Acute Myocardial Infarction: Setting Priorities for Effectiveness Research

Division of Health Care Services
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Acute Myocardial Infarction:

Setting Priorities for Effectiveness Research

Report of a Study by a
Committee of the INSTITUTE OF MEDICINE
Division of Health Care Services

Patrick H. Mattingly and Kathleen N. Lohr, editors

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Summary

In late 1988, as part of planning an "Effectiveness Initiative," the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services (DHHS) asked the Institute of Medicine (IOM) to conduct four workshops. The first was intended to identify high-priority clinical conditions for this research program; the last three were focused on specific conditions—breast cancer, acute myocardial infarction (AMI), and hip fracture. These workshops had three goals: (1) to examine each clinical condition in detail; (2) to identify key patient management topics for each condition that deserve further investigation of effectiveness; and (3) to propose appropriate research strategies or approaches to be used by HCFA and other public and private organizations that conduct effectiveness research. This report presents the IOM committee's recommendations from the AMI workshop.

The committee recommended that effectiveness research give separate attention to four nonclinical, or methods, topics. First was the continued improvement of the clinical and diagnostic information available in the HCFA Medicare data bases for effectiveness research. Specifically, the committee recommended the development of methods that will more accurately identify AMI patients for any effectiveness studies, such methods to involve both the nature and the extent of damage to the heart. Cases of AMI and specific treatments may not be identified in the routine HCFA data set because of coding problems. HCFA has sought to remedy these problems and is developing methods by which the Medicare Peer Review Organization (PRO) agencies might obtain routine clinical data. The committee recommended that the PRO methodology for obtaining such data

program be clarified and validated. The committee also encouraged HCFA in its efforts to involve clinicians in the design and evaluation of the data base and to improve the access to these data for qualified investigators.

Second, effectiveness research should examine the methods used to stratify risk in acute AMI and the effect of these methods on patient management and outcomes. The committee recommended the funding of extramural research to validate stratification and triage decision methods that would permit determination of effectiveness in clinically important subsets of patients. This includes assessments of comorbidity as a major determinant of risk. Physicians employ a variety of methods to determine risk for individual patients and to assign patients to diagnostic and treatment modalities. The validity of these stratification methods and the subsets of patients receiving certain tests and treatments should be examined in differing clinical environments. The "natural experiments" created by these stratification methods should be analyzed with particular attention to compliance with recommendations from randomized controlled trials, to the use of resources, and to patient outcomes. These observational trials should form the basis for a prospective study to identify a valid, reliable, and practical stratification method for future effectiveness research.

The third methodologic topic was attention to the definition and measurement of outcomes. The committee recommended study of three related issues: (1) more comprehensive definitions of the elements of outcomes in line with recent developments in the field of health status and quality-of-life measurement; (2) better definitions of alternative "best outcomes" (from the patient's point of view) that take health status and quality of life into account; and (3) expansion of techniques for acquiring data to measure outcomes as they relate to AMI.

The committee recommended further that DHHS give considerable priority to understanding and developing these methods for use throughout its effectiveness research effort (not just for AMI). Use of reliable and valid generic measures of health status coupled with selected disease-specific measures is an appropriate, desirable, and practical research strategy. For all patients, measures of morbidity (including pain and other symptoms), functional status (including physical capacity and ability to function in daily life), psychological and emotional well-being, social functioning and support networks, and general outlook on health are important. Patient values and preferences need to be taken into account, so it is important to differentiate between outcomes and patient preferences for outcomes and to encourage the acquisition and use of information on patient preferences, given different outcomes. The committee recommended that DHHS solicit outside expert opinion to define an adequate, appropriate set of outcome measures

and to propose instruments for measuring these outcomes in effectiveness research both generally and for AMI.

The committee noted several other outcome issues regarding AMI. There is a need to identify additional clinical outcome measures, such as exercise tolerance or congestive heart failure, to be included in the data base. In the elderly, certain outcomes, such as return to work, may not be as relevant as they are in younger patients, and measurement of other outcomes such as exercise tolerance may be limited by other, noncardiac conditions.

The fourth methods issue concerned variations in the patterns of care and use of treatment modalities in different settings. The committee recommended that work on understanding patterns of care be supported and that work be linked to issues relating to the three high priority patient management topics identified for the effectiveness initiative. These studies should consider variations in types of hospitals, geographic regions, and types of providers (e.g., generalists or specialists). Although these observations will not directly demonstrate differences in effectiveness, they could form the starting point for detailed prospective studies.

The committee also identified three clinical, or patient management, issues that it judged were of high priority for an effectiveness research effort focused on AMI. Two related to risk stratification and the choice and effectiveness of diagnostic and therapeutic options; a third focused on thrombolytic therapy more specifically.

First, the committee recommended that research be supported to identify the effectiveness of specific diagnostic and treatment modalities in the Medicare age group, whether alone or in groupings based on risk stratification methods. Further, they recommended that such investigations start with, but extend beyond, observation of variations of practice patterns and surveillance of specific risk stratification strategies linked to appropriate outcomes. Of particular concern is the vast array of diagnostic tests such as catheterization, exercise testing with or without radionuclide studies, and echocardiography, which themselves can be (and are widely) used for risk stratification or prognostic purposes without good evidence of their appropriateness or effectiveness among the elderly or, at least, particular subgroups of elderly patients.

Second, the committee recommended that the use of pharmacologic agents, particularly thrombolytic drugs, be monitored in both the inpatient and the outpatient settings. As for other interventions, individual drugs or groups of drugs, alone or in combination with invasive procedures, should be analyzed with regard to variations in outcomes. The clinical effectiveness of many of the drugs used in AMI remains to be demonstrated in the elderly. Although thrombolytic agents have been shown to be effective in

reducing mortality and short-term morbidity in younger patients and some Medicare patients, the long-term outcomes in the elderly have yet (and need) to be determined. Limitations in the current HCFA data base in recording information about drugs, particularly in the nonhospital setting, also must be overcome.

Third, because of the crucial role that risk stratification plays in choosing among diagnostic and therapeutic options for patients with AMI, the committee recommended that explicit attention be directed at ways to assign or stratify risk to individual patients with AMI. The committee had concluded that risk stratification methods are not well established and that doing so was a critical patient management issues both amenable to, and necessary for, effectiveness research. For instance, outcomes of specific competing therapies, such as angioplasty and thrombolysis, might be tracked according to patient subgroups defined by different risk stratification approaches. Then one (or more) model(s) using stratification parameters based on these comparative analyses could be evaluated as a predictor of outcomes in another group of Medicare patients. If successful, these models could then be applied prospectively.

Introduction

EFFECTIVENESS INITIATIVE

In 1988, the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services (DHHS) proposed an Effectiveness Initiative, the purpose of which was to bring the resources of Medicare to bear on the question of what works in the practice of medicine. HCFA outlined two purposes for the Effectiveness Initiative: (1) assess the overall merit of competing health care interventions and (2) provide information that will help clinicians in the management of their patients, assist and improve the peer review process (e.g., of the Medicare Peer Review Organizations [PROs]), and aid policymakers in allocating Medicare resources. HCFA also identified a specific set of activities for the Effectiveness Initiative: (1) monitor time trends in the use of services by the Medicare population; (2) analyze geographic (population-based) variations in the use of services and in outcomes of care; (3) assess interventions through clinical demonstrations, observational studies, and randomized controlled trials (RCTs); and (4) conduct feedback and education activities.

Other purposes are integral to this program as well. The progress in planning for effectiveness and related research throughout DHHS since 1988, and the transfer of responsibility for effectiveness research to the Public Health Service as part of the Medical Treatment Effectiveness Program, make this fact clear. Among these other purposes are improving patient outcomes, providing information useful in the development of practice guidelines, and identifying critical issues for further research. Thus, although this monograph discusses work conducted in 1989 for HCFA in the context of the original Effectiveness Initiative, it should be seen as pertinent to the full

range of activities anticipated for effectiveness research supported by DHHS in 1990 and beyond.

THE IOM CLINICAL WORKSHOP

For guidance on this new program initiative, HCFA had consulted widely with individuals and organizations in the medical, health financing, and health services and policy research communities. It then requested the Institute of Medicine (IOM), National Academy of Sciences (NAS), to make recommendations about clinical conditions that should receive priority attention at the outset of the agency's proposed Effectiveness Initiative. Conceptually, this emphasis on the clinical condition reflected a decision to choose this unit of analysis rather than to focus on specific procedures or technologies.

To respond to HCFA's initial request for assistance in planning the Effectiveness Initiative, the Institute appointed a study committee and convened a "clinical workshop" in October 1988. The clinical workshop committee recommended five clinical problem areas: stable and unstable angina, acute myocardial infarction (AMI), breast cancer, congestive heart failure, and hip fracture. These conditions were given priority because they met several key selection criteria including high prevalence, burden of the illness on elderly persons, appreciable variations in the use of services and in outcomes, high costs, and alternative ways to manage patient care that reflect professional and clinical disagreement or uncertainty.[1]

In addition to these general points, the 1988 workshop committee also noted that AMI is important in the elderly for several specific reasons. Outcomes for survivors of the acute event are highly variable and unpredictable, with different responses to treatment and variable long-term disability. Practice patterns are changing rapidly because of new therapies and data. The committee also commented on other important dimensions of AMI, including (1) prevention, prognosis, and the role of exercise; (2) aspects of prehospital care, such as speed of diagnosis, resuscitation, initiation of treatment, and transport to sites of definitive care; (3) special management issues relating to the elderly; (4) pharmacologic agents (e.g., thrombolytic, antiarrhythmic, and antiplatelet agents); (5) locus of care; (6) rehabilitation; (7) disability and quality of life, including return to work or daily functioning; and (8) psychological aspects of diagnosis, treatment, and prognosis (e.g., anxiety and depression).

[1] The 1988 clinical workshop committee also recommended a second tier of clinical conditions that could receive leer attention: cataracts, depressive disorders, prostatic hypertrophy, and transient ischemic attacks with or without occlusion. The report of this committee was published as *Effectiveness Initiative: Setting Priorities for Clinical Conditions* in April 1989; it is available from the National Academy Press (Report No. IOM-89-04).

CONDITION-SPECIFIC RESEARCH WORKSHOPS

Purpose

Following the clinical workshop, HCFA asked the IOM to conduct research and methods workshops for the three clinical areas on which the agency decided to focus first: breast cancer, AMI, and hip fracture. The research workshops had three objectives: (1) to examine each clinical condition in greater detail; (2) to identify central topics within each condition deserving further investigation in terms of "effectiveness" as contrasted with "efficacy"; and (3) to propose appropriate research strategies and methods.[2]

The distinction between effectiveness and efficacy is especially important in this context. Efficacy typically refers to the outcome of an intervention when it is applied in "ideal," well-controlled circumstances, such as those inherent in prospective randomized controlled trials (RCTs). That is, efficacy is concerned with whether the intervention works at all. Outcomes of interest may be quite technical and oriented to physiologic variables and survival. By contrast, effectiveness is understood to mean the outcome of that intervention when it is applied in the "everyday" or "average" circumstances of medical practice. These situations may involve patient subgroups that differ considerably from those studied in the RCTs. In addition, outcomes here may extend more broadly into quality-of-life concerns, such as physical and social functioning and emotional well-being.

Recent multi-center clinical trials have established the efficacy of various diagnostic and therapeutic interventions in AMI (e.g., thrombolysis). These trials, however, do not always include the older Medicare-age patients, particularly those over 75, and they typically do riot consider outcomes beyond short-term mortality and improvement in physiologic functioning. Therefore, the effectiveness of some interventions in older elderly patients, particularly with respect to long-term physical and emotional functioning, remains unclear.[3] Other questions not likely to be resolved by efficacy studies center on differences in medical interventions and outcomes in groups of patients who differ on demographic or clinical grounds.

[2] The reports on the other two workshops to identify patient management topics for breast cancer and hip fracture were published in 1990 (respectively. *Breast Cancer: Setting Priorities for Effectiveness Research* and *Hip Fracture: Setting Priorities for Effectiveness Research*). Both are available from the National Academy Press.

[3] Several meant clinical trials have studied the effectiveness of thrombolytic agents (and in one study thrombolytics and percutaneous transluminal coronary angioplasty) in reducing in-hospital mortality from AM. Some of these studies have included patients up to age 75 and have demonstrated improved in-hospital survival in the over-70 age group comparable to the survival of younger patients (albeit with a significantly greater occurrence of bleeding complications in the over-70 age group). However, these studies include few patients over age 75. Studies of other treatment modalities such as coronary artery bypass surgery have not generally included sufficient numbers of patients over 65 to amble definitive conclusions.

Research Workshop Committee

To discharge the research workshop tasks, the IOM appointed a "core committee" of clinicians and researchers according to NAS procedures; it was chaired by Kenneth I. Shine, M.D., Dean of the School of Medicine, University of California, Los Angeles. For each condition-specific research workshop, the core committee was augmented with additional clinicians and researchers with recognized expertise in the condition of interest. The members of the AMI committee are listed at the beginning of this report.

The committee was charged with two responsibilities: (1) to recommend to the HCFA administrator a small number (five to eight) of AMI patient management issues in the elderly that should receive priority in the Effectiveness Initiative and (2) after reaching some consensus on the patient management issues for initial study, to suggest specific research strategies or approaches that might be implemented to address those issues. An underlying premise was the need to understand what aspects of the present or proposed Medicare data bases might be used in this research, what should be added to the current data bases, and what studies must be conducted independently of the HCFA data bases.

The remainder of this report summarizes the background information on the clinical aspects of AMI and conveys the committee's deliberations, findings, and recommendations. The appendix describes the study and workshop activities.

The Knowledge Base for Key Clinical Issues in Acute Myocardial Infraction

The clinical research investment in AMI is quite large and continues to grow. Efficacy studies, when done properly, contribute immensely to the knowledge base, although they cannot necessarily be applied across all the major clinical questions and population groups. Two questions in selecting key patient management topics for effectiveness studies are, therefore: what unanswered questions remain, and are they suitable for projects outside the realm of RCTs?

Several clinical subjects are briefly reviewed here because they provide the context within which the committee's discussions took place. They include diagnosis and management of myocardial infarction in five phases: prehospital, emergency room, coronary care unit, hospital, and posthospital. Other issues centered on treatment options—whether pharmacologic, invasive, or surgical—during the acute hospital phase. These particular subjects raised issues that influenced or led to specific patient management and research recommendations that are discussed more fully later in this report.

This section, which is intended as an introduction for a general audience and not as a detailed clinical text, was based on materials submitted by several members of the committee who have special clinical expertise in cardiovascular disease. In part it reflects information contained in the clinical literature cited in the bibliography at the end of this report, which was current as of the date of the workshop (May 1989); advances in the knowledge base as documented, for instance, in results of relevant RCTs released since that time are not reflected here because they could not have been brought into the workshop discussions. The clinical topics themselves were not debated during the workshop.

The majority of clinical practice in the diagnosis and treatment of AM is based on studies performed on people under age 60. The body of information on the elderly, particularly above age 70 or 75, is growing but remains small. Although efforts are made in this section to note where relevant studies have included older patients, readers should assume that the following knowledge base applies mainly to a younger population.

ETIOLOGY

An AMI—commonly called a heart attack—occurs when decreased blood flow to the heart causes ischemia (damage or injury) of myocardial (heart muscle) tissue. In most cases, an AM is caused by occlusion (blockage) of one or more coronary blood vessels by a thrombus (blood clot), and it is accompanied by severe crushing chest pain. In a minority of AMIs, but more commonly in the elderly, patients experience no pain. In some cases the reduced blood flow is caused by a blood vessel problem other than a thrombus. The underlying cause of most AMIs is atherosclerotic coronary artery disease, which causes progressive obstruction of the arteries in the heart, beginning in early adult life. Clinical research has established that several risk factors influence the development of coronary disease, particularly family history, diet, lack of exercise, obesity, serum fats (mainly cholesterol), smoking, and presence of diabetes or high blood pressure.

EPIDEMIOLOGY

Coronary heart disease is present in about 1.5 percent of adults ages 35 to 54, but it is estimated to be present in about 8 percent of people over age 65. AM occurs in more than 1.5 million people in the United States annually and leads to more than 500,000 deaths, making it the nation's leading cause of death. About 1.5 percent of the adult population will sustain an AM each year. For those age 65 and over, these risks escalate considerably: 4 percent will have an AM diagnosed yearly.

The difference between sexes in these age groups is quite striking, with the risk of AMI increasing more with age for women than for men. Between ages 45 and 49, the annual incidence of AMI is 13 per 1,000 men and 2 per 1,000 women; between ages 75 and 79, the difference narrows to 57 and 30 per 1,000 persons, respectively. Above age 80 the rates for men and women are essentially equal.

Although AMI is the leading cause of death in the United States, the mortality rate differs considerably by age and sex; the general population mortality rate and those from more selective clinical trials also differ. Of

the approximately 500,000 deaths per year reported due to AMI, 49 percent occur in women. About 81 percent of the AMI deaths occur in the Medicare population age 65 and over; of these, 53 percent occur in women. About 40 percent of AMI patients age 65 and over die within one year of the AMI. These data are derived from carefully designed epidemiologic studies in which unrecognized or "silent" MIs may be identified through periodic electrocardiograms (ECGs); rates reported for the general population are lower, which probably reflects the incidence of such unrecognized infarctions.

The total cost to HCFA and to patients for diagnosis and treatment of AMI in the hospital is estimated at $1.7 billion annually for Medicare patients ages 65 and older. These costs do not include costs of hospital admissions for chest pain or other conditions that prove not to be an AMI nor do they include the costs of extensive nonhospital services, including post-AMI diagnostic and prognostic testing, physician visits, skilled nursing facility (SNF) care, and home care.

These data about the incidence, mortality, and cost of AMI in the Medicare population emphasize that AMI is an event in the natural history of a common disease process that begins in early adult life, progresses with age, and is influenced by well-established risk factors, some of which are remediable or modifiable. Before an AMI, patients may have been severely restricted by chest pain or seriously debilitated by complications of previous episodes; alternatively, they may have been entirely free of symptoms, or they may have had a previous AMI without complication. For many, life after an AMI is uneventful; others suffer major complications, including heart failure, angina, recurrent infarction, arrhythmias (heart rhythm disturbances), and sudden death. Many of the elderly who survive an AMI have substantial limitations in functional capacity and general quality of life, in part because of other chronic conditions.

Measuring the effectiveness of diagnosis and treatment of AMI must recognize, therefore, the multiplicity of factors contributing to the outcome of an AMI, both immediate and long term. Not all controlled clinical trials include patients from the Medicare age group, particularly those over age 75. Measures found to improve outcomes in these trials may not be effective in Medicare patients, especially women, because they may be in a more advanced stage of coronary disease and frequently have other significant complicating illnesses.

In the past decade, dramatic "high-tech" therapies for AMI have become routine. They include use of clot-dissolving medications (thrombolytics), breakup or compression of atherosclerotic plaques and clots by means of catheters threaded into the heart (percutaneous transluminal coronary angio

plasty or PTCA), and surgical implant of blood vessels from other parts of the body to bypass those that are clogged (coronary artery bypass graft [CABG]). In certain patients, these procedures can save lives and improve the quality of life for many patients with AMI and its complications. RCTs have shown, however, that these procedures do not always improve patient outcomes following an AMI and, in fact, may be harmful and costly. Clouding this clinical picture for Medicare patients is the fact that the majority of patients included in the critical RCTs are under age 75. Therefore, regardless of proved efficacy in younger patients, the effectiveness and outcomes of these invasive and costly therapies must be better documented in those over age 75.

DIAGNOSIS AND MANAGEMENT

Although substantial attention has been focused in recent years on the newer treatments of AMI, early diagnosis and management have been the focus of much research during the previous decades. Thus, identifying patients with possible AMI as early as possible in the community, getting them to emergency medical care, and continuing their diagnostic evaluation and subsequent treatment in a coronary care unit (CCU) have been major contributors to the almost 40-percent decrease in mortality from AMI over the last 20 years.

The speedy and accurate diagnosis of AMI is critical for several reasons. First, the greatest danger of death is within the first several hours. Correct early identification of an AMI and rapid initiation of cardiac monitoring can result in effective treatment of life-threatening arrhythmias during the initial hours. Second, intravenous thrombolytic drugs are probably successful in preventing or mitigating damage in an AMI primarily in the first few hours. When given in the first four hours, such drugs may reduce the risk of death by 50 percent, whereas six or more hours later, the benefit is probably less. Third, for patients with extensive AMIs that lead to serious complications such as shock or heart failure, early monitoring makes potentially life-saving evaluation and therapy possible. Fourth, in addition to assuring rapid diagnosis of patients with an AMI, it is also important to diagnose those patients who are not having an AMI. Unnecessary CCU admission may have adverse medical and psychological consequences for the patient, ties up critical hospital CCU resources, and generates appreciable costs each year. However, many patients admitted to the CCU who have not had an AMI are still appropriate for CCU care because of other clinical conditions that require close monitoring, such as patients with syncope or arrhythmia with chest pain.

Prehospital Care

The average delay for patients of all ages presenting to the hospital after the onset of symptoms of a AMI is three hours or more. For the elderly, times may differ as a function of whether patients come from the community or from a custodial setting. More than 60 percent of the deaths from AMI, amounting to more than 300,000 annually, occur before arrival at a hospital. In many communities, emergency medical services (EMS) have been established in the past 20 years that are capable of the prehospital diagnosis and initial treatment of several life-threatening conditions, including AMI. In most of these communities, however, 50 percent or more of patients with "heart attack" symptoms do not call for emergency help before coming to the hospital, thereby exposing themselves to enormous risk at this most critical phase.

The goals of optimal prehospital care are to improve early diagnosis and maximize early treatment through emergency services, thus reducing the delay from onset of chest pain to initiation of definitive treatment. Prehospital electrocardiography, done by EMS personnel, is now feasible and has been shown to affect early triage of the patient with heart attack symptoms. ECGs can be sent by telephone or radio and interpreted by a physician in a remote emergency room; that practitioner can, then, decide to initiate therapy before the patient arrives at the hospital or make arrangements for rapid hospital treatment after arrival.

The major prehospital delays in treatment are caused by lack of patient recognition or admission of the problem and delay in self-transportation to the hospital. Additional delay can occur at the hospital if emergency room medical and nursing personnel do not have well-defined protocols to assess patients rapidly and identify those subsets appropriate for specific treatments. With earlier recognition by the patient of the potential seriousness of symptoms, state-of-the-art EMS intervention can effectively extend the capabilities of the hospital into the community, for example by routinely initiating thrombolytic treatment of appropriate patients in their homes or during transport. A time saving of one to one and one-half hours could result in less damage and fewer deaths from AMI.

Emergency Room Care

The development of new tests and computer-assisted diagnostic aids notwithstanding, the practice of diagnosing AMI in the emergency room (ER) has changed little in decades. At that stage, diagnosing AMI is still based primarily on the physician's evaluation of presenting symptoms, physical examination, and ECG results.

In evaluating the patient's *presenting complaints*, both the past history and the character of the current symptoms are important. A patient with a past history of coronary disease is more likely to be having an AMI than a patient with prior evaluation for similar symptoms who demonstrated no coronary disease. Similarly, a complaint of heavy crushing chest pain radiating into the left arm is strongly suggestive of AMI, whereas chest pain that is clearly made better or worse by moving or taking a deep breath or that can be related to recent trauma is not suggestive of AMI. Other presenting symptoms, such as sudden collapse and loss of consciousness, can be strongly suggestive, but more often the presenting complaints are not clear or specific. Atypical presenting symptoms of AMI, such as confusion or agitation, or strokes are more frequent in the elderly.

The *physical examination* can reveal telling changes in blood pressure and pulse, but these usually are not clearly abnormal until some time after the presenting symptoms or ECG are strongly suggestive of an AMI. Thus, physical examination may play only a minor role in diagnosis, except by identifying alternative causes for chest pain such as a broken rib or pneumonia.

In the ER, the *ECG*, interpreted in conjunction with the presenting complaint, may provide the critical information. Specific changes in the ECG, (referred to clinically as new Q waves, ST elevation or depression, T wave elevation or inversion) strongly suggest an impending or ongoing AMI. Many ECG changes, however, are equivocal and not diagnostic, and the physician must integrate the ECG with the symptoms and examination; in the face of a normal or equivocal ECG, patients with strongly suggestive history or symptoms and examination will be admitted, and those without will be sent home. In the elderly, this decision is complicated by the increased incidence of AMI without specific ECG changes.

Other diagnostic tests have not proved as useful in diagnosing AMI in the ER. Creatine kinase, an enzyme released by damaged heart muscle, is very helpful in establishing the diagnosis of AMI over 12 to 24 hours, but it has not proved valuable in the early ER diagnosis because up to one-half of AMI patients will have normal values on a blood sample taken in the emergency room. Likewise, high-technology tests such as echocardiography and scintigraphy are not useful in the ER. A promising assist to the ER diagnostic process is the use of computer-supported mathematical modeling, which predicts acute ischemic disease based on the presenting symptoms and ECG. In one trial, this instrument decreased CCU admission for those who did not have an AMI by 30 percent and did not increase the number of patients inappropriately sent home with an AMI.

Of the 1.5 million patients admitted from an ER into the CCU each year

for a suspected AMI, only about one-third actually prove to be having an AMI. The diagnostic error in the ER is 10 times more likely to be a false-positive admission of those without an AMI than a false-negative decision to send home the patient with an AMI. This ratio of false-positives to false-negatives is prudent, and some of those admitted without a diagnosis of AMI are properly hospitalized for conditions such as acute myocardial ischemia or unstable angina. Nonetheless, the high rate of false-positives implies considerable unnecessary cost, poor allocation of high technology resources, and dislocation for many of the patients so treated. Thus, a major goal in improving care for patients with possible AMI is to improve immediate diagnostic labeling.

Coronary Care Unit

Most hospitalized patients with AMI are managed initially in a critical care unit. Larger hospitals will have two types of units; a coronary care unit (CCU) that cares only for patients with AMI and related heart problems, and an intensive care unit (ICU) that cares for all other types of critically ill patients. Smaller hospitals may have only an ICU. While undergoing either diagnostic tests or medical therapy, the AMI patient is monitored electronically at all times (pulse and ECG) to allow immediate detection of life-threatening complications. The risk of sudden death or serious arrhythmia is highest in the first few hours after an AMI and diminishes greatly after 24 hours. In patients with evidence of hemodynamic, instability (high or low blood pressure, shock, or heart failure), invasive hemodynamic monitoring (such as with a Swan catheter or other techniques) may be appropriate. The availability of specially trained physicians and nurses in the CCU offers rapid treatment, including cardioversion or defibrillation (electrically restarting a heart beat or converting an arrhythmia to normal heart rhythm), emergency medications (for instance antiarrhythmic drugs), and insertion of pacemakers to maintain effective cardiac rate and rhythm. Routine pharmacologic therapy during CCU stay is summarized below.

Length of stay in CCUs or ICUs for AMI patients has progressively shortened over the 25 years that these units have been in use. This has resulted from the recognition and stratification of risk of complications, the development of continued monitoring in less intensive care units (so-called step-down or intermediate care units), and remote monitoring of patients in routine hospital rooms. However, the criteria for caring for an AMI patient outside the CCU are not fully agreed upon. Certain low-risk patients may derive little benefit from CCU care, particularly after 72 hours from onset of AMI, and there is concern that others including very elderly patients may be

harmed by the isolation and psychological stress. For example, many elderly patients with uncomplicated AMI remain in the CCU after the initial 48 hours for monitored observation on lidocaine to suppress ventricular ectopy. Recent studies strongly suggest that such treatment is not effective, except in certain high-risk patients.

Hospital Care

Several diagnostic procedures are often used during the hospital stay to assess complications and stratify risk. Echocardiography (computer-simulated pictures of the heart made with sound waves) and radionuclide imaging or scintigraphy (pictures of the heart made with radioactive materials) are useful for evaluating the patient with structural damage, such as mitral regurgitation (damage to one of the heart valves), septal defect (a hole between the major heart chambers), or pericardial effusion (fluid collected around the heart). For patients who develop heart failure or dysfunction without clinical evidence of structural abnormalities, scintigraphy can be of substantial value in evaluating the functioning of the heart's major chambers. Recognition of how such ventricular dysfunction contributes to heart failure in the AMI patient can lead to additions to or modifications of therapy that may reduce morbidity and mortality. Other diagnostic methods have been used less frequently during the in-hospital phase (for example, radionuclide myocardial infarction imaging with technetium-99m [Tc99m] pyrophosphate or radiolabeled antibody to cardiac myosin to visualize damaged heart muscle directly; myocardial perfusion imaging with thallium-201 [T1-201] chloride and Tc99m isonitrites).

Evaluation of AMI patients before discharge from the hospital is useful for prognostic risk stratification and thus for planning appropriate therapy. An excellent method of risk stratification is "submaximal" exercise testing alone or with myocardial perfusion imaging with T1-201 (a picture of blood flow to the heart muscle). Numerous published reports have documented that this approach can effectively classify patients into those with low, intermediate, and high risk. Several other methods to stratify risk (computerized thallium clearance rates, single photon emission computed tomography, photon emission tomography, and rest and submaximal exercise radionuclide scintigraphy) have not proved to be more advantageous. Of particular note is positron emission tomography, or PET scanning. This method gives a cross-sectional image of the heart showing biochemical activity as well as anatomy and may be superior to T1-201 perfusion study for demonstrating surviving myocardium. Although it is not considered cost-effective in comparison to other methods for routine use, PET scanning has great potential

value as a research tool. Ambulatory ECG monitoring provides a means to detect potentially fife-threatening arrhythmias, but it is of no proven value for risk stratification compared with submaximal exercise testing alone or with radioactive T1-201 imaging.

Some centers use other diagnostic methods. For instance, high-speed computerized axial tomography (CAT scan) and magnetic resonance imaging (MRI) provide higher resolution images than standard CAT scanning or radionuclide imaging, but they are more expensive and complicated. In addition to a detailed picture of the heart and its function, MRI can assess the extent of heart muscle damage. However, it is much more expensive and often presents substantial logistical problems; hence, the cost-effectiveness of MRI must be evaluated further before it is used routinely after an AMI. Other diagnostic techniques including continuous 12-lead ECG monitoring or specialized heart enzyme studies are used in some institutions, particularly in conjunction with thrombolytic techniques.

Posthospital Care

The ambulatory management of the AMI patient after acute hospitalization represents a continuum from the hospital period. Much less is known, however, about the effectiveness of the variety of diagnostic tests routinely used to define further the clinical status of patients with coronary disease. The physician is presented with the dilemma of balancing risks, costs, and discomfort to the patient in an attempt to estimate the future risk for the patient and to identify appropriate treatment such as rhythm-controlling drugs or revascularization procedures. These decisions are particularly difficult for patients over 75 years old, because there is less documentation of the effectiveness of these tests and therapies in this age group, particularly on their quality of life. For many elderly patients the risk of the diagnostic procedure itself must be weighed against the risks of further myocardial damage and reduction of functional ability if no other interventions are attempted.

Ambulatory diagnostic testing falls into four general categories: (1) routine office tests, such as ECG, echocardiography, and serum lipids, to follow changes in myocardial ischemia and risk factors; (2) exercise testing, to measure residual myocardial ischemia; (3) ambulatory ECG monitoring, to detect arrhythmias; and (4) catheterization and coronary angiography, to assess the coronary anatomy and ventricular function, the primary determinants of outcome.

Patients with established coronary artery disease after an AMI are routinely tested with repeat ECGs and various blood tests, including blood glucose

and serum lipids, particularly cholesterol. Although serial ECGs have been shown to provide valuable information for future prognostication, there are no established norms for the value or frequency of blood tests, nor is there documentation that additional therapy based an these tests will in any way improve the patient's health status. For example, it is currently unclear whether careful monitoring of cholesterol, with aggressive dietary or pharmacologic treatment, will improve outcomes in the elderly patient after AMI. Furthermore, cholesterol values are notoriously unreliably low until six to eight weeks after an infarction, so they should not be obtained until after that time. Some experts believe that a lipoprotein profile, not just cholesterol, can be supported as superior at the six-to-eight week point.

Exercise testing is often performed in the AMI patient four to six weeks after hospital discharge to evaluate myocardial function and ischemia even though "submaximal" testing was performed during hospitalization. This procedure can be most valuable in identifying conditions not present during hospitalization and in identifying patients who have a high risk of death from coronary artery disease. This information may, in turn, determine the need for further evaluation or changes in management, although the effect of early revascularization on longevity in these patients is not known. Exercise testing in the Medicare age patient may be constrained by many patients' limited capacity to undergo the test because of other noncardiac illnesses. Most patients ages 65 to 75, however, can exercise adequately or can be tested with a different activity such as arm exercise.

Patients who continue to have chest pain, demonstrate myocardial ischemia on exercise testing, or give evidence of heart failure after AMI by the need for medication, cardiomegaly, or restricted activity due to shortness of breath or fatigue are often considered candidates for invasive diagnostic studies. In some cases, they may be candidates for revascularization procedures. The effect of these invasive procedures on longevity or functional status in the elderly, particularly those over 75 years of age, remains unclear.

Sudden death from an arrhythmia is the most frequent serious late complication of an AMI, occurring in patients under age 65 with a peak incidence at six weeks after the AMI. Although ambulatory ECG monitoring in this period may be effective in identifying potentially threatening abnormal activity, the effects of its routine use are unknown. Moreover, further electrophysiologic testing to evaluate these arrhythmias or their prophylactic treatment have not been shown to reduce mortality, particularly in view of the potentially increased mortality and morbidity of these procedures themselves in the elderly.

THERAPEUTIC OPTIONS

Treatment of AMI begins with emergency procedures in the community and continues through all phases of hospital and posthospital care. All AMI patients should be considered candidates for emergency care, including cardiopulmonary resuscitation (CPR), rapid transport to a fully staffed ER, hospitalization, CCU care with careful monitoring for complications, supportive nursing care, and education and rehabilitation to reduce risk of further myocardial injury or complications upon return to family and community. Special considerations may apply, however, in selected situations (such as when "do not resuscitate" orders have been written for extremely ill patients).

Two major categories of therapeutic intervention can be employed at the appropriate time during the course of an AMI: pharmacologic therapies and surgical or other invasive procedures. The choice of one or more of the options under these categories is concurrent with the diagnostic efforts described above. They may be initiated to prevent immediate or late death, to reduce the risk of complications, to reduce symptoms or increase function, and to reach or improve "expected" outcomes predicted by diagnostic risk stratification.

Pharmacologic Therapy

Choosing appropriate pharmacologic therapies is predicated on many different clinical factors, including the extent of damage to the heart muscle, recurrence of symptoms, coexisting conditions, and complications of the AMI. These factors can interact in many ways, making the clinical decisions even more complex. Further difficulties are presented by uncertainty about the effectiveness of particular drugs for some patients (especially the elderly), about new medications, and about new or different ways to administer established drugs. Other controversies involve the routine versus selective use of some pharmacologic agents and the use of certain agents in ambulatory rather than inpatient settings.

Patients with chest pain suggestive of AMI can be divided quickly into three therapeutic groups: (1) patients with early transmural injury, which refers to damage to the full thickness (more than two-thirds) of the cardiac muscle and is often denoted "Q wave" infarction; (2) patients with late transmural or Q wave injury; and (3) patients with nontransmural injury, which refers to damage only to partial thickness (less than two-thirds) of the cardiac muscle and is often denoted "non-Q wave" infarction.

Group 1 patients are admitted to the hospital with specific ECG changes

(e.g., ST elevation) and with no more than four to six hours having passed since the onset of chest pain. Usual practice would include the use of intravenous morphine, nasal oxygen, and nitroglycerin either orally or intravenously. Intravenous lidocaine has often been recommended to suppress cardiac arrhythmias for 12 to 24 hours, but this approach is used only with great caution in the elderly. Immediate administration of a thrombolytic agent is indicated, except when explicit contraindications are present. Aspirin should be given orally. If the thrombolytic drug is tissue plasminogen activator (tPA), it should be followed by intravenous heparin; if the thrombolytic agent is streptokinase, heparin is probably unnecessary and possibly risky; and if urokinase is the drug of choice, the heparin issue has not been decided. (Both aspirin and heparin act to prevent clotting of blood.) Given evidence of continued ischemia and no contraindications, most physicians would add drugs that can reduce myocardial ischemia, such as beta blocker, a calcium channel blocker, or both. Intravenous nitroglycerine, angiotensin-converting enzyme (ACE) inhibitors, and vasodilators (blood vessel dilators) are examples of other drugs currently being used in AMI.

Group 2 patients with transmural infarction have specific ECG changes (ST elevation with Q waves) but are diagnosed more than six hours after the onset of their symptoms. Use of thrombolytic agents for this group remains controversial. Research data suggest mixed benefits from thrombolytics after four to six hours, but recent studies indicate that streptokinase may be helpful for up to 24 hours. Otherwise, management is similar to early transmural AMI.

Group 3 patients may not have specific ECG changes, but they do have nonspecific ECG abnormalities and a history strongly suggesting AMI. Thrombolytic agents are not routinely used but are under investigation. Aspirin should be begun immediately, and in most cases heparin is given for one to four days. Anti-ischemic agents (nitrates, beta blockers, and calcium channel blockers) and narcotics may be used for appropriate indications, such as chest pain or congestive heart failure.

Patients with recurring symptoms including specific ECG changes (ST elevation) may be catheterized and may benefit from repeat administration of the thrombolytic agent. Chest pain alone is treated by intensification of other treatments and by catheterization in some cases.

Patients manifesting clinical signs of congestive heart failure as a complication of AMI are appropriately managed initially with diuretics. Some centers add digitalis glycosides to this regimen, whereas others avoid them and instead use ACE inhibitors (in the inpatient setting).

Patients with major damage to the left ventricle of the heart (the chamber

that pumps blood to the rest of the body) warrant more intensive and prolonged anticoagulation with heparin and aspirin or warfarin. This strategy aims, to prevent blood clots from breaking off and moving to the brain or limbs (thromboembolism).

During the hospital stay, while beginning to walk around and undergoing further tests, most patients with Q wave AMI should be placed on beta blockers. This is particularly true for those with extensive AMI or chest pain even at low exercise levels. Recurrent episodes of pain are usually an indication for catheterization and possibly for coronary angioplasty or revascularization.

The only medications shown to reduce short-term mortality in Group I AMI patients are thrombolytic agents, aspirin, and early beta blockers. Thrombolytic agents should be administered within one to two hours after the onset of symptoms, if possible, but some benefit extends to as long as 24 hours after the onset of symptoms. In some patients the time of onset of symptoms is uncertain, and so it is not unreasonable to administer the agent even if the time since onset may exceed four to six hours.

Invasive Procedures

The uncertainties and controversies about invasive procedures are as great as those concerning drugs. The issues arise for patients who have survived the acute event, for those who have never suffered an AMI but who are believed to be at some (or high) risk for one, and for those who are in the middle of an evolving AMI or are only a few hours post-AMI.

For patients who have recurrent or persistent chest pain or evidence of further cardiac damage even after use of thrombolytic agents, PTCA or CABG may be helpful. Performed after diagnostic catherization, PTCA involves threading a small tube into the obstructed coronary blood vessel and Mating the atherosclerotic narrowing. Conventionally, this is done by inflating a tiny balloon; new research is testing the efficacy of lasers or other devices for this purpose. The use of PTCA in patients who arrive at the hospital too late to receive thrombolytic therapy (e.g., after four to six hours) has been advocated. The mortality rate is high in such cases, however, and this approach is not used routinely in the elderly. Much research must be done to identify patients most likely to benefit from the procedure. A recent series of RCTs showed that performing PTCA immediately on patients who had received thrombolytics did not improve their survival or cardiac function, and these reports established that such procedures can be correlated with more bleeding complications.

CABG is performed most frequently as an elective procedure for symptomatic patients with advanced obstruction of several coronary vessels. Although it is not routinely done during an AMI, in selected unstable patients it can be life-saving within hours or days of an AMI. In some cases CABG may be the first choice when catheterization reveals obstructions in multiple coronary vessels that are not amenable to PTCA. CABG is also performed as a back-up to PTCA, either following complications with the latter procedure or when critically narrowed or clot-obstructed vessels cannot be dilated. Although CABG can be performed in the early hours following AMI with comparatively low risk and successful outcome in selected patients, no adequately sized, prospective controlled trials have been conducted and its use in this setting is highly individualized or uncertain.

The effectiveness of these potentially life-saving therapies needs to be documented in the Medicare age group, because most clinical studies have been done with patients under age 75. Mortality rates from subsequent AMI are substantially higher among elderly than younger patients; surgery in these patients also has a greater risk of complications. Nevertheless, the survival rate in the elderly group over age 70 may be better with surgery than with medical treatment.

Rehabilitation

Rehabilitative care after myocardial infarction should help restore the patient to the pre-illness lifestyle and level of function. It should, additionally, favorably modify conventional coronary risk factors, limit psychosocial disability, and reduce the increased complications of immobility in the elderly.

Elderly patients are more likely than younger patients to experience a severe and complicated AMI and a longer hospital stay. Prescriptive exercise rehabilitation—which is gradually progressive, predominantly aerobic, low-impact, modest-intensity physical activity (for example, walking)—can enhance functional capacity and reduce symptoms brought on by activity. Thus, it often enables patients to maintain independent living. An increase of exercise tolerance to a level designed for return to gainful employment is less frequent. Exercise test (treadmill or bicycle) results are used to prescribe safe and appropriate levels of exercise training and to measure the resulting improvement in exercise tolerance.

The life expectancy of a woman in the United States who has reached age 65 is almost 19 additional years; for a man of that age, it is about 15 additional years. These figures may well justify the delivery of education and

counseling designed to modify conventional coronary risk factors, even though the effects modifying most risk factors after an AMI in elderly patients are not definitively known.

Coronary risk modification, which is designed to retard the progression or effect regression of atherosclerosis, has proved feasible in elderly populations; selected components of risk reduction can significantly improve survival in some elderly patient groups. The American Heart Association has removed the term "premature" from its mission statement of "reducing death and disability from heart disease" and indeed has reversed the priority order for "death" and "disability"; both steps emphasize the advocacy for coronary risk reduction, including in the elderly. Smoking cessation, control of hypertension by diet and drugs, weight reduction or weight control, control of hyperlipidemia predominantly by diet, and regular exercise are the recommended interventions. Teaching elderly patients how to simplify work and conserve energy can further extend the duration of independent living for coronary patients with limited residual function.

By age 80, as many women as men have AMIs. Attention is thus required to maintain and enhance exercise capacity in elderly women, who generally decrease their habitual activity level with aging more than men do even before infarction. Additional benefits of exercise training include limiting bone loss and osteoporosis and maintaining joint stability and muscle and tendon strength, both of which can limit falls and the resultant impairment. These points were also emphasized by the IOM committee that considered hip fracture, another of the three conditions included in the Effectiveness Initiative project.

The psychosocial complications of myocardial infarction—particularly fear, depression, and dependency—can be decreased by exercise rehabilitation and by the social support offered by a peer group in supervised exercise settings. Psychosocial counseling, based on prognostic information obtained from exercise testing approaches and from risk reduction, can further improve psychosocial status. The perception of personal health status can be improved by education and counseling. Perceived health status often correlates with the outcome of illness, thus perhaps affecting the outcome. The threatened loss of independence that commonly accentuates most psychosocial complications can be retarded or reversed by the rehabilitative approach to care.

Restoration of physical capacity, decrease in symptoms, and resultant improvement in function and comfort are measurable outcomes of health care that are valued by AMI patients including the elderly; these can be assessed by a number of quality-of-life measures. Patient awareness that

lifestyle components can favorably influence the course of coronary illness has provided further incentive for secondary preventive interventions. Provision of rehabilitative services to elderly coronary patients recovering from an AMI may prove the most economical approach to limiting or delaying the need for costly custodial care. The challenge to the clinical community is to deliver dim rehabilitative services in a cost-effective manner.

Factors Important for the Selection of Key Patient Management Issues and Related Research Activities

Before discussing high priority patient management issues in AMI, the committee briefly reviewed its understanding of the major reasons that AMI had been selected for the Effectiveness Initiative research program. Coronary artery disease is very prevalent among elderly women and men, and AMI is the leading cause of death in the United States for all age groups above 40. However, the individual outcome for those who survive the acute event is less predictable; that is, an AM can lead to chronic disability in some patients but to little chronic problem in others. New diagnostic and therapeutic interventions have developed rapidly in recent years, and much data from clinical trials of these interventions are accumulating. The multiple patterns of treatment for young and elderly AMI patients include many high-cost and high-risk procedures, with little clear relation between specific therapies and long-term outcome, particularly functional health status and psychological aspects.

SELECTING PATIENT MANAGEMENT ISSUES

Several factors affect the selection of key patient management issues for AMI in elderly patients. These factors are not equally well documented in the clinical, research, or health policy literature. The IOM committee believed, however, that all of them were sufficiently important to be considered as the panel identified specific study topics. These factors include:

- Epidemiologic aspects of AMI among the elderly (e.g., higher or lower prevalence of more advanced coronary disease in particular subgroups)

- Important health status and quality-of-life burdens of the illness for elderly patients
- Different treatment options for the elderly, characterized, for instance, by whether different therapies have different likelihoods of prolonging survival, producing major impairment and disability, or improving the patient's physical functioning, emotional well-being, and independence
- High degree of professional and clinical uncertainty about some alternative strategies for managing the care of AMI patients, especially the very elderly
- Substantial variation across geographic areas in the per-person use of services for AMI, including those related to prevention and management of risk factors; that is, variation beyond that explained by differences in patient characteristics or health resources in the areas
- Substantial variation across geographic areas or institutions in the outcomes of care for AMI; that is, variation beyond that explained by the differences in the severity or stage of illness (i.e., case mix) or sociodemographic characteristics of patients
- Relatively high costs to the Medicare program of reimbursing for the services provided to patients to prevent, diagnose, and treat AMI and to manage postmyocardial infarction care
- Relatively high out-of-pocket costs to the Medicare beneficiary for services to prevent, diagnose, and treat AMI and to manage postinfarction care that are not covered or are only incompletely covered by the Medicare program.

SELECTING RESEARCH TOPICS AND ACTIVITIES

Content, Conduct, and Use of Research

In specifying research activities focused on high-priority AMI topics, the committee raised three additional points concerning the content, conduct, and use of this research. First, it endorsed four generic areas of concern identified at the 1988 clinical workshop to set priorities for the Effectiveness Initiative: (1) clarification of the implications of the difference between efficacy and effectiveness for the overall purposes of the research program; (2) screening and prevention of the illness; (3) generation and use of reliable and valid outcome measures that relate to functional status and quality of life; and (4) mental and emotional dimensions (cognitive functioning;

anxiety and depression). With respect to the last two, the committee noted that several good measures of health-related quality of life (relating to functioning, emotional well-being, and so forth) are currently available or could be adapted for effectiveness research.

Second, in principle, several approaches can be used to this research initiative, either sequentially or simultaneously. They fall into the following basic categories (in increasing order of complexity, rigor, and expense): cost, utilization, and outcome monitoring through analysis of administrative data; observational (cross-sectional, case-control, or longitudinal-cohort) studies with a richer data set than that afforded by routinely collected administrative data; quasi-experimental studies and demonstrations; and, potentially, RCTs.

In addition, projects based on newer, or nonexperimental techniques, such as meta-analysis, decision analysis, and cost-effectiveness analysis, should be included among the research options. In short, the committee concluded that all these approaches should be considered potential investigational methods for effectiveness research. The committee also emphasized the importance of evaluating beforehand the trade-offs implicit in selecting one approach over another and in pursuing combined approaches.

Third, studies on specific illnesses serve as prototypes for examining other, similar conditions. For instance, studies of primary and secondary prevention, early diagnosis and treatment, staging of acute disease in relation to outcome, treatment options, and quality-of-life outcome measures related to AMI provide opportunities to address conceptual and methodologic issues for other illnesses that are prevalent in the Medicare population, that have both acute and chronic aspects, or that affect the cardiovascular system.

Data Issues

The 1988 clinical workshop had questioned the availability and quality of data for effectiveness research in HCFA's existing (or anticipated) administrative files. This remained a critical issue, as evidenced by appreciable discussion of the topic by the AMI work-shop committee.

The committee underlined the importance of HCFA's ability to acquire additional data through special studies, surveys, and patient follow-up activities, for several reasons. Data available on pre- and posthospital events, particularly those in physician office records, must be expanded, and problems (e.g., missing data or uninterpretable information) with office records must be addressed. The relative lack of documentation of deaths that occur before hospitalization or at some time after hospital discharge for AMI

needs to be taken into account. Two substantial problems in coding—coding rules for the diagnosis of AMI in hospital records and the lack of flexibility and responsiveness in creating new codes for new tests and treatments—must be confronted. Considerable effort should be made to enhance the collection of outcome information that is pertinent to elderly AMI patients. For example, return to work or ability to drive a car, outcomes that might be relevant at age 50, may be less important at age 75.

The development of the Uniform Clinical Data Set (UCDS) (see the appendix) and the use of the Medicare Peer Review Organizations (PROs) to abstract this information from clinical records were considered. Some committee members raised concern about the accuracy of such records, the value of retrospective abstracting rather than concurrent analysis, and the lack of clinical peer review of both the data set itself and the PRO methodology. These difficulties were particularly emphasized with regard to risk stratification methodologies and identification of the sequence of diagnostic and therapeutic events.

Notwithstanding these concerns, current data sets were considered useful for monitoring variations and trends in the use of tests and treatments and for assessing the relation of certain services to simple short-term outcomes, particularly survival, some complications, and reinfarction. These data would be useful, for example, in looking at differences by geographic region or size and type of hospital. Moreover, claims data may be valuable as a source for generating hypotheses, building a convincing case for more detailed data collection, and constructing decision models that could be tested with rigorous study designs.

Key Patient Management Topics for Effectiveness Research in Acute Myocardial Infraction

PRELIMINARY DISCUSSION AND SELECTION OF MAJOR TOPICS

The appendix describes the workshop and its preliminary activities, including a homework exercise to identify provisional patient topics of high priority for effectiveness research. It also briefly describes presentations by HCFA staff on the Medicare data system and an analysis of Medicare data on AMI and cardiovascular disease.

At the workshop, the committee reviewed the homework results and the HCFA data analyses and then discussed AMI studies that might be appropriate for the Effectiveness Initiative. This session made clear the number and complexity of unanswered questions about the appropriate management of individuals who are at risk for, who are experiencing, and who have had an AMI. Many of these questions still lie in the realm of efficacy rather than effectiveness —that is, whether a test, a procedure, or a drug works at all, rather than how well it works in the average practice of medicine. These issues may belong more in the arena of clinical and biomedical research of the sort conducted by the National Institutes of Health (in particular the National Heart, Lung and Blood Institute) than in the area of effectiveness research.

Thus, the committee tried to narrow its task to clarifying what more limited set of questions could be satisfactorily addressed in one of three ways: (1) with existing HCFA administrative data of the sort on which the preliminary analyses presented at the workshop were based; (2) with existing HCFA data augmented by clinical data from medical records abstracted by PROs or from specially conducted patient surveys and follow-up studies; and (3) by carefully planned longitudinal studies that combine all necessary

inpatient and ambulatory information (e.g., evidence of prior coronary disease, prehospital care, drug or surgical therapy, rehabilitation impact, and quality-of-life outcomes).

To this end, the committee generated numerous topics on which the opening discussions focused. Some of these topics cut across several issues, such as the need to examine patterns of care by geographic and rural or urban area, by hospital and type of practitioner, and by type of intervention (e.g., pharmacologic, invasive, surgical, or some combination). Other topics included risk stratification of patients and the need to study various staging methods and their relation to outcomes.

Ten categories of study topics were advanced by committee members and recorded during the early part of the discussion; they are reported, in somewhat condensed form, in Table 1. Some relate to clinical issues involving the use of diagnostic and therapeutic modalities such as laboratory testing and catheterization and other invasive interventions. Others relate more to research methods, such as outcome measures, or to crosscutting topics, such as risk stratification, treatment modality, and outcomes. From this discussion and listing, members were asked to vote for up to five topics that should receive the highest priority attention in the effectiveness program for AMI. These were tabulated and the highest ranking topics formed the basis for the remaining discussion. The following section elaborates this discussion and the committee's recommendations.

Table 1 Provisional Patient Management Topics Relating to Acute Myocardial Infarction

Risk Stratification after AMI
Timing related to MI: early versus late
Use of diagnostic or therapeutic procedures to stratify risk
Guidelines for stratification based on existing administrative data
Prospective study to validate stratification testing and criteria
High-risk versus low-risk treatment plans
Patients appropriate for no stratification
Available data on effectiveness of stratification over age 65
Procedures in Early Diagnosis and Treatment
Catheterization, angioplasty, and surgical procedures
Echocardiography positron emission tomography scans
Defibrillation
Use of coronary care unit (CCU)
Aggressive (invasive) versus nonaggressive (medical) treatment
Continued use of outmoded diagnostic tests

Pharmacologic Treatment

Thrombolytics (streptokinase, tPA, and urokinase)
Relation of pharmacologic agents to other therapies such as angioplasty

Outcomes

Mortality: before hospital, during hospitalization, early and late after hospitalization
Other outcome measures—functional status, quality of fife, activity, pain
As related to: caregiver (primary versus specialist); geographic location; site of cam (community versus teaching center); diagnostic and or therapeutic measures; stratification; in-hospital care (CCU); length of stay

Variations in Treatment and Outcomes

Geographic (location of care, origin of patient); individual physicians and groups; specific hospitals
Relationship to outcomes
Implications for cost
Value as "natural experiments"

Post-AMI Issues

Prognosis for different risk categories
Cardiac rehabilitation
Sudden death

Primary Prevention

Role of pre-event risk identification
Concern for neglect of this area, as primary prevention occurs before Medicare age

Prehospital Care

Precipitating events
Recognition, initial treatment out of hospital
Emergency room

Physician Education

Guidelines for patient management

Comparative Analyses of Different Modalities

Aggressive versus nonaggressive management
Angioplasty versus CARG
Value of thrombolytic treatment
Additional diagnostic tests

SUMMARY OF RECOMMENDATIONS

The workshop discussion did not (nor was it intended to) propose testable hypotheses or *specific* research questions. Rather, it was meant to identify a broader set of research priorities that could be pursued by using data available in the near term (e.g., through Medicare files) or data that could be collected relatively efficiently by independent effectiveness research projects. A more precise selection of topics depends on a more detailed assessment of data needs, on the one hand, and realistic data available, on the other. The following discussion describes the major groups of questions that the committee felt an effectiveness research agenda might include.

The committee recommended attention to four data and methodologic issues and three patient management issues. The former all involve research strategies that might be used to address the three patient management issues. The data and methodologic priorities call for the following:

1. *improvement of the clinical and diagnostic information available in the HCFA data bases*;
2. *improvement of risk stratification methods*, with particular attention to the relationship between these methods and the delineation of high- and low-risk subgroups, appropriate interventions for each, and resultant outcomes;
3. *more effort to define outcomes*, particularly those other than mortality, such as functional status and quality of life; and
4. *further examination of variations in the patterns of care and the use of treatment modalities in different settings*, for example, by type of facility, geographic region, or type of physician (i.e., specialist or generalist).

The three patient management or clinical topics for early priority in effectiveness research are

1. *selection of diagnostic and therapeutic procedures*, particularly angioplasty and invasive techniques or surgery;
2. *selection of pharmacologic therapies*, including thrombolysis; and
3. *use of diagnostic tests and guidelines to stratify risk and guide treatment*. In this context, "guide treatment" alludes to decisions about aggressive versus nonaggressive treatment, including no intervention. (By "aggressive," the committee referred to invasive diagnostic, therapeutic, and surgical interventions, and by "nonaggressive," to conservative medical and pharmacologic management.)

Other patient management issues receiving attention in the discussion and in the second round of committee voting on key topics included primary prevention, prehospital care, rehabilitation, and physician education about clinical management.

METHODS ISSUES

Improvement of Clinical Information in HCFA Data Bases

The committee developed two specific recommendations regarding clinical information in the HCFA data base. The first involves coding accuracy; the second, the validation of PRO data collection methods.

The committee recommended the development of methods that will more accurately identify acute myocardial infarction patients for any effectiveness studies. These would involve both the nature and the extent of damage to the heart.

The literature demonstrating a high incidence of false-positive diagnosis of AMI through the coding system, when compared to clinical documentation, occasioned great concern among committee members. This problem is compounded by the recognized incidence of AMI that occurs without acute ECG changes, although evidence corroborating the infarction may well emerge after the acute hospitalization and therefore not be captured in the data coded for the acute event.

The committee recognized the significant limitations of the ICD-9-CM[4] classification (code number 410) for this purpose. Although improvements have been made in this area, considerable reassurance about accurate diagnosis will be required before any effectiveness studies using these hospital data bases will have satisfactory credibility, at least to the practitioner community. The committee also noted that the effect (or the incentives) of reimbursement must be considered. For instance, reported increases of AMI in administrative databases may arise from efforts by hospitals to improve reimbursement levels by "up-coding."

The current coding system is limited in its ability to adjust to new therapies that are critical in determining effectiveness. Thrombolytic therapy is considered a drug, and this is not currently captured in the inpatient data set. Also, when angioplasty was introduced as a frequent intervention, it was almost two years before codes were agreed upon. Therefore, a process must be established, perhaps assisted by a group of acknowledged experts in the field, that would identify state-of-the-art changes and rapidly develop coding to capture these types of critical information.

The committee recommended clarification and validation of the PRO methodology for obtaining routine clinical data that may be essential to the DHHS effectiveness research program.

The administrative data sets available to Medicare rely chiefly on claims data. Abstracted clinical records reviewed by PROs may be another source

[4] International Classification of Diseases, ninth revision, clinical modification.

of information (see the discussion of the UCDS in the appendix). The pool of PRO-abstracted records, however, is based partly on a random sample and partly on samples of varying sizes of a wider array of cases that might have quality, utilization, or other problems. The validity and usefulness of the resulting data for research are subject to considerable question. For example, how random is the sample of AMI patients chosen for review? Because charts are reviewed retrospectively, can issues of timing and risk stratification be evaluated? The committee was concerned that the current design and implementation of data acquisition by the PROs would not be adequate to support certain elements of effectiveness research, such as the analysis of risk stratification. Independent validation of the methods is required to provide convincing recommendations about effectiveness to the scientific and business communities.

In a related finding, the committee strongly urged HCFA (and DHHS, more broadly) to involve experienced clinicians in the development and analysis of data for the effectiveness program. Physicians show considerable enthusiasm for the opportunity to develop clinical data that will support a determination of effectiveness, and every effort should be made to capitalize on this interest. The committee was concerned with the perception that experienced clinicians in private and academic practice were not being adequately involved in certain elements of the effectiveness initiative within HCFA. For instance, evaluation of existing data bases and development of critical new data bases such as the UCDS appeared to be proceeding within HCFA with only limited participation and review from practicing clinicians. In addition, the committee concluded that the methods adopted for effectiveness evaluations, and the use of administrative mechanisms such as the PROs to collect data, should be subjected to peer review by qualified clinicians and health service researchers outside HCFA.

Having stated the caveats noted above, however, the committee strongly supported HCFA initiatives to provide access to its data bases for qualified health sciences investigators at minimal or no cost. The committee was convinced that such access to data files would allow creative investigators to identify new projects and important issues and problems that might not otherwise be examined.

Improvement of Risk Stratification Methods

The committee recommended the funding of extramural research to validate stratification and triage decision methods that would permit determination of effectiveness in clinically important subsets of patients.

Physicians use many methods to stratify risk and to determine acute and subsequent care for their AMI patients. They may apply these stratification methods systematically, or idiosyncratically and variably, depending on availability of tests or delay in access to testing. The methods themselves may be based on published information, data found in the individual patient record, or personal experience. Relevant clinical data include results of echocardiography, radionuclide studies, exercise tests, other physiologic information, and the presence of hypertension and other coexisting conditions. At the present time, none of these methods has been viewed as ideal for stratifying risk in the Medicare age group, and none by itself adequately explains the marked variations in mortality of elderly AMI patients. In the absence of a reliable and valid risk stratification method, review agencies will find it difficult to identify homogeneous subgroups of patients within which to measure the effectiveness of interventions.

Patient stratification methods can vary across geographic locations, between rural and urban areas, between teaching and community hospitals, and among physician specialties. Thus, it is particularly important to assess how the "local" environment in which care is provided, which is essentially equivalent to local stratification schemes, may correlate with the appropriateness of the intervention.

For example, clinical trials indicate that angioplasty provides no immediate benefit in the early stages following thrombolytic therapy. Hence, the use of angioplasty in different settings could be followed to ascertain whether this procedure is being performed in elderly patients soon after thrombolytics, despite the findings in these clinical trials; whether this utilization varies by setting; and what implicit or explicit local stratification method explains this variation.

In sum, the variety of methods used by physicians to stratify risk and aid their therapeutic decision making should be tracked because these methods may influence the use of interventions such as CCUs, thrombolytic therapy, angioplasty, or surgery, as well as the outcomes of these interventions. Particular attention should be paid to decisions on resource utilization that become inevitable once a particular risk has been determined. As noted with the angioplasty example, this research could begin with an analysis of existing data sets, identify "natural experiments" in the differing risk stratification methods that exist in practice, and then generate relevant clinical hypotheses that could be tested by ongoing surveillance or more targeted research, such as one or more "pilot" studies. The committee was convinced, however, that a prospective study will eventually be needed to provide a sufficiently reliable, valid, and practical method for stratifying AMI patients that will allow appropriate and unambiguous interpretation of effectiveness data.

Definition of Outcomes

Because definitions of outcomes are so central to effectiveness research the committee recommended further efforts to develop more sensitive and comprehensive measuring of the range of experiences patients may have.

The committee proposed three related priorities: (1) more comprehensive definitions of the elements of outcomes in line with recent developments in the field of health status and quality-of-life measurement; (2) better definitions of alternative "best outcomes" (from the patient's point of view) that take health status and quality of life into account; and (3) expansion of techniques for acquiring data to measure outcomes for acute myocardial infarction. The committee recommended further that the Department of Health and Human Services give considerable priority to understanding and developing these methods for use throughout its effectiveness research effort (not just for acute myocardial infarction).

Several committee members noted that survival alone may not be regarded by some patients (or their families or physicians) as the best outcome following AMI. To the extent this is true, death or length of survival after AMI may be an incomplete indicator of outcome, because it gives no indication of morbidity (including chest pain), functional status (including capacity for physical activity and activities of daily living), psychological and emotional well-being, social functioning, support networks, and general outlook on health status. For many patients, these measures may be more important than survival per se; that is, some patients may see the highest possible quality of life after AMI as the best outcome. For this reason, it becomes important to differentiate between outcomes and patient preferences for outcomes. Information on patient preferences, given different potential outcomes, must be obtained. In general, the committee judged that these dimensions of health status should be viewed as independent of the need or use of health care services, although measures based on utilization could form part of more comprehensive sets of outcome variables.

The committee recommended that the Department of Health and Human Services solicit outside expert opinion to define an adequate, appropriate set of outcome measures and to propose instruments for measuring these outcomes in effectiveness research both generally and for acute myocardial infarction.

Consensus is emerging that, for health status and quality-of-life measurement, use of reliable and valid "generic" measures of health status coupled with selected "disease-specific" measures is an appropriate, desirable, and practical research strategy. The committee concluded that existing HCFA

data bases lack the necessary range of measures of functional status, although it was given to understand that HCFA is attempting to add a simple, physician-based functional status measure to its claims forms. In the short run at least (or in the event that the measure selected for the claims form is inadequate), this information would have to be obtained directly from patients (or proxies). All in all, the committee believed that the application of *patient-based* measures of acceptable reliability and validity must be an integral part of effectiveness research over the longer term.

With regard to AMI, the committee called attention to several specific concerns. First is the need to identify specific outcome measures such as exertional pain, exercise tolerance, recurrence of infarction, and congestive heart failure that must be captured in the longitudinal data base. Little change has occurred in outcomes such as mortality after introduction of "life-saving" interventions, and more specific outcomes of these treatments must be identified. The possibility that a variety of treatments may produce the same outcome must also be considered.

The committee also noted that several common outcome indicators that might be valid in younger age groups, such as return to work or ability to drive a car, may not be valid or desirable in Medicare patients following AMI. Also, evaluation of exercise capacity or exertional pain may be thwarted by the inability of elderly patients to exercise or in some cases to feel pain in the same ways or to the same extent as younger patients. Thus, the committee strongly urged DHHS support to extramural work that will produce reliable and valid instruments for functional assessment and quality of life in the Medicare population not only with regard to acute myocardial infarction, but also as part of a broader charge to define outcomes satisfactorily for all projects carried out under the aegis of effectiveness.

Examination of Variations in the Patterns of Care and Use of Treatment Modalities in Different Settings

The committee recommended that work on understanding patterns of care be supported and be linked to issues relating to the three high priority patient management topics identified for the Effectiveness Initiative.

A major dimension of effectiveness research is analysis of the way in which patterns of care change over time as a function of numerous epidemiologic, clinical, and health care system factors. These factors include geography, type of community, type of hospital or other facility, type of practice and physician specialty, cost, and reimbursement. This aspect of effectiveness research reflects the extraordinary concern about three general problems: wide, unexplained variations in population-based rates of use of

services; high levels of use of inappropriate services and procedures; and differences in practice styles that appear to reflect areas of professional disagreement. The committee fully supported the use of HCFA databases, augmented as appropriate by information obtained from patient records, in this effort.

With respect to AMI, several factors discussed below should be part of a comprehensive set of analyses of patterns of care and variations. Many of these variations are cultural; others are matters of habit. For example, it was noted that physicians have a tendency to use many previously employed diagnostic tests, even when newer or better tests become available and common practice.

Type of hospital including size, teaching involvement, and role as primary or referral facility may have a profound effect on the interventions that are available to the patient and on outcomes. Length of stay, care in specialized units such as the CCU, use of remote monitoring, and access to bypass surgery or state-of-the-art technologies can be compared through data from facilities in similar geographic areas serving similar patients. Particular attention to those facilities that have made major investments in highly specialized units employing invasive technology may be valuable.

Differences in practices of different types of physicians may also prove instructive, particularly the care provided by generalists such as family physicians and internists compared with that rendered by cardiologists. Group practices, particularly those that try to influence clinical practices or that use formal clinical guidelines and specialty cardiology practices that use advanced technology, may demonstrate marked differences in patterns of care, patient outcomes, and costs relative to other types of practices.

Geographic location of both patient and treating institution should be examined, particularly with regard to distance between the patient's home (perhaps by ZIP code) and hospital, the geographic region of the country (e.g., East versus West Coast), or location in a rural or urban area. Allowances must be made for differences in outcome that are influenced by the sophistication of evaluation and treatment before the patient reaches a hospital or by the circumstances surrounding a transfer from one hospital to another after initial evaluation and stabilization. Small area analysis may provide a valuable starting point for identification of geographic variations. These studies may not determine the effectiveness of the treatments employed, but they will be a useful starting point for detailed prospective studies. Of particular interest will be the identification of patients who did not have an invasive procedure, determination of why the procedure was not undertaken, and clarification of the relationship among length of stay, mortality, morbidity, and clinicians' use of tests to determine risk stratification in these patients.

PATIENT MANAGEMENT TOPICS

Selection of Diagnostic Tests and Therapeutic Procedures

The committee recommended that research continue to be supported to identify the effectiveness of specific diagnostic and treatment modalities in the Medicare age group, whether alone or in groupings based on risk stratification methods. Further, it recommended that such investigations proceed from observation of variations of practice patterns and from surveillance of specific risk stratification strategies linked to appropriate outcomes.

Workshop discussion touched repeatedly on the wide array of diagnostic tests and treatment procedures commonly used in AMI. These tests and procedures are often employed in "packages" or sequential groupings, depending on the relative risk assigned to the patient, as described earlier in the section on the clinical knowledge base. This complex armamentarium led to several general questions about the role of individual or combinations of diagnostic and therapeutic interventions in AMI.

As a case in point, given the findings of recent clinical trials, the choice of thrombolysis or angioplasty (or a combination) as the most appropriate treatment in many patients is a major decision point. These trials did not involve many patients in the Medicare age range (particularly individuals over age 75) and, therefore, may not be applicable to patients who are 75 or 85 years of age, for example. Nevertheless, the research findings are likely to be followed as a rationale for the treatment of Medicare patients. Because these important results may not apply as well to Medicare patients, however, the committee judged that the outcomes of thrombolysis and angioplasty must be observed and analyzed. For example, Medicare data could be analyzed to document the rate of cerebrovascular accidents or other bleeding complications after the use of thrombolytics (or angioplasty, or both) in the elderly.

Another concern was raised about the use of certain diagnostic tests such as catheterization, exercise testing, echocardiography, radionuclide imaging, scintigraphy, and more recently PET scanning and MRI for risk stratification or prognostic purposes. Although these procedures enjoy widespread use based on published research and local customs, there is no clear indication of either efficacy or effectiveness in Medicare patients, and the cost and especially the risk to the elderly patient are not well understood. Furthermore, as newer modalities are added, older methods are not dropped, even though the purpose and value of these procedures has been supplanted. This adds a further complexity to the patient management topics warranting investigation through effectiveness research.

Selection of Pharmacologic Therapies

The committee recommended that the use of pharmacologic agents, particularly thrombolytics, be monitored in both the inpatient and the outpatient settings. As for other interventions, individual drugs or packages of drugs, alone or in combination with invasive procedures, should be analyzed with regard to variations in outcomes.

A variety of pharmacologic agents is used to treat AMI, either alone or in combination with other drugs or treatments. The drugs employed in the acute period are often superimposed on long-term medications used to treat ischemic heart disease both before and after infarction. Although the efficacy and appropriate use of these medications is well described in the biomedical and clinical literature, how effective they are for AMI patients of all ages, especially the elderly, is less well documented. Beta blockers, nitrates, calcium blockers, nitroprusside, and anticoagulants are used in different combinations and sequences; choices of medications, sequences, and combinations vary by types of institutions, practitioners, and presenting clinical state and comorbidities of patients. Also, these agents may be used in conjunction with other interventions such as catheterization, angioplasty, and coronary artery bypass surgery, a phenomenon that adds another important layer of complexity to these questions of effectiveness.

Of particular interest is the role of thrombolytic therapy—streptokinase, tPA, or related compounds—in the Medicare population. Although the efficacy of these drugs in preventing death and reducing morbidity from AMI has been demonstrated recently in clinical trials, these studies did not include many elderly patients. Anecdotal experience of committee members suggested a similar benefit in the elderly under age 75, but the risks may be greater, and fewer elderly patients may present with a clinical picture suitable for the use of thrombolytics.

One useful tactic might be to identify cohorts of elderly AMI patients who received no interventions, those who receive only thrombolysis, those who received only invasive or other procedures, and those who received both thrombolytic drugs and procedures. Another might be to obtain specific data on the extent to which thrombolytic therapy is used in the Medicare population. Information about thrombolytic therapy as a function of patient age, location and type of provider, use of other pharmaceuticals and hospital setting would be important background information for future studies.

The HCFA administrative databases do not currently capture information on drug use in the ambulatory setting.[5] Because thrombolytics are catego

[5] At the time of this workshop, the committee anticipated that better data on medication use would become available when the Medicare Catastrophic Coverage Act took effect. This legislation was reversed, but the need for these data did not diminish, and for effectiveness research purposes, the problem of data collection simply worsened.

rized as a drug, their use as a major intervention in the early stage of hospital or prehospital care does not appear in administrative discharge data. Consequently, the current Medicare databases will be of limited value in evaluating the effectiveness of pharmacologic or, specifically, thrombolytic therapy.

To address these questions, therefore, effectiveness research will need to reach beyond insurance claims files to find several other types of information. For instance, the percentage of patients discharged with a transmural (Q wave) AMI who are treated with thrombolytic agents should (in principle) be reasonably uniform across institutions. If this is so, then in the presence of "equivalent" diagnostic ECG changes, the time between arrival and administration of thrombolytics should be indicative of the quality of care in a particular hospital. For example, if all patients in a given hospital received a thrombolytic agent no earlier than three and one-half to four hours after first appearing in the emergency room, this would suggest inordinate delays in patient assessment and administration of a thrombolytic agent. Such information might also be useful in examining the effectiveness of different thrombolytics in relation to ECG changes.

The routine use of other drugs or the uniform use of agents that are appropriate only under specific conditions would suggest excessive use of these pharmacologic agents. In some hospitals, patients with non-transmural (non Q-wave) myocardial infarction would routinely undergo cardiac catheterization even with favorable response to medical treatment. In other settings the response to exercise on medical management would be used as an indicator for cardiac catheterization. Variations in current practices between regions and hospitals should lead practitioners, investigators, and policymakers to focus on strategic issues such as risk stratification when choices about employing therapeutic and diagnostic measures are to be made.

Use of Diagnostic Tests and Guidelines to Stratify Risk and Guide Treatment

The committee recommended that explicit attention be directed at ways to assign or stratify risk to individual patients with AMI as an element in the choice of diagnostic and therapeutic interventions.

The role of risk stratification in choosing among diagnostic and therapeutic options for AMI patients is difficult to overstate. Approaches to risk stratification may be used (or not used), and well (or poorly) used, in patient care decision making every day across the nation. Effectiveness studies must, therefore, identify stratification methods presently in use (which, as

noted earlier, vary enormously) and correlate them with appropriate outcomes. *Within* risk groups, then, the outcomes of competing interventions could be measured to establish which methods best define patients for whom one treatment is more effective than another.

Given some understanding of adequate risk stratification, variations in practice might serve as early "natural experiments." Trends in the outcomes of, for example, angioplasty or thrombolysis in the elderly could be identified and associated with decision making based on different approaches to risk stratification. Such information might, over time, be fed back to physicians or otherwise disseminated, with the hoped-for result being progressive alteration in the practice of physicians, better use of good risk stratification methods, and the associated better interventions in appropriate patients.

These comparative analyses could focus on the selection of appropriate aggressive treatment (versus conservative management) for patients identified as being, for instance, at high (versus low) risk of death or complications. More precise definitions of risk categories would provide a framework for surveillance of both existing and new therapies. The committee noted that such surveillance data should be obtained as a function of age and risk-adjusted for severity of illness and comorbidities.

In short, proven risk stratification methods are essential for appropriate decision making about patient care. Because such methods are not well established, the committee concluded that developing such approaches was, in fact, a critical patient management issue both amenable to—and necessary for—effectiveness research. A model using stratification parameters based on these comparative analyses could be evaluated as a predictor of outcomes in another group of Medicare patients. If successful, these stratification methods could then be applied prospectively.

Conclusions

The committee reached several interrelated conclusions. First, with some critical caveats, the HCFA data bases can be used to compare and contrast patterns of care, both diagnostic and therapeutic, across a variety of communities, care settings, and providers. Thus, the use of specific treatment modalities that have been documented to be effective in clinical trials in younger patients, which therefore can be expected to be routinely employed in older patients, can be analyzed. The committee pointed out those clinical issues, particularly the use of thrombolytic agents, angioplasty, and bypass surgery—alone or in combination—that are most in need of ongoing surveillance.

Second, the use of HCFA data sets is limited by several vexing problems that will hinder effectiveness research on the Medicare population, at least for AMI. These limitations include the variability in diagnostic coding of AMI, the lack of relevant ambulatory data both before and after hospitalization, and the inadequacy of coding for common interventions and new interventions as they are put into practice.

Third, although the most drastic outcome of AMI—death—is often documented even if it occurs outside the hospital, the data set lacks good outcome measures such as long-term functional health status. This major limitation can be overcome by determined effort, which clearly includes a commitment to collecting a broad set of health-related quality-of-life information at least in part directly from patients.

Fourth, the common use of risk stratification methods at various phases in the diagnosis and treatment of AMI provides opportunity for natural experiments in effectiveness where clinical trials would be impossible or too

expensive. With improvements in databases and recording of outcomes as cited above, the effectiveness of these stratification methods in identifying the most appropriate care for the elderly should be readily testable. In some cases—when conclusions cannot be drawn from, say, the HCFA administrative data or effectiveness research projects alone—effectiveness analyses may indicate the need for specific RCTs, and the committee judged that this would be a valuable input into improving health care delivery and health services research over the long run.

Analysis of observational natural experiments based on risk stratification of patients by clinicians must include adjustment for risk of patients selected to receive different treatments, including adjustments related to comorbidity. Methods must be developed to identify and adjust for death or severity of illness and comorbidity in groups of patients prior to the assignment of treatment plans, perhaps based on surrogates such as prior hospitalization or by random samples of these groups from the Medicare data base. Without such methodological attention in advance, comparisons of outcomes with different treatments will be suspect.

Substantial reductions in mortality over the last 25 years have not changed the status of AMI as the leading cause of death. The availability of powerful new drugs and technologies holds promise for even further improvements, but their effectiveness in the elderly is often unclear. This workshop highlighted the value of available patient and administrative records in evaluating the effectiveness of these measures in the elderly. Moreover, it provided direction to future research in assessing the long-term outcomes of AMI and in identifying those diagnostic and treatment modalities most appropriate for clinical trials. This research will be essential in ensuring survival and high quality of life for many elderly in the face of increasing health care costs.

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Appendix A

Background and Conduct of the Workshop

STRUCTURE OF THE WORKSHOP

This appendix describes the acute myocardial infarction (AMI) workshop project and the materials developed or used as background for committee discussions. The main elements of the project were background reading, information on data sets of the Health Care Financing Administration (HCFA) and analyses done for the workshop, and a committee homework exercise that yielded a first-round set of patient management topics.

The workshop was conducted in three public sessions and an executive session, in addition to the previous evening's reception and background session. The first public session featured presentations by Michael McMullan and Henry J. Krakauer of HCFA, a brief review by Kenneth I. Shine (chair of the study committee) of the factors that the committee should keep in mind in recommending patient management topics, and a brief review of the homework exercise by Kathleen N. Lohr (of the Institute of Medicine [IOM] staff). The second session consisted of general discussion by the committee of the preliminary set of patient management topics, followed by a round of "voting" on the main patient management topics. The third session accomplished further refining of the patient management issues and a discussion of the primary research strategies related to those issues. The executive session focused on the final recommendations the committee wished to endorse.

BACKGROUND READINGS

The IOM staff compiled a large set of background materials, which was forwarded to the committee before the meeting, to establish the context of the Effectiveness Initiative and familiarize members with the issues to be discussed. These readings centered on Medicare data files; work in progress funded by the National Heart, Lung and Blood Institute of the National

Institutes of Health and the National Center for Health Services Research; and recent reports of the findings of studies relating to use of services and efficacy of various treatment regimens (see Bibliography).

HCFA DATA

Medicare/Medicaid Decision Support System

The description of the Medicare decision support systems included a simplified version of the flow of data into the Medicare system. That flow starts with entitlement and demographic data for about 33 million Medicare beneficiaries, which are obtained initially by the Social Security Administration (SSA). Health care providers and contractors are the primary source of Medicare utilization data. Providers (e.g., institutional providers, home care agencies, suppliers, and physicians) submit bills to fiscal intermediaries (for Medicare Part A) and carriers (for Medicare Part B); they in turn adjudicate and then pay the bills and pass them are in the system. These utilization data are merged with the SSA demographic information, and from these main sources, several basic record groups are developed.

Basic Record Groups

The first record group is the Health Insurance Master (HIM) Enrollment record, developed from the SSA file; these data, which are updated daily, include dates of birth and death, sex, race, residence, dates of entitlement, and dates of enrollment into health maintenance organizations. This is a rich source of data for identifying beneficiaries and drawing samples for follow-up research studies. The second file, the Provider of Service (POS) Record, contains considerable information on hospitals, skilled nursing facilities, home health agencies, independent laboratories, ambulatory surgical centers, and similar providers for Medicare. The third and fourth files are the Utilization Records for Medicare Parts A and B billing information, including hospital days of care, diagnoses, surgical procedures, physician visits, charges, and payments. The fifth main record group is the Provider Cost Report Record, which has cost, accounting, and other data from participating institutional providers.

For effectiveness research, other "derivative" files may be important sources of information: MEDPAR (Medicare Provider Analysis and Review file), MADRS (Medicare Automated Data Retrieval System), and BMAD (Medicare Annual Data System for Part B). The SSA-based HIM file provides the beneficiary identification number and demographic infor

mation; that information can be used to enter these other files for more detailed utilization information.

MEDPAR is a 100 percent file of Part A inpatient care (about 10 million admissions per year). Because it has person-level data with unique identifiers, it can be used to identify individuals who have received inpatient services related to the diagnosis of AMI. Among the information elements on this file are principal and secondary diagnoses and surgical procedures (ICD-9-CM [International Classification of Disease, ninth revision, clinical modification] codes), days of care, charges, and provider. This file is updated quarterly.

MADRS is a newer 100 percent file that links Part A and Part B data for all persons receiving inpatient hospital care; as of mid-1989, it covered 1986, 1987, and 1988 and is updated monthly. It allows the creation of episodes of care; Medicare-covered inpatient and outpatient care given to a beneficiary before and after a hospitalization can be identified. For this file, which contains about 250 million records per year, Part B (outpatient) data are in summary form only.

The BMAD file is built on a 5 percent sample of beneficiaries and contains about 21 million records, which are updated annually. It provides somewhat more information than the MADRS file on all outpatient services for this sample, such as expenditures, place and type of service, visits, and procedures; the last are coded with the HCFA Common Procedure Coding System (HCPCS), which is based on CPT-4 (Current Procedural Terminology, fourth version) codes.

An example was offered of how existing data sets might be used to conduct analyses related to AMI (especially to monitor trends and examine variations in the use of services). First, researchers would select the ICD-9-CM code for acute myocardial infarction and then enter an inpatient file to extract all records for individuals who had services with that code. Then, because of the presence of unique beneficiary identifiers, the researchers could enter a file that contains information, for each beneficiary, on all institutional services and some summary data on outpatient care. Third, to obtain more detailed information on physician and supplier services, researchers could then examine a file that contains considerably more detailed data on a 5 percent sample of beneficiaries (i.e., BMAD).

Acquiring Additional Clinical and Outcomes Data

HCFA can obtain additional clinical information (such as data on treatments administered and physiologic aspects of the disease itself) from selected inpatient medical records. One mechanism may be through the Medicare PROs by means of the proposed Uniform Clinical Data Set.

In 1987, HCFA's Health Standards and Quality Bureau (HSQB) began a complex project to develop a data set for use by the Medicare Peer Review Organizations (PROs) and the wider research community; it was intended to contain far more detailed clinical data than heretofore available in HCFA data files. Known as the Uniform Clinical Data Set (UCDS), this project is part of a set of steps meant to expand and improve the ability of the agency to assure the quality of care delivered to Medicare beneficiaries, by using the PROs as the principal mechanism. A second purpose of the UCDS is to permit the development of more and better information about what works in the practice of medicine, precisely the aim of effectiveness research. The availability of extensive clinical information collected in UCDS formats would support much more thorough and detailed analysis of patterns of interventions and of outcomes than is possible simply with billing data. Thus, for patients with particular medical conditions, such as acute myocardial infarction, a large body of information could be made available to the medical community and for intramural and extramural research.

The basic operating premise of the UCDS is that relevant clinical data will be abstracted from medical records of all inpatient admissions that are reviewed by the PROs. (This currently amounts to about 20 to 25 percent of all Medicare admission in a year, or about 2.0 to 2.5 million admissions; of these, about 3 percent are a truly random sample of admissions, and the remainder are cases mandated for review for various reasons. However, the large denominator—2.0 to 2.5 million—should reduce the potential impact of the nonrandom. portion of this sample.) PRO personnel will abstract medical records either on-site or at a central office using desktop or laptop computers. The total number of data elements available on the UCDS is about 1600, although not every data element is needed or relevant for every case. The contents of the UCDS fall into 10 major categories:

I. Patient Identifying Information
II. Patient History and Physical Examination and History and Physical Exam Findings
III. Laboratory Findings
IV. Imaging Findings and Other Diagnostic Test Findings
V. Endoscopic Procedures
VI. Operative Episodes
VII. Treatment Interventions
VIII. Medication Therapy in Hospital
IX. In-hospital Course
X. Patient Discharge Status and Discharge Planning

Detailed guidelines that describe precisely the data to be acquired have been developed; for an example relating to AMI, see Table A.1.

As of April 1989, the project was in a pilot-test phase. Field testing of the whole approach was to be conducted in late 1989 and early 1990. An assessment and recommendation as to whether to go forward with this approach were expected late in 1990. HCFA is also working to develop mechanisms to collect measures of functional impairment and other patient outcome data more directly.

Acute Myocardial Infarction Analyses Illustrating the Use of Medicare Data

HCFA staff compiled an array of data tables from their analyses of Medicare files on myocardial infarction, exercise testing, revascularization, and other cardiovascular conditions and interventions illustrative of the types of analyses that might be done with AMI data. These materials were distributed the evening before the meeting and were further elaborated in presentations at the workshop. The data summarized the longitudinal experience of patients with ischemic heart disease, including mortality rates, morbidity (as evidenced by rehospitalization, with dissection by time and cause, and ambulatory services), and disability (as evidenced by use of skilled nursing facility and home health agency services).

The first set of analyses examined the incidence of exercise testing in the ambulatory setting and the events that follow it. In 1985, some 18,000 Medicare patients in the 5 percent Medicare sample reported in the BMAD file had electrocardiographic or radionuclide exercise testing, of which about one-third occurred in patients with ischemic heart disease identified in a prior hospitalization. This latter group, about 6,000 patients, was excluded from the analyses. There was almost a three-fold increase in the use of radionuclide testing between 1985 and 1986, although this increase was still less than 10 percent of the total undergoing stress testing.

A marked increase in the risk of hospitalization occurs in the immediate period after exercise testing, for cardiovascular causes such as angina, AMI, congestive heart failure, arrhythmias, or interventions (e.g., bypass surgery or angioplasty). There is a three- to four-fold increase in the incidence of admission for an AMI in the 30 days after testing, but no apparent increase in the mortality rate for those admitted with an AMI. After 180 days the risk of admission is about four times greater for noncardiac than for cardiac reasons, implying significant other comorbidities in this population.

However, interpretation of these data is subject to several problems: there is no equivalent time to event analysis, but in any year about 20 percent of

TABLE A.1. Example of Data Elements Relevant to Acute Myocardial Infarction Recorded for the Uniform Clinical Data Set: Cardiac Catheterization and Ventriculogram

Formal report of the first cardiac catheterization and/or ventriculogram performed during the admission or up to 6 weeks before admission; if more than one test, use the one closest to admission. Catheterization takes precedence over ventriculogram. Any procedure done in an operating room, minor treatment room, at the bedside, or in the radiology suite can be included. All appropriate categories of specified findings are checked.

The general rules for recoding information for the UCDS are to change default values on the computer screen ("F") to "T." The specific findings to be recorded for catheterization or ventriculogram are the following. The reviewer changes F to T unless a percentage is called for, in which case the worst percentage is recorded, or other information is specified.

Normal
AV shunt
Ventricular/atrial septal defect

Valvular defects:
- Aortic stenosis (<1 sq cm)
- Aortic regurgitation (moderate or severe)
- Mitral stenosis (<1 sq cm)

Stenosis: left main (%)
Stenosis: left anterior descending (%)
Stenosis: circumflex (%)
Stenosis: right (%)
Cardiac output (liters/minute) (%)
LV ejection fraction (%)
Abnormal chamber size/wall motion
Ventricular aneurysm
Congenital anomalies (patent ductus, ventricular septal defect)
Aortic aneurysm
Dissecting aortic aneurysm
Other abnormal findings

Coronary artery grafts — number
Number with >70% stenosis

Pressures
- Left ventricular — systolic; diastolic
- Aortic — systolic; diastolic; mean
- Pulmonary artery (including Swan-Ganz) — systolic; diastolic

SOURCE: "Resource Manual for Uniform Clinical Data Set (UCDS)" prepared by Case Mix Research, Queens University, Department of Community Health and Epidemiology, Kingston, Ontario, Canada in association with Wisconsin Peer Review Organization (WIPRO), Madison, Wisconsin, 1988.

Medicare beneficiaries are hospitalized, compared with 25 percent of exercise-tested persons; there are no baseline data establishing the risk of admission for all Medicare patients from all causes during a similar time period; and the data cannot distinguish between the stress test as the incident discovery of ischemic disease in the patient and as a follow-up in a patient with known ischemic disease not previously recorded in Medicare data. These problems were discussed at length by the committee.

The second set of analyses presented by HCFA staff concerned the frequency of admission for AMI and the relationship of admission rates to mortality after discharge and readmission at a later date. Over the period 1984–1987, there was a yearly decrease in the number of admissions for AMI, but a relative increase in the percentage of total admissions because of a greater decrease in admissions for all other causes. The aggregate mortality one year after AMI was about 25 percent *from all causes*; this trend was stable over the entire period. Following AMI there is a 70 percent risk of readmission for any cause in the first two years, and a 60 percent risk for cardiovascular reasons; 20 percent of these readmissions occur in the first 30 days after the initial hospitalization, most for cardiovascular reasons. During this 1984–1987 period there was approximately a two-fold increase in readmission for invasive procedures such as angioplasty, catheterization, or bypass surgery. Although the overall rate of readmission and duration remained relatively stable over the period, the associated expenditures rose substantially.

The third set of analyses attempted to characterize the charges for health care services following hospitalization for AMI and extending for an average of six months thereafter. Ambulatory utilization was posited as a surrogate of morbidity, as was use of support services (skilled nursing facilities, home health) for disability. No HCFA data are available for pharmaceutical utilization in an ambulatory setting. During 1984–1987, there was a 50 percent yearly increase in charges for ambulatory services, with a concurrent 8 percent average increase in all Medicare charges, indicating a relative increase in ambulatory services. However, no conclusions can be drawn from this increase as to whether it represents an increase or decrease in overall morbidity, including both inpatient and outpatient care.

Several issues raised by the committee members before the meeting were addressed during the ensuing discussion. First, the *accuracy of the ICD-9-CM code for AMI* has been questioned as the result of several published analyses. In 25 to 30 percent of hospitalizations with the principal diagnosis of AMI, there are no substantiating clinical objective findings (e.g., electrocardiographic changes or enzyme elevations) in a clinical database abstracted by the PROs for different HCFA projects. If patients who died in the first day (often before objective changes) are separately classified in the

analyses the mortality risk of those without objective findings drops to 16 percent at 30 days, as compared to 21 percent for those with objective findings. One committee member cautioned that in the elderly population specifically, several other factors must be considered, including a higher percentage of older patients with no apparent change on repeated ECG and the possibility of a longer period of time between the incidence of infarction and admission.

Second, because of the committee's interest in *risk stratification*, efforts by HCFA to model the predictive value of various clinical findings, test results, or interventions were reviewed. In general, age, the presence of an arrythmia (particularly atrioventricular dissociation), and mental disorientation are associated with an excess risk of both short- and long-term mortality. As for interventions, based on data in 1985 angioplasty and bypass were associated with a reduced risk of death, whereas thrombolytic agents showed a beneficial trend, but one lacking great statistical significance.

HOMEWORK EXERCISE

The homework exercise was conducted as the first part of a modified Delphi process, in which committee members completed questionnaires to nominate three major patient management topics and then to elaborate the research activities they would recommend for those specific topics.

Table A.2 lists the topics nominated in the first round. Of these 10 categories, the issues mentioned most often dealt with risk stratification, use of thrombolytic agents, use of invasive interventions, and outcomes. The attention to outcomes other than death—health status and quality of life, as represented by functioning, emotional well-being, return to usual activities (e.g., work)—was striking. In addition, issues of costs, cost-effectiveness, and cost-efficiency were noted with some frequency.

The research strategies that correspond to these study topics were quite varied. Tables A.3 through A.8 provide the full results of the homework exercise and recommended research activities. The tables cover the categories listed in Table 1 of the text, and the entries in each table correspond, at least roughly, to the study topics. The information here represents the news of skilled clinicians, some of whom specialize in the care of patients with cardiovascular disease, and experts in research and other fields relevant for effectiveness work. The workshop format did not allow for full exploration of all the issues raised by the AMI committee members, but they did believe that the breadth of topics concluded in these tables will provide guidance for a rich research agenda.

Table A.2 Summary of Key Patient Management Topics Nominated by Acute Myocardial Infarction Committee in Round One of the Homework Exercise

A. Primary prevention and patient/public education strategies
B. Out-of-hospital, prehospital, and emergency room treatment
C. Use of thrombolytic therapies
D. Use of invasive and surgical procedures
E. Invasive/surgical versus noninvasive or drug options
F. Use of other technologies
G. Risk stratification for post-AMI management
H. Other outcome research topics
I. Rehabilitation

Table A.3 Summary of Research Activities Recommended for Primary Prevention, Patient/Public Education, Physician Education, and General Management in Acute Myocardial Infarction

PRIMARY PREVENTION AND PATIENT/PUBLIC EDUCATION STRATEGIES
I. Hypertension
1. Test usefulness of treating moderate hypertension with drug therapy in low-risk patients
II. Patient education
1. Develop tools to educate patients about lifestyle and prognosis following AMI
2. Develop strategies to modify risk factors (dietary and blood pressure control) for individuals with family history as a risk factor and encourage compliance
III. Public education
1. Develop methods and models (e.g., use of media; strengthen 911 system; town meetings) to inform patients and public about risk factors, etc., and to reinforce behavior toward adherence to recommended practices and guidelines
2. Test mechanisms for decreasing delay in diagnosis and treatment of AMI (and reducing mortality), with specific attention to public education of early warning signs versus increasing the number or changing the location of health care facilities
PHYSICIAN EDUCATION AND GENERAL MANAGEMENT ISSUES
I. Primary care practitioners
1. Examine role of primary care provider (versus cardiologist) in routine management of cardiac conditions (including management and referral decision making)
II. Decision trees
1. Develop decision trees or other aids for physicians to manage coronary/cardiac conditions in general and AMI in particular
III. Physician education
1. Implement physician education programs centered on "best" uses of current treatments, especially those that may prevent complications of AMI

Table A.4 Summary of the Research Activities Recommended for Out-of-Hospital, Prehospital, and Emergency Room Treatment, and for Rehabilitation in Acute Myocardial Infarction

OUT-OF-HOSPITAL, PREHOSPITAL, AND EMERGENCY ROOM TREATMENT
I. Helicopter transport
1. Determine the relationship of helicopter transport systems (especially for rural areas) to outcome
II. Reorganization of emergency room
1. Test the reorganization of the emergency room for more efficient triage (diagnosis and treatment) of potential AMI patients (i.e., chest pain)
III. Early intervention
1. Test systems for very early intervention versus triage of patients to tertiary care facilities, including benefits of prehospital electrocardiography and diagnosis and the value of initiating very early therapy in the home through emergency medical services (EMS) systems
REHABILITATION
I. Rehabilitation services
1. Determine and evaluate range of rehabilitation and related services used to return cardiac patients to optimal quality of life and functional status
II. Formal cardiac rehabilitation programs
1. Determine effectiveness of formal cardiac rehabilitation programs in terms of functional status, quality of life, return to work, etc., for asymptomatic and complicated post-AMI patients

Table A.5 Summary of Research Activities Recommended for Use of Therapies and Procedures in Acute Myocardial Infarction

USE OF THROMBOLYTIC THERAPIES
I. Optimal timing, criteria, and variations in use
1. Determine the optimal timing and route for administration of thrombolytic therapies
2. Determine whether current criteria for use of intravenous thrombolytic agents can be extended to include more than 75 percent of AMI patients
3. Determine the variations in practice patterns of use or nonuse of thrombolytic therapy, learn whether patients receiving thrombolytic therapy use fewer resources or have better outcomes
II. Comparative effectiveness and cost-effectiveness
1. Determine the comparative effectiveness of thrombolytic therapy and other pharmacologic interventions (e.g., calcium channel blockers, beta blockers, prophylactic lidocaine) in peri-infarction period
2. Determine the cost-effectiveness of thrombolytic therapy in general, of aggressive thrombolytic therapy, and of the use of tPA versus less expensive agents such as urokinase and streptokinase

III. New thrombolytic agents

1. Study whether and how new thrombolytic agents influence patient management decisions and outcomes

USE OF CATHETERIZATION

I. Related to admission

1. Examine the role of catheterization during and after an admission for AMI

II. Optimal catheterization rate

1. Define/determine the optimal rate of catheterization in the year following uncomplicated AMI (optimal being defined as the rate that will identify patients who will benefit from angioplasty or coronary artery bypass graft without incurring excessive cost or risk)

USE OF SURGICAL INTERVENTION

I. Outcomes

1. Determine the outcomes (mortality; morbidity; quality of life) of angioplasty and/or CABG in post-AMI patients in general, in post-AMI patients who have no symptoms and a normal exercise ECG/thallium scan, and as a function of age

II. One vessel and more than one vessel disease

1. Determine whether angioplasty lowers the risk of AMI in patients with more than one vessel disease

III. Alternative regimens

1. Examine alternative diagnostic and treatment regimens for cost-efficiency and cost-effectiveness, with attention specifically to multiple angioplasty versus surgery following one angioplasty

2. Determine the degree of small-area variation in repeat CABG, over time

IV. During hospitalization

1. Examine the role of angioplasty (specifically percutaneous transluminal coronary angioplasty (PTCA)) during hospitalization for AMI

USE OF INVASIVE/SURGICAL VERSUS NONINVASIVE OR DRUG OPTIONS

I. Early treatment alternatives

1. Compare the diffusion and then the effectiveness of streptokinase, tPA, and PTCA in early treatment of AMI

II. Primary angioplasty in different patient groups

1. Evaluate the value of primary angioplasty in three groups: those who would otherwise be candidates for thrombolytic therapy, those who are not candidates for thrombolytic therapy, and those who would otherwise receive no treatment whatsoever

III. Immediate invasive/surgical treatment

1. Determine whether immediate invasive post-AMI evaluation and consequent therapy (PCTA, or CABG, or both) confers a significant benefit or improvement in prognosis as compared with "routine" thrombolytic care for all patients and for only high-risk patients

IV. Suppression of post-AMI arrhythmias

1. Determine whether invasive (electrophysiologic) studies or noninvasive (treadmill; Holter) analyses provide more effective ways to suppress post-AMI arrhythmias in high-risk patients

USE OF CORONARY CARE UNITS AND OTHER TECHNOLOGIES

I. Automatic devices

1. Test whether use of automatic nonimplantable defibrillator and heart rate and blood pressure automatic system reduces CCU costs by allowing movement of CCU patients to regular beds

2. Determine what types of patients require, or do not require, CCU care when the main purpose of the CCU is to detect life-threatening arrhythmias

Table A.6 Summary of Research Activities Recommended for Risk Stratification of Patients After Acute Myocardial Infarction

I. Risk stratification procedures

1. Identify current procedures and examine their relation to modalities of care and outcome

2. Test use of "presence and severity of silent ST segment depression" as an element of stratification

3. Determine the effects on patient management and decision making

II. Influence of risk stratification testing on outcomes

1. Determine whether and how data from tests used for stratification (e.g., echocardiography studies and ambulatory monitoring) influence patient management and outcomes

2. Determine what easily collected outcomes data could be added to inpatient records to improve prognostication

III. Post-AMI testing and detection of high-risk patients

1. Examine the prognostic accuracy of post-AMI testing in various patient subgroups

2. Determine an appropriate strategy for detection of high-risk patients to implement before discharge

IV. Standard prognostic battery and "optimal" stratification

1. Establish a standard prognostic battery and define an "optimal" risk stratification strategy for elderly patients with AMI

V. Cost savings of early risk stratification

1. Test early risk stratification as a means of cost savings by distinguishing high-risk patients needing PTCA or CABG from those warranting early discharge

Table A.7 Summary of Research Activities Recommended for Other Outcomes Topics Mentioned for Acute Myocardial Infarction

I. Health status outcomes of AMI
1. Determine the health status outcomes of AMI including disability, functional recovery, and quality of life for elderly AMI patients in general and for those treated by different modalities, under different payment systems, in different facilities, and with different sociodemographic characteristics
II. Outcomes and influence of age
1. Examine outcomes versus cost of resuscitation as a function of age
2. Determine influence of age on outcomes and as a determinant of treatment strategy
III. Predictors of poor recovery
1. Determine predictors of poor psychosocial recovery or cardiac invalidism