, there may be a use for EBCT in ruling out acute coronary syndrome (ACS) in symptomatic patients.
- Patients pay cash for the EBCT scans. The cost is likely to become lower with time; however, the cost to Medicare for the followup of false positives is great.
- A public education program is needed to inform the public about the small benefit from free-standing EBCT and related scans. Is this the role of the Subcommittee or the Government?
- The discussion should be broader than just EBCT but rather about the use of technology in general.

This discussion will be continued by the Executive Committee. Another issue is whether community rural hospitals can appropriately treat acute MI (AMI). It was noted that EBCT does not have much impact on emergency medical services (EMS) or acute care.

#### EMS SYSTEM UTILIZATION (PRIORITY AREA #1)

#### **Use of EMS by Patients With ACS: Discussion of Revised Paper (Dr. MacLeod)**

Dr. MacLeod led the discussion of the draft paper entitled "Use of Emergency Medical Services by Patients With Acute Coronary Syndrome Symptoms: Overview and Future Directions." The paper provides a general overview for health policymakers and also serves as the underpinning for the Stakeholders' Meeting on EMS Utilization by providing what we know right now. This paper could lead to more focused articles for specific journals.

The Subcommittee discussed whether the paper should also provide standards for EMS care, recommendations, and conclusions. It was noted that there is a separate paper on the prehospital 12-lead ECG as a standard of care (to be discussed later in the meeting). A previous publication, *EMS Education Agenda for the Future: A Systems Approach*—produced by the National Highway Traffic Safety Agency, the National Association of EMS Physicians, and the National Association of EMS Directors—addressed three components: history, current status, and recommendations for the future.

The audience for the paper will depend on where it is published. It has been crafted for a non-EMS audience. Health policy leaders—including legislators, EMS medical directors, hospital leaders, etc.—should be able to use the document as a reference when they build an EMS system.

#### Suggestions

- Mention other prehospital care providers (non-EMS). Discuss the variety of EMS structures.
- Briefly state (e.g., in one paragraph) that interventions for ACS have applicability to other diseases (e.g., stroke and heart failure) but the focus should remain on ACS.
- In the conclusion, clearly summarize what we know in a bulleted list (e.g., 7–10 things). Also improve and clarify the call to action.
- The calls to action should be by target audience.
- Advocate a systematized integration of systems (EMS, emergency department [ED], hospital, cardiac care unit) to focus on a response to a given disease or threat. This paper goes beyond ACS to also include such diseases/threats as stroke and trauma.
- Mention additional partners, such as the Centers for Disease Control and Prevention (CDC) program on heart disease and stroke, to get State and local health departments involved.

Committee members were asked to send comments and editorial suggestions to Dr. MacLeod or Ms. Hand in 1 month. The paper will then be revised and sent to the Coordinating Committee.

### Draft Agenda for EMS Stakeholders' October 2004 Meeting to Problem Solve Around Issues Related to Improving EMS Utilization by ACS Patients (Ms. Michos)

Ms. Michos describes plans for the Stakeholders' Meeting on EMS Utilization that will be held in October 2004 (see slides, attachment O). The Health Systems Subcommittee recognized the need to bring all the stakeholders together to look at the data and the research that has been done, talk about the issues, and see where we should be going. Meeting goals are to:

- Review what we know about barriers and facilitators to utilization of EMS based on a background paper.
- Educate attendees about the benefits of 9–1–1/EMS use for people with possible ACS.
- Identify the optimal targets of where we want to be in terms of transportation and care of individuals with possible ACS.

- Establish an action plan with recommended strategies to improve systems and gain the buy-in of the target audience.
- Gain consensus for monitoring, implementation, and evaluation of the action plan. All participants (e.g., prehospital component, health department, system managers) will complete a mini contract of what each organization will do.

Ms. Michos reviewed the agenda for the 2-day meeting, which would include large-group sessions with speakers; breakout sessions to identify optimum targets, strategies to achieve them, and action plans; presentations from the breakout groups; and a summary followed by next steps.

Ms. Michos said that the meeting will focus on interaction between the Coordinating Committee and outside groups. She asked for comments on the agenda and suggestions for speakers and facilitators. The meeting will be held in the Washington, DC metropolitan area; dates for other meetings and conferences that members might attend in October will be considered in choosing the date. The following comments were made:

- Prepare suggested targets and evidence for them in advance of the meeting; otherwise, there will be disagreement about numbers used for targets. Examples of concrete goals (for which data can be obtained) are to increase the proportion of patients with AMI and ACS who are transported by EMS; and to increase the number of patients who receive aspirin in the prehospital setting. Tie the goals into the goals of Healthy People 2010.
- Include discussion on disparities in accessing EMS. Address gender, racial, and age
  disparities and barriers such as insurance coverage, associated financial concerns, and
  differences in experiencing and recognizing symptoms. Recognize geographical and
  regional differences, as well as differences in socioeconomic status and education.
  For example, urban African Americans tend to use EMS more, but those from rural
  regions have the longest response time. Invite representatives from racial/ethnic
  groups to the meeting. Do not constrict the breakout groups too much; accept the
  flow of ideas.
- Disseminate the Small Group Session Kit for the "Act in Time" 1-hour lesson plan on symptom recognition. We need to know how effective we have been and how to increase effectiveness in the community. The lesson plan might be updated after the meeting. Identify what member organizations can do to get the message out.
- Consider the issue of how communities go about allocating resources. This may be determined by local politics and economics. Even in the same town and same ethnic group, people will have different reasons for not calling 9–1–1.
- Give EMS the tools and data to assess the number of patients who are not being transported in their community. Offer the opportunity to collaborate with State cardiovascular health programs (e.g., epidemiologists in the State programs can provide data).

- Find out how to get data from hospital admissions. The Behavioral Risk Factor Surveillance System (BRFSS) includes a question about calling 9–1–1 and could provide community-specific information. There is a proposal to change the standard BRFSS to include a cardiovascular module.
- Broaden the audience for the meeting (which was originally EMS) to include Coordinating Committee organization staff, potential EMS users such as patients, groups at risk, and general consumers. Involve the American Association of Retired Persons, National Association of Area Agencies on Aging, and the Cardiovascular Council of the Association of State and Territorial Chronic Disease Program Directors.

Suggested speakers include Dr. John Canto, who will talk about where we are now, and Dr. Carolyn Clancy of the Agency for Healthcare Research and Quality (AHRQ), who will speak about disparities and the need for data. Members were asked to send other suggestions for speakers.

#### **EVIDENCE-BASED TECHNOLOGIES (PRIORITY AREA #2)**

### Prehospital 12-Lead ECG—A Call for Implementation in EMS Systems Providing Advanced Life Support (ALS): Presentation and Discussion (Dr. J. Lee Garvey)

Dr. Garvey discussed the draft paper "Prehospital 12-Lead Electrocardiography—A Call for Implementation in EMS Systems Providing Advanced Life Support (ALS)," which recommends that all EMS providers who perform ALS should have 12-lead ECGs at their disposal (see slides, attachment P). There are good data indicating that this underutilized technology can speed time-to-treatment with both fibrinolytic drugs and percutaneous coronary intervention (PCI). The technology has been endorsed for urban and suburban systems by the American Hospital Association, the American College of Cardiology (ACC), and the National Association of EMS Physicians. Dr. Garvey noted that there are probably fewer ALS providers in rural areas because of cost issues, and that the Subcommittee's recommendations will not put the burden on volunteer or rural systems lacking resources.

#### Dr. Garvey also made the following points:

- There have been several generations of prehospital monitor—defibrillators and most have an option for 12-lead ECG. Most paramedics receive basic training in 12-lead interpretation; others can receive it in 12–16 hours of training. An early concern was that an undue delay would be experienced in on-scene time, but this is not thought to be of consequence.
- Reduced time-to-treatment is the major benefit—34 minutes till thrombolytics and 23 minutes till PCI. A 30-minute faster time-to-treatment translates to 1 year of additional survival and a 0.5 percent additional mortality benefit. The technology also can activate a hospital's internal response to a code ST-elevation MI (STEMI).
   Dr. Garvey suggested rewording the draft to read "cardiac destination hospital and activation of a code STEMI program." The phrase "cardiac destination hospital"

would replace "centers of excellence." This would enhance the ability to treat patients within 60 minutes of symptom onset.

- The baseline for current use of prehospital 12-lead ECGs is not well understood. The best estimate was from a survey of U.S. cities (published in 2000), which found that 43 percent of EMS systems were using 12-lead ECGs. A paper published in the early 1990s by Aufderheide et al., indicated that some hospitals use this technology for the majority of STEMI patients but not for all chest pain patients.
- Cost estimates are \$9,000-\$25,000 per device. It might be less expensive to upgrade monitor-defibrillators to a 12-lead device. Training and disposable supplies are not a big expense. There is only one abstract in the literature on cost benefit of the technology (Potluri, 1998). Based on a literature search, the author concluded that the technology is relatively inexpensive and decreases after years of use. Outcome measures were cost per year of life saved and cost per life saved. Another measure of benefit is to quantify the value of early treatment (cost per year of life saved).
- Prehospital 12-lead ECGs are the key to implementing cardiac destination hospital triage protocols.

Dr. Garvey identified several questions that should be more fully addressed in the draft:

- (1) How many EMS systems use prehospital 12-lead ECG? (2) What other barriers exist?
- (3) What proportion of AMI patients receive care within 60 minutes of symptom onset?

The following points were raised during the discussion:

- Small and large hospitals may differ in terms of preparing for the patient. Large hospitals may activate their catheterization laboratory based on the prehospital interpretation of the 12-lead ECG. The goal is to speed treatment by transmitting data from the prehospital provider to the decisionmakers at the hospital.
- The incremental cost should be considered rather than the cost of the device. When considered in relation to the cost for defibrillators, ambulances, and salaries, the cost of the device is not that high.
- The cost of training and quality improvement could be larger than estimated.
  Paramedics may not use the device because they have not had training. Some
  training covers how to use the device and transmit the data (to be interpreted by a
  physician); other training includes interpretation. Computer interpretation is
  evolving.
- Most hospitals use the same electronic systems for data storage, and many prehospital
  providers use electronic documentation. An identifier is needed for electronic
  medical records. The National EMS Information System will provide an interface
  between electronics and the prehospital EMS information system.

• Prehospital 12-lead ECG should be a quality indicator. A benchmark goal could be to have 75 percent of STEMI patients transported by paramedics receive a 12-lead prehospital ECG. We know that 40 percent of the Nation's largest 200 communities have 12-lead ECG capability, but we do not know what percentage use it. Someone estimated that national usage was probably about 25 percent.

Dr. Garvey asked Subcommittee members to send additional comments to him within 1 month. The next iteration of the paper will be sent to members, and separate conference calls for each paper will be held.

#### **QUALITY IMPROVEMENT (PRIORITY AREA #3)**

#### **National Committee for Quality Assurance**

Dr. MacLeod said that another priority is to work with organizations that perform quality measurement on a national basis, such as the National Committee for Quality Assurance (NCQA). Another followup conference call was held with Dr. Joachim Roski, Assistant Vice President, Quality Measurement, and Dr. Philip Renner, Director of Performance Measures, both of NCQA, to advocate for the following proposed quality improvement measure for health plans to monitor: the proportion of AMI patients brought to the hospital by ambulance. When this measure was discussed by the NCQA's Measurement Advisory Panel, several concerns were raised: (1) the importance of this measure relative to others cardiovascular measures (e.g., low-density lipoprotein cholesterol reduction, smoking cessation, etc.); (2) cost effectiveness; and (3) how health plans would respond. The Subcommittee needs to build a response to these concerns and report back to NCQA.

Subcommittee members made the following comments during discussion:

- Cost effectiveness is extremely important, but difficult to determine.
- It would be difficult for a health plan to design an intervention to increase the use of ambulance use by heart attack patients. Consider a different prehospital indicator.
- Health plans could educate high-risk patients to have a plan for when they have symptoms. The results can be determined by monitoring insurance claims to see the percentage of patients who called 9–1–1. Part of the concern is having health plans not discourage the use of EMS because of the cost.
- The absence of cost effectiveness is not evidence that EMS should not be encouraged. The fact that it reduces mortality is evidence of effectiveness. An absolute risk reduction number could be given.
- There is a lack of empirical evidence to support the measure. A good literature review is needed to see if patients transported by ambulance have a better outcome than those who do not.

• Other NCQA evidence-based cardiovascular measures come from the American Heart Association (AHA) and the ACC. AHA and ACC are planning to make a stronger recommendation for prehospital 12-lead ECGs for STEMI patients. A measure could be the percentage of patients with AMI who have a prehospital 12-lead ECG.

Dr. MacLeod will ask the Science Base Subcommittee for data on decreased mortality resulting from the use of a prehospital 12-lead ECG. The topic will then be revisited with NCQA. However the Subcommittee will continue to pursue use of 9–1–1 by AMI patients as a measure.

#### ADJOURNMENT

Dr. MacLeod thanked the participants and adjourned the meeting.



### **National Heart Attack Alert Program**

## Science Base Subcommittee Meeting

### NATIONAL HEART ATTACK ALERT PROGRAM SCIENCE BASE SUBCOMMITTEE

#### Meeting Summary March 22, 2004

#### **Subcommittee Members**

F.A.C.E.P. (Chair)
Robert J. Zalenski, M.D., M.A. (Vice Chair)
Stephen V. Cantrill, M.D., F.A.C.E.P.
Robert H. Christenson, Ph.D., D.A.B.C.C.,
F.A.C.B.
Arthur A. Ciarkowski, M.S.E., M.B.A., M.P.A.
Charles L. Curry, M.D.
Gerald DeVaughn, M.D., F.A.C.C.
Robert L. Jesse, M.D., Ph.D.
Ijaz Kahn, M.D., F.C.C.P., F.A.C.C.

Joseph P. Ornato, M.D., F.A.C.P., F.A.C.C.,

(Substitute for David D. Gutterman, M.D., F.C.C.P.)
Bruce A. MacLeod, M.D., F.A.C.E.P.
John McGinnity, M.S., P.A.-C.
Robert A. McNutt, M.D., F.A.C.P.
Harry P. Selker, M.D., M.S.P.H.

#### **Other Coordinating Committee Members**

James M. Atkins, M.D., F.A.C.C. J. Lee Garvey, M.D. Lawrence Jones, M.D. George Mensah, M.D.

#### NHLBI Staff

Mary M. Hand, M.S.P.H., R.N. Teri Manolio, M.D., Ph.D. Jean L. Olson, M.D., M.P.H. George Sopko, M.D.

#### **Contract Staff**

Jill K. Arvanitis, M.P.H., C.H.E.S. Judith Estrin, M.A.

### **WELCOME AND INTRODUCTIONS** (Drs. Joseph Ornato and Robert Zalenski)

Dr. Ornato welcomed the members of the Science Base Subcommittee and asked them to introduce themselves.

#### SCIENCE BASE SUBCOMMITTEE LITERATURE SEARCH REPORTS

Dr. Ornato said that the Subcommittee periodically has a systematic review of the literature related to the NHAAP. Prior to the meeting, members were mailed copies of the literature review for the period from July 1, 2002 to December 31, 2003. Subcommittee members would now provide reports on the abstracts.

#### Phase I: Patient/Bystander Aspects and Actions (Dr. Charles Curry)

Dr. Curry said that he did not find anything earthshaking in the literature review for this area. One study (Adamson et al., 2003) found that ethnicity, socioeconomic position, and gender did not affect general health-seeking behavior.

#### **Phase II: Prehospital Aspects and Actions**

### Part A: Emergency Medical Services (EMS) Systems Configuration for Acute Coronary Syndrome (ACS) Patient Management (Dr. Ornato)

Dr. Ornato said that no results were reported for this section.

### Part B: Prehospital Diagnosis and Treatment/Technologies (Drs. Bruce MacLeod and Harry Selker)

Dr. MacLeod said that he was surprised by the huge number of abstracts dealing with prehospital fibrinolytics. The Subcommittee should look at these studies in depth and examine the data. Regarding the issue of percutaneous coronary intervention (PCI) versus thrombolytics, some abstracts indicate that PCI may be better even if there is a delay in transport. There may be competing messages if we advocate prehospital fibrinolytics. We must be cognizant of all factors related to response times. There are a variety of comparisons of therapy—the issue is not well resolved.

Dr. Selker added that mortality rates go both up and down with time-to-treatment. Analyses of biomarkers are usually retrospective and do not predict how to use the results in real time. (A meeting on cardiac markers will address this issue.) There is good clarity on prenotification of hospitals using 12-lead electrocardiograms (ECGs). Dr. Ornato added that the American Heart Association/American College of Cardiology (AHA/ACC) Writing Committee has almost finished guidelines on ST-elevation MI (STEMI), and the Health Systems Subcommittee is producing a paper advocating the universal use of 12-lead ECG.

We can ask the Agency for Healthcare Research and Quality (AHRQ) to do an analysis on an as-needed basis of critical issues (e.g., PCI vs. fibrinolytics); this is a funding issue. AHRQ plays an advisory role to the Centers for Medicare & Medicaid Services (CMS). If the topic is reimbursement related, it may have a better chance of being funded. For example, PCI involves substantial cost to Medicare.

### Part C: Sudden Cardiac Death/Out-of-Hospital Cardiac Arrest (Mr. Arthur Ciarkowski and Dr. Ornato)

Dr. Ornato said that a theme in the literature is the importance of early defibrillation. De Maio et al. (2003) ran a logistics regression model showing that there is less than an 8 minute response interval for providing optimal EMS defibrillation. The cutoff is not a straight line but an exponential drop. This fits with the paper by Weisfeldt and Becker in *Circulation* several years ago about the different phases in resuscitation. Dr. Ornato mentioned two abstracts on law enforcement agency defibrillation (Mosesso et al., 2002 and Myerburg et al., 2002). The Myerburg paper had both positive and negative findings, reemphasizing that resuscitation is not solved simply by early defibrillation. While a survival rate was observed for victims of ventricular fibrillation (VF) or pulseless ventricular tachycardia, this benefit was diluted by the observation that 61 percent of the initial rhythms were nonshockable. The prevalence of VF as the initial rhythm has decreased the initial rhythm from 50 to 25 percent. It is possible that patients are being seen at different points in time, and there is also a selection bias (some patients

have increased awareness). Thus, the prevalence of VF has dropped despite EMS responses being equal or faster than a decade ago.

Public access defibrillation is another theme of the abstracts. Mr. Ciarkowski said that three abstracts deal with device design and human factor issues. Silfvast et al. (2002) found that devices with an automated external defibrillators (AED) rhythm display inhibited users from using the device correctly. He suggested two ways to design the best devices: use the standards developed by the American Association of Medical Instrumentation in 1993 and 1996; and deal with industry trade groups to make sure devices are comparable and that best practices are used for device design.

#### **Phase III: Hospital Aspects and Actions**

### Part A: Diagnostic/Treatment Technologies and Strategies (Drs. Robert Christenson, Robert McNutt, Selker, and Zalenski)

Dr. Christenson said that the data for troponin use continue to be compelling for risk factor stratification and diagnosis. Several retrospective studies indicate that the evidence is not there yet to support the use of naturiuretic peptides for risk stratification of non-STEMI patients. Several studies from the Treat angina with Aggrastat and determine Cost of Therapy with an invasive or Conservative Strategy (TACTICS) and Thromblysis in Myocardial Infarction (TIMI) groups are helping with the development of guidelines for biomarkers.

Dr. Zalenski said that changing the triage/disposition of patients with STEMI could save lives. The PRAGUE-2 study (Widimsky et al., 2003) showed that patients who present more than 3–12 hours late after acute myocardial infarction (AMI) symptom onset had a mortality advantage with PCI compared to fibrinolytics.

Dr. McNutt made a strong case for improving the quality of research in cardiovascular disease, noting that oncology does a better job than cardiology. As an editor of the *Journal of the American Medical Association*, he has seen 60 percent of these articles and they were rejected due to lack of scientific rigor, composite endpoints, and discrepancies in the data. All-cause mortality is the only good outcome measure (not disease-free survival). Dr. McNutt recommended that the Government declare a war on heart disease, organize the States around regionalization of medical care; establish a clearing house for information (e.g., updated information on clinical trials); develop a Physician Data Query<sup>®</sup> for heart disease such as the one for cancer; and establish a way to improve the quality of the literature and organize it. He also suggested that the National Institutes of Health must address funding in cardiology research, which dominates which questions are asked. Cancer research receives more Federal funding; while many trials on heart disease are funded by industry.

Dr. Christenson noted the need for national registries and surveillance for cardiology. One suggestion was to get the Food and Drug Administration (FDA) to address risk management and standardization of clinical trials to allow comparison of trials. Dr. Selker agreed that the science is disappointing, based largely on observational data. Large databases show high or low risk but do not help in clinical care.

#### Part B: Management/Treatment Outcomes (Drs. Stephen Cantrill and Gerald DeVaughn)

Dr. Cantrill said that 25 percent of the abstracts in this section deal with glycoprotein (GP) IIb/IIIa receptor antagonists—their use and misuse. It would help if the sponsoring drug companies were listed. We need to know which subpopulations are helped by treatment and the cost of treatment. Twelve percent of the studies dealt with the use of statins post-ACS. Five studies dealt with the efficacy of transferring patients to a center that did emergency PCI. This is an important concept to address, as it would free community hospitals from having to provide emergency angioplasty. Other papers dealt with the following topics: the emerging use of drugeluting stents; the lack of beta-blockers for ACS; the use of PCI in older populations; and the Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines (CRUSADE) initiative.

Dr. DeVaughn said that he was impressed by the information on transporting patients. We need to know more about the advantages of rerouting EMS services in urban communities.

#### **Phase IV: General/Crosscutting Aspects and Actions**

### Part A: Cost Benefit, Economic, and Reimbursement Aspects (Mr. Ciarkowski, Dr. Ijaz Kahn)

Mr. Ciarkowski said that he did not see anything that stood out in this section. The main topic was the use of implantable cardioverter defibrillator (ICD) versus antiarrythmics—indicating that devices are better than drugs. There is a push to show that the use of ICD is cost effective, but ICD must be done in appropriate patients. Dr. James Atkins added that persons who benefit from ICD do so in the first 3 months; after that, the benefit is not clear. Currently, 100,000 of these devices are implanted. The guidelines suggest that 400,000 more be implanted, and this would be a budget breaker. Articles on the relative benefit of percutaneous transluminal coronary angioplasty (PTCA) versus coronary artery bypass grafting contradict each other. The AHRQ provides an algorithm for scoring the literature as part of technology assessment. There is a lot of "data dredging" because databases are not designed to answer some questions. We need to find out if there is an opportunity in the first hour to use fibrinolytics vs. PCI. Composite outcomes are needed.

### Part B. Professional/Patient/Public Education Considerations (Dr. Curry and Mr. John McGinnity)

Mr. McGinnity reported that a small number of the 63 articles in this section dealt with treating depression, with no significant differences in outcomes. There were also no significant outcomes from hospital delay educational programs, nursing programs, and educational videos. He was interested in the research on C-reactive protein (CRP). A statin article showed lower mortality with highest CRP levels.

Dr. Curry said that the article by Dr. Steven Nissen emphasized that atherosclerosis is a metabolic problem and needs to be treated before it gets beyond a certain point. This supports the use of statins and other drugs to prevent atherosclerosis.

#### Part C. Health Care Systems (Drs. MacLeod and McNutt)

Dr. MacLeod said that there is no theme in this section and a lot of duplication. Hypothermia as a treatment for angioplasty is promoted. Dr. McNutt noted that as systems respond to improve their time to PCI, they get worse with time to thrombolysis. An evaluation of this tradeoff is warranted from a systems perspective, especially since there is reduced mortality benefit from PCI. He suggested a clinical trial.

Dr. Cantrill added that several articles dealt with this issue in an oblique way, looking at patients who received thrombolysis, those who received thrombolysis and were transferred for PCI, and those who were transferred from PCI. One subgroup benefited from a combination of lysis and PCI. Other comments included the following:

- A hospital that does just thrombolysis or just PCI will do it well.
- Problems occur when the catheterization laboratory is not open.
- Every facility should commit to a plan for treating AMIs. The standard is to give lytics in 30 minutes and angioplasty in 120 minutes. We must gather data from hospitals on time from door to balloon and identify problems to correct.

#### Part D: Ethical Aspects (Dr. Zalenski)

Dr. Zalenski said that one study raises the issue of who gets CPR. Another points out England's EMS systems vary in what they provide; this is true in the United States as well.

#### Part E: AMI Epidemiology (Mr. Ciarkowski and Mr. McGinnity)

Mr. McGinnity said that some articles indicate that out-of-hospital mortality is decreasing while others indicate it is staying the same. Several studies looked at the use of left ventricular hypertrophy to predict survival in AMI. One study found that mortality from AMI decreased with decreasing risk factors.

#### Part F: Medico-Legal Aspects (Mr. Ciarkowski and Mr. McGinnity)

This section included only one article. Mr. Ciarkowski noted that the literature search may not be capturing relevant information. For example, other sections included policies that affect health care. Regarding *The International Statistical Classification of Diseases and Related Health Problems* (ICD), the CMS released a policy clarifying that investigational devices are reimbursable, and the FDA issued guidance on the type of data to be collected in clinical trials of ICDs.

#### Part G: New Information Technologies (Drs. Cantrill and McNutt)

Dr. Cantrill said that this section was generally disappointing, but several abstracts were of interest. One on a computerized support system for decisionmaking based on evidence for asthma and angina showed no effect on patient care. This demonstrates a problem in coupling the human with the computer system. Another study matched clinical questions with appropriate

databases, and the weak link was the human. Another study was a discrete event simulation model for patients with coronary artery disease (CAD), showing that increased vascularization had considerable implication for resource use but little affect on patient mortality.

### Part H: Guidelines on Recognition, Diagnosis, Treatment, and Management of Patients With AMI/ACS and Sudden Cardiac Arrest (Drs. Christenson and DeVaughn)

Dr. DeVaughn said that providers fall short of complying with guidelines (e.g., for the use of beta-blockers). The CRUSADE study gets the guidelines to physicians who can make incremental changes in outcomes and shows that adherence to guidelines reduces mortality. Only half of clinicians follow guidelines. Some members thought there should be more guidelines (e.g., to serve as reminders or checklists), but others felt that there are discrepancies in guidelines and that clinicians do not know which of the many guidelines to follow. Electronic guidelines should clearly indicate which are most important. Guideline adherence could be encouraged by linking compensation to following the guidelines.

### ESTABLISHMENT OF AN ACS PATIENT SURVEILLANCE SYSTEM: UPDATE (Ms. Mary Hand and Dr. Teri Manolio)

Providing background, Ms. Hand said that the establishment of an ACS patient surveillance system was identified as a priority area for the Science Base Subcommittee at the NHAAP's 10-year meeting. Part of addressing this priority area is a projected meeting to discuss the establishment of an ACS patient surveillance database that would be standardized in the 4,200 emergency departments (EDs) in the United States. It is envisioned in the priority area that an ACS database would be superimposed on a planned public health surveillance system for monitoring bioterrorism agents. At the last NHAAP meeting, Dr. Daniel Pollock discussed the Center for Disease Control and Prevention's (CDC's) National Electronic Disease Surveillance System (NEDSS), which is being implemented by 100 existing public health surveillance and information systems. When completed, NEDSS will electronically integrate a variety of surveillance activities, with attention to the required confidentiality and reporting. Dr. Pollock expressed his support for convening a workshop to discuss the establishment of the surveillance database. Also at the last Science Base Subcommittee meeting, Dr. Wayne Giles provided an overview of the CDC's Coverdell Stroke Registry. In February 2001, an expert panel on data elements met with representatives from the Brain Attack Coalition and other Federal agencies. CDC planned to use the prototype for the ACS surveillance. Stroke is the first chronic condition to be rolled into the NEDSS.

Dr. Manolio said that data are needed on ACS as well as related diseases such as heart failure and stroke, and it may be appropriate to focus on the highest priorities first. Her office plans to look at long-term outcomes, including outpatient settings and geographic and racial/ethnic diversity. NHLBI plans to move ahead with seeking funding for an initiative on cardiovascular disease (CVD) surveillance. The AHA is interested in meeting with the NHLBI and others to identify key roles and priorities for CVD surveillance. Dr. Manolio asked the Subcommittee for advice, and the following comments were made:

• Hospitals are concerned about unfunded Federal mandates. Who would pay to enter the data in the surveillance system? How much of a burden will it be?

- The Surveillance, Epidemiology, and End Results (SEERs) national database shows that there is very little subjective information that is dependent on chart review; the data sources are poor. A sampling strategy will be needed, and Federal support will be needed to get a 10 percent sample.
- How will the data be captured? The broadest inclusion criteria for ACS symptoms are needed to encompass women, older individuals, and members of ethnic groups. One way is to include the ECG of every person who goes to the ED. The ECG is a standard test and could serve as a standardized denominator across hospitals. However, some people will be missed if they do not get an ECG. In addition, information on angiography and other procedures should be gathered.
- The Working Group should include people on the Science Base Subcommittee, nonproprietary representatives from the computer industry, and representatives from groups that interface with hospital databases (biosurveillance groups, the CDC, etc.).
- The research program must identify core measures to achieve goals. Nobody knows the MI rate; a registry would solve this problem. Epidemiological studies will provide information but will not address which treatments are better.
- Clinical trials should be conducted by State (e.g., fibrinolytics in California and PCIs in Illinois). This is what is done in Europe; in the United States, we have been doing secondary data analysis. A concern is that in both States, two-thirds of the patients who die of CHD never get to the ED.
- How can we capture out-of-hospital deaths? Average time of onset from symptoms is 2 hours; 68 percent of malpractice suits for missed MI are against primary care providers.
- Guidelines are needed for measurement and interpretation. A multidisciplinary approach would get input from nurses, emergency medical technicians, and cardiologists. The NHAAP is an ideal forum for this.
- A randomized controlled trial (RCT) to reduce out-of-hospital sudden death is looking at several strategies, including lay persons' use of cardiopulmonary resuscitation and calling 9–1–1, and application of AEDs. The goal is to double the number of survivors.
- Recommendations included: (1) review the guidelines; (2) focus on out-of-hospital deaths; (3) determine how to resolve the reperfusion dilemma; and (4) include the state of clinical research in ACS.
- Development of a surveillance system should be done in conjunction with an effort to improve clinical research.

The Cardiac Markers: Establishing Guidelines and Improving Results meeting will be held May 21–22, 2004. (A brochure is in the meeting packet.)

### ADJOURNMENT (Dr. Ornato)

Dr. Ornato said that he will summarize the Science Base Subcommittee's discussion at the March 23, 2004 Coordinating Committee meeting. He thanked the members and adjourned the meeting.



### **National Heart Attack Alert Program**

### **Attachments**

# ATTACHMENT A LIST OF ATTENDEES

### NATIONAL HEART ATTACK ALERT PROGRAM COORDINATING COMMITTEE MEETING

#### **Participants**

#### March 23, 2004

Organization	Representative
Agency for Healthcare Research and Quality	Daniel Stryer, M.D.
American Academy of Insurance Medicine	Lawrence D. Jones, M.D.
American Academy of Physician Assistants	John McGinnity, M.S., P.AC
American Association for Clinical Chemistry, Inc.	Robert H. Christenson, Ph.D., D.A.B.C.C. F.A.C.B.
American Association of Critical Care Nurses	Diane L. Carroll, R.N., Ph.D.
American Association of Health Plans	Andrea G. Gelzer, M.D.
American Association of Occupational Health Nurses	Patricia Hirsch, R.N., M.Ed. (Substitute for Carol Cunningham Base, R.N., M.S.,B.S.N., COHN-S)
American College of Cardiology	James M. Atkins, M.D., F.A.C.C.
American College of Chest Physicians	Ijaz Kahn, M.D. (Substitute for David Gutterman, M.D.)
American College of Emergency Physicians	Stephen V. Cantrill, M.D., F.A.C.E.P.
American College of Occupational and Environmental Medicine	Emmett B. Ferguson, M.D., M.P.H.
American College of Physicians	Robert A. McNutt, M.D., F.A.C.P.
American College of Preventive Medicine	George K. Anderson, M.D., M.P.H., F.A.C.P.M.
America's Health Insurance Plans	Andrea G. Gelzer, M.D.
American Heart Association	Joseph P. Ornato, M.D., F.A.C.C., F.A.C.E.P.
American Hospital Association	Nancy E. Foster

American National Red Cross Don K. Vardell, M.S.

(Substitute for Pat Bonifer-Tiedt, Sc.M., M.S.)

American Nurses Association, Inc. Carol Bickford, Ph.D., R.N.-C. (Substitute for

Christine M. Crumlish, Ph.D., R.N.)

American Public Health Association Barbara Hatcher, Ph.D., R.N.

Association of Black Cardiologists Gerald DeVaughn, M.D., F.A.C.C.

Centers for Disease Control and Prevention George Mensah, M.D.

Centers for Medicare and Medicaid Services Jay Merchant, M.H.A.

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.

International Association of Fire Chiefs Mary Beth Michos, R.N.

International Association of Fire Fighters Jonathan Moore, E.M.T.-P. (Substitute for

Lori Morre, Dr.P.H., M.P.H., N.R.E.M.T.-P.)

National Association of EMS Physicians Bruce MacLeod, M.D., F.A.C.E.P.

National Association of State Emergency

**Medical Services Directors** 

Jimm Murray

National Black Nurses Association David E. Simmons, Jr., M.S.N., R.N.,

C.N.N.

National Center for Health Statistics Richard Gillum, M.D., F.A.C.C.

National Heart, Lung, and Blood Institute Barbara Alving, M.D.

National Highway Traffic Safety Administration Drew E. Dawson

National Medical Association Charles L. Curry, M.D.

Society for Academic Emergency Medicine Robert J. Zalenski, M.D., M.A.

Society of Chest Pain Centers and Providers J. Lee Garvey, M.D.

Society of General Internal Medicine Harry P. Selker, M.D., M.S.P.H.

#### **Absent**

American Medical Association Mark S. Antman, D.D.S., M.B.A.

American Pharmacists Association M. Ray Holt, Pharm.D.

Department of Defense, Health Affairs Thomas M. Wiley, M.D., LTC, MC, USA

Department of Veterans Affairs Robert L. Jesse, M.D., Ph.D.

Health Resources and Services Administration David B. Snyder, R.Ph., D.D.S.

National Association of Emergency Medical

**Technicians** 

Christopher Cebollero, M.S., N.R.E.M.T.-P.

#### **Invited Speakers**

Thomas Aversano, M.D.

Johns Hopkins University

Octo Barnett, M.D. Massachusetts General Hospital

Rita Kukafka, Dr.P.H. Columbia University

Ransom Weaver University of Pennsylvania

Helmuth Orthner, Ph.D., A.C.M.I.

University of Alabama at Birmingham

#### NIH and NHLBI Staff

Milton Corn, M.D. National Library of Medicine

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

National Heart, Lung, and Blood Institute

Nancy A. Hart, M.A. National Institute on Neurological Disorders

and Stroke

Christine Krutzsch, M.S.

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Donald Lindberg, M.D. National Library of Medicine

Terry Long National Heart, Lung, and Blood Institute

Gregory J. Morosco, Ph.D., M.P.H. National Heart, Lung, and Blood Institute

George Sopko, M.D. National Heart, Lung, and Blood Institute

#### Guests

Robert J. McNellis, M.P.H., PA-C American Academy of Physician Assistants

Garst Reese National Library of Medicine

Paul Selker Student

Deanna Simmons, R.N.

National Black Nurses Association

Gamanu Wijetunge National Highway Traffic Safety

Administration

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Mark Brown, C.M.P. (MasiMax)

Judy Estrin, M.A. (AIR)

Rebecca Ryan (MasiMax)

Patricia Smith (MasiMax)

# ATTACHMENT B COORDINATING COMMITTEE AGENDA

#### National Heart Attack Alert Program (NHAAP) Coordinating Committee Meeting National Heart, Lung, and Blood Institute

#### **Special Focus: Informatics Technology for the NHAAP**

#### Natcher Conference Center, Room E1/E2 National Institutes of Health Bethesda, Maryland

### Tuesday, March 23, 2004 9:00 a.m.-3:30 p.m.

#### **Agenda**

9:00 a.m.	Welcome and Introductions	Dr. Barbara Alving	
	Informatics Technology for the NHAAP—Project Presentations		
9:15 a.m.	♥Introduction to NHAAP Informatics Technology Projects	Dr. Donald Lindberg Dr. Milton Corn	
	Patient Delay (Phase I) Projects		
9:30 a.m.	♥Patient-Initiated Emergency Response System (PIERS)	Dr. Thomas Aversano	
9:45 a.m.	♥MI-HEART: The Impact of Tailored, Web-Based Health Information	Dr. Rita Kukafka	
10:00 a.m.	♥Heart Sense—A Game for Heart Attack Prehospitalization Delay Reduction	Mr. Ransom J. Weaver	
10:15 a.m.	Phase I: Panel Discussion	Phase I Investigators, Dr. Joseph Ornato, Ms. Nancy Foster, and Dr. Diane Carroll	
11:00 a.m.	Break		
	Prehospital Delay (Phase II) Projects		
11:15 a.m.	♥Integrated Information Technologies for Emergency Medical Care	Dr. Helmuth Orthner	

11:30 a.m.	♥EMS Clinical Trial of ECG-Based Predictive Instruments (TIPI-5-EMS)	Dr. Harry Selker
11:45 a.m.	♥Glucose-Insulin-Potassium (GIK) Study: Immediate Myocardial Metabolic Enhancement During Assessment and Treatment via EMS (IMMEDIATE) Trial (TIPI-6-IMMEDIATE)	Dr. Selker
12:00 noon	Phase II: Panel Discussion	Phase II Investigators, Dr. George Anderson, Dr. Robert McNutt
12:30 p.m.	Lunch	
1:30 p.m.	Hospital Delay (Phase III) Project	
	♥Chest Pain: The First 60 Minutes	Dr. Octo Barnett
1:45 p.m.	Phase III: Panel Discussion	Phase III Investigator, Dr. Stephen Cantrill
2:00 p.m.	Reflections: The Promise of Informatics to Change the Behavior of Patients, Providers, and Health Care Systems for Early Recognition and Response to Heart Attack Patients	Dr. Angelo Alonzo
2:15 p.m.	<b>Executive Committee and Subcommittee Reports</b>	Dr. James Atkins
	Education Subcommittee	Mr. David Simmons, Jr.
	Health Systems Subcommittee	Dr. Bruce MacLeod
	Science Base Subcommittee	Dr. Joseph Ornato
3:15 p.m.	Other Announcements and Reports	Committee Members
3:30 p.m.	Final Comments and Adjournment	Ms. Mary Hand