Hip Fracture: Setting Priorities for Effectiveness Research

Division of Health Care Services
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Hip Fracture: Setting Priorities for Effectiveness Research

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

Kim A. Heithoff and Kathleen N. Lohr, editors

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Institute of Medicine Division of Health Care Services HCFA Effectiveness Initiative Hip Fracture Research Workshop Committee

KENNETH I. SHINE, *Chair*, Dean, School of Medicine, University of California, Los Angeles

CHRISTINE K. CASSEL, Chief, Section of General Internal Medicine, University of Chicago, Chicago, Illinois

JOHN F. FITZGERALD, Assistant Professor of Medicine, Indiana University School of Medicine, Indianapolis

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G. RICHARD SMITH, Associate Professor of Psychiatry, Department of Psychiatry, University of Arkansas for the Medical Sciences, Little Rock

HAROLD C. SOX, Professor and Chairman, Department of Medicine, Dartmouth Medical School, Hanover, New Hampshire

Study Staff

Division of Health Care Services
KARL D. YORDY, Director
KATHLEEN N. LOHR, Senior Professional Associate
RICHARD A. RETTIG, Senior Staff Officer
KIM A. HEITHOFF, Research Assistant
Division of Health Promotion and Disease Prevention
MARIA ELENA LARA, Program Officer

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Contents

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 asked the Institute of Medicine (IOM) to conduct three research workshops—one each on breast cancer, acute myocardial infarction, and hip fracture. These research workshops had three objectives: (1) to examine each clinical condition in detail; (2) to identify key patient management topics for each condition that deserve further "effectiveness" investigation, as contrasted with "efficacy"; 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 workshop on hip fracture.

The committee recommends that explicit attention be given to four methodologic issues in hip fracture effectiveness research. First, currently available health and functional status measures must be synthesized and "disease-specific" measures developed for the study of hip fracture risk and prognosis. These measures should include indices of frailty; activities of daily living (ADLs) and "instrumental" activities of daily living (IADLs); cognitive functioning; sociodemographic variables; physiologic parameters; and predisposing causes of fractures.

Second, the committee recommends that HCFA focus on two outcome issues: (1) a more comprehensive definition of outcomes, in line with recent developments in health status assessment and quality of life measurement; and (2) techniques for acquiring data that cross the full spectrum of care delivery sites. HCFA should continue to seek expert assistance to develop outcome measures other than mortality, including guidance for selecting the instruments for general effectiveness use as well as for hip fracture. The

committee supports current HCFA efforts to use information in addition to billing data, including measures of functional status, patient satisfaction, and other indicators of health status.

Third, longitudinal follow-up is needed to obtain better information about short-, mid-and long-term outcomes. Outcomes of medical or surgical management must be stratified by type of surgical procedure, health status and comorbidity at admission, and living situation before fracture. The committee recommends that HCFA establish a sample registry of the elderly as they enter the Medicare system and follow these beneficiaries as they age. When linked to Part A and Part B utilization information, this data set could provide valuable risk stratification and patient classification information for hip fracture and many other clinical conditions.

Fourth, improved methods for risk stratification and classification of comorbidities need to be developed. Case mix indices for hip fracture must be developed (including a measure of prefracture frailty), to predict, for example, cost, mortality, and ADL functioning 6 months postfracture. In light of this task, the committee expresses concern about the reliability and validity of current HCFA data. Two separate issues emerged: (1) accuracy of the HCFA coding procedures (e.g., determining whether an individual has fractured a hip or whether a given procedure was performed); and (2) the validity of conclusions given that certain types of adjustments have been made or that certain outcomes have been observed. Validity studies must be included in the effectiveness initiative.

A final methodological issue not addressed specifically by the hip fracture committee but considered by the core committee to be integral to effectiveness research is patterns of care and variations in those patterns.

The committee also recommends three clinical or patient management topics for initial study in an effectiveness research program: prevention of hip fracture; treatment options for hip fracture—particularly as a function of age, frailty, comorbidities, and provider characteristics; and rehabilitation—particularly as a function of type and intensity of service, site of care, and provider characteristics.

Priority targets for prevention research are osteoporosis and falls. Each was identified as a major risk factor for hip fracture, and each is potentially modifiable. Prevention research for falls should include preventing falls per se and reducing fracture risk for falls that do occur. Pathophysiologic processes, the primary aging processes, and behavioral and environmental factors associated with falls must also be examined. Studies on medications should be pursued as corollary to understanding prevention issues. Effective prevention would dramatically decrease mortality and morbidity and result in substantial cost savings to Medicare. Research is needed to determine the effectiveness of preventive interventions in elderly populations, to find good ways to disseminate preventive practice information to

community physicians, to evaluate the acquisition and use of this knowledge by community physicians, and to evaluate the effectiveness of these interventions in a community setting. Cost and benefit analyses of prevention interventions should be done before and after enrollment in Medicare.

Considerable professional uncertainty exists about alternative treatment options. Research is needed to address the effectiveness of selected surgical interventions, the appropriateness of nonsurgical (medical and supportive) management, and other treatment issues that predict very high costs of care. Effectiveness research on hip fracture treatment alternatives should be aimed at developing scientifically based indications to determine which patients should have open or closed reduction with internal fixation, prosthetic replacement of the femoral head, or primary total hip replacement. Four other clinical treatment effectiveness issues recommended for investigation include: impact of comorbidity, patient predictors of excessively long lengths of stay or high costs of care, better clinical data sets, and payment incentives affecting clinical decision making.

Studies in rehabilitation should focus on three areas: (1) appropriate rehabilitation programs for different kinds of hip fractures; (2) appropriate rehabilitation programs for different kinds of patients; and (3) examination of sites for delivery of rehabilitation services to determine which are most effective. HCFA should concentrate its effectiveness research for rehabilitation on four areas: (1) a minimal data set; (2) timing and intensity issues; (3) longitudinal follow-up across settings of care; and (4) hypothesis generation.

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. The objectives of the Effectiveness Initiative were, first, to assess the overall merit of competing health care interventions and, second, to provide information that would help clinicians in managing their patients, improve the peer review process (e.g., of the Medicare Peer Review Organizations [PROs]), and aid policymakers in allocating Medicare resources. HCFA also identified four activities to support these objectives: (1) monitoring time trends in the use of services by the Medicare population; (2) analyzing geographic (population-based) variations in the use of services and in outcomes of care; (3) assessing interventions by clinical demonstrations, observational studies, and randomized controlled trials (RCTs); and (4) feeding back information to clinicians in education programs.

Planning for effectiveness and outcomes research within DHHS in 1988 and 1989, and the recent transfer of effectiveness research to the Public Health Service, incorporates the above purposes and adds responsibility for the development of practice guidelines. Although this monograph reports on work conducted for the HCFA Effectiveness Initiative, it pertains to all effectiveness research supported by DHHS.

THE IOM CLINICAL WORKSHOP

In 1988, HCFA consulted widely with individuals and organizations in the medical, health financing, and health services and policy research

communities for guidance on its program initiative. It then asked the Institute of Medicine (IOM), National Academy of Sciences, to recommend the clinical conditions that should receive priority attention. Conceptually, this reflected a decision to choose the clinical condition as the unit of analysis rather than specific procedures or technologies.

In October 1988, the IOM appointed a study committee and convened a "clinical workshop." The clinical workshop committee recommended five clinical priorities; stable and unstable angina, acute myocardial infarction, breast cancer, congestive heart failure, and hip fracture.[1] These five conditions met several selection criteria, including high prevalence, burden of the illness on elderly people, appreciable variations in the use of services and in outcomes, high costs, and controversy about alternative ways to manage patients that reflects professional uncertainty.

Hip fracture was recommended for several other reasons. It is almost exclusively a disease of elderly people, there is little clinical disagreement about diagnosis, and the acute phase is universally treated in hospitals. Disagreement exists about certain aspects of the treatment: length of hospital stay, surgical options (pinning, replacing the femoral head, total hip replacement), and timing of surgical interventions; and about etiology and prevention. Issues of long term care and of long-run functional outcomes are also very important.

CONDITION-SPECIFIC RESEARCH WORKSHOPS

Purpose

After the clinical workshop, HCFA asked the IOM to conduct condition-specific workshops for three high-priority clinical areas: breast cancer, acute myocardial infarction, and hip fracture. These workshops had three objectives: (1) to examine each clinical condition in 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.

The distinction between effectiveness and efficacy is especially important. Efficacy typically means the outcome of an intervention when it is applied in "ideal," well-controlled circumstances, such as those inherent in prospective randomized controlled trials. Outcomes of interest may be quite technical and oriented to physiologic variables and survival. By

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

contrast, effectiveness concerns the outcome of an intervention realized when it is applied in "everyday" or "average" circumstances (such as the daily practice of medicine); these situations may involve patient subgroups that differ considerably from those studied in RCTs. Outcomes, moreover, may embrace broader quality of life concerns, such as physical and social functioning and emotional well-being.

Research Workshop Committee

For the condition-specific research workshops, the IOM appointed a "core committee" of clinicians and researchers in 1989; it was chaired by Kenneth I. Shine, M.D., Dean of the School of Medicine, University of California, Los Angeles.[2] For each workshop, the core committee was augmented with clinicians and researchers with recognized expertise in the condition of interest.

Committee Charge

The hip fracture committee was charged with two responsibilities: (1) to recommend to the HCFA administrator a small number of issues in hip fracture patient management for the elderly population that should receive priority in the Effectiveness Initiative; and (2) to suggest specific research strategies to be employed by HCFA and other public and private research organizations that address these issues. Secondary questions were how the present or proposed Medicare databases might be used to further this research, what should be added to the current databases, and what studies must be conducted independently of the HCFA databases.

This monograph reports on the hip fracture workshop, presents background information on clinical aspects of hip fracture, and summarizes the committee's deliberations, findings, and recommendations. The appendix documents the study and workshop activities.

[2] Five members of the core committee had also been members of the clinical workshop committee (Drs. Shine, Murray, Nelson, Smith, and Sox), and three are new (Drs. Henderson, Keeler, and Schwartz).

The Knowledge Base for Key Clinical Issues in Hip Fracture

DEFINITIONS

The term hip fracture is something of a misnomer. It actually refers to a fracture of the upper end of the thigh bone (femur). The anatomic characteristics of hip fractures are important for three reasons. First, the hip joint and its attached muscles are critical in the ability to stand and to walk. Second, this part of the skeleton is subject to complex forces and stresses during the activities of daily living. These forces and stresses are very different from those that occur during a fall. The hip, in effect, is designed to withstand the stresses associated with daily living but is poorly designed to withstand the impact from a fall. Third, the location of the fracture, as well as its severity, influences the choice of therapy (i.e., type of surgery).

Fractures are categorized into one of three groups according to what part of the bone is involved (see Figure 1). One group involves the *femoral neck*, which is just below the head of the femur. Another involves fractures around the *intertrochanteric crest*; this bone links the greater and lesser trochanters, which are prominent bony eminences situated essentially between the femoral neck and the upper part of the main shaft of the femur, to which the major skeletal muscles are attached. *Subtrochanteric* fractures start at or below the lesser trochanter and involve the femoral shaft itself.

A final important aspect of hip fracture is the effect of the fracture and subsequent treatment and healing on the acetabulum, which is the cup-shaped depression in the pelvis into which the head of the femur fits. Of concern is pre-existing damage or deformity of the acetabulum or injury to the cartilage resulting from the fracture or subsequent treatment. In such cases the socket does not provide a smooth or congruent receptacle for

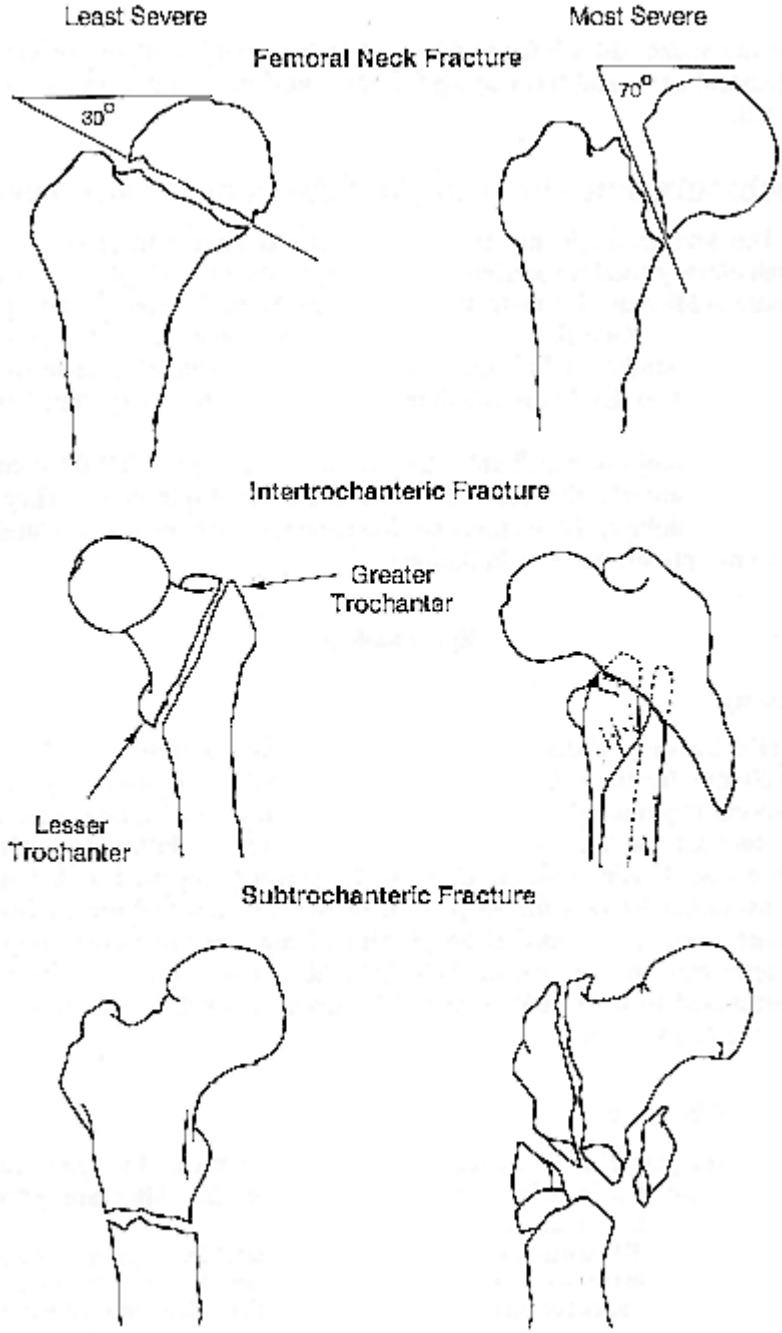

Figure 1
Examples of Main Types of Hip Fracture

cases the socket does not provide a smooth or congruent receptacle for the femoral head, and this may significantly influence the type of treatment selected.

EPIDEMIOLOGIC AND CLINICAL ASPECTS OF HIP FRACTURE

The investment in hip fracture research is large and growing. Although efficacy studies contribute immensely to the knowledge base, results of those studies do not address all the major clinical questions and population groups. One reason for selecting patient management topics for effectiveness studies, therefore, is to identify the remaining unanswered questions and to determine whether they can be addressed by alternatives to RCTs.

Several subjects, which are briefly reviewed here, provided the context for the committee's discussions of those unanswered questions.[1] They include epidemiology, risk factors and prevention, surgery issues, nonsurgical treatment options, and rehabilitation.

Epidemiology

Frequency

Hip fracture causes significant morbidity and mortality. There are 260,000 hip fractures in the United States each year, and they occur almost entirely among elderly people.[2] The medical, social, and economic consequences for hip fracture victims are severe, for instance, resulting in an excess 1-year mortality of 12 to 25 percent, impaired ambulation, and institutionalization for 33 percent or more of hip fracture survivors. In some studies, as many as 50 percent of hip fracture victims require long-term care for the rest of their lives. Total direct medical care costs are estimated to be $6 billion per year, much of which is reimbursed by Medicare or Medicaid.

Demographic Aspects

Hip fracture risk is related to age, sex, and race. Incidence rates in women are nearly twice those in men. Rates in whites are greater

[1] This section is based on materials submitted by several members of the committee who have special expertise in hip fracture. In part it reflects information contained in the literature cited in the bibliography at the end of this report. The topics themselves were not debated during the workshop.

[2] The annual incidence of hip fracture among people age 65 and older, of whom there are 31,800,000, is 8.2 per 1,000.

than those in Hispanics, which, in turn, are greater than those for Asians and blacks. Incidence rises dramatically with age; in North America and northern Europe, it begins to rise at about age 40 and doubles every 5 to 7 years through age 90. Rates approach 6 per 1,000 women per year for those between the ages of 75 and 79, 21.4 per 1,000 for those between the ages of 85 and 89, and 48.6 per 1,000 for those over age 90. For white women over age 85, rates as high as 30 to 50 per 1,000 per year have been observed.

Relationship to Aging

The interaction of hip fracture and age is not well understood. Some individuals are described as "doing really well until they broke a hip and went downhill quickly." For them, the hip fracture was the "beginning of the end," a signal of compromised ambulation, greater risk of postsurgical complications, especially delirium, an increased sense of frailty[3] associated with the fear of falling, and of need for use of an aid in walking. At the other extreme, hip fracture may signal an "end of the beginning," a clinical manifestation of aging and frailty that was previously subclinical or the cumulative effect of small declines reaching a threshold that precipitates the hip fracture. Most clinicians suspect that both perspectives are valid. For some patients hip fracture is a precipitating event, and for others it signals decline that is well underway.

There are different implications depending where in relation to these conditions a particular individual is. If the fracture is an acute injury that can precipitate a major decline in an otherwise intact individual, treatment strategies must be developed accordingly and adverse side effects or inadequate rehabilitation must be avoided. If, by contrast, it reflects a clinical manifestation of decline, the patient might not be expected to return to prefracture levels of functioning. Other aspects of choice of treatment and long-term support then come into play. Research is needed to determine how to classify patients and how to apportion scarce resources to achieve the maximum recovery level for each patient.

As people age, changes occur in the cardiovascular, musculoskeletal, and neurological systems, and they occur at different rates. Subtle physiological changes over time influence the susceptibility threshold or margin of safety against severe (or even minor) illness, that is, an individual's

[3] The term frailty is used throughout this report but has no specific meaning. The term is a shorthand for any one or more of a set of attributes or circumstances that are associated with an unusually high probability of some adverse event, hip fracture in this instance. The task of identifying specifically the determinants of the adverse event of fracture is the first step in the research agenda. Determining effective ways to alter risk-promoting attributes —i.e., prevention—is the second step.

ability to return to homeostasis after physical or biological trauma. These are all considered physiological changes, not frailty per se. Being able to assess these changes and relate them to probabilities of outcomes will enhance the medical profession's ability to select appropriate interventions and treatments rather than making decisions based largely on age.

Risk Factors and Prevention of Hip Fractures

The concept of postponement is critical in the prevention of hip fracture. Given the exponential increase in the hip fracture rate (doubling every five to seven years) with age, the incidence of the condition might be reduced by as much as 50 percent if the onset of this exponential rise could be uniformly postponed by only five years. This suggests that important opportunities for prevention exist within the Medicare population if the risk factors for hip fracture could be better understood. For example, a person who enters Medicare at age 65 will have an 8-fold to 16-fold increase in the risk of hip fracture over the next 20 years. Even a moderate reduction in the progression of these incidence rates could reduce both suffering and costs.

Most hip fractures result from moderate trauma, usually a fall from a standing height. Thus, the risk factors for hip fracture include those for falls and those for sustaining an injury during the fall (such as decreased bone strength resulting from osteoporosis and the severity of the fall itself). Prevention must focus on reducing the risk of falls, on reducing the injury potential of those falls that do occur, and on increasing bone strength.

Falls

Falling is a common event for elderly people. Between 30 and 50 percent of the elderly suffer at least one fall per year, and a subset of this group is at risk for more frequent falls. Those in the latter group have the highest risk of fracture. A major determinant of whether a fall results in a fracture is thought to be bone strength, although other factors such as the type of fall (e.g., direction and site of impact),[4] muscle mass, and protective

[4] Some experts argue that falls and, in particular, the severity of the fall (including its direction, site of impact, and use of protective mechanisms) may well dominate fracture risk in comparison with issues of bone strength and osteoporosis. Data are not yet available to allow a simultaneous assessment of both bone density and fall severity; this is a critical question because its answer influences the potential efficacy of intervention efforts aimed at maintaining bone strength, reducing falls, or reducing the severity of falls that do occur. Intervention efforts aimed at either maintaining bone strength or reducing the number of falls have not conclusively shown significant reductions in hip fracture incidence. It remains to be seen whether interventions aimed at reducing the injury potential of falls would be as or more effective.

responses during the fall are also important. Falls are caused by various combinations of environmental, intrinsic, and activity-related factors.

As many as half of all falls involve environmental conditions such as structural hazards, icy sidewalks, inadequate lighting, frayed rugs, and electrical cords. These factors are less important in precipitating falls in institutionalized populations.

Host factors include acute or chronic disease (such as Parkinson's disease), mental or neurologic impairment, abnormalities of gait or balance, muscle weakness, and use of certain medications. A small percentage of falls result from a single, overwhelming event such as fainting.

Psychotropic medications have been consistently associated with a two-to-three-fold increase in the risk of falls and hip fractures. Geriatricians advise that psychotropic drugs should be prescribed only when they are absolutely necessary, that doses be as low as possible, that they be given for the shortest possible duration, and that selected drugs within a therapeutic class be used. For example, if a benzodiazepine is prescribed, then one of the drugs with a short half-life should be chosen.

Although evidence from controlled trials is not available, one can reasonably assume that careful assessment and targeted interventions may decrease the risk of elderly people falling. This involves identification of the presence and severity of certain diseases and disabilities, especially problems of sight, balance, neurologic functioning, musculoskeletal deficits, and systemic disease. Assessment also involves identification of relevant medications and environmental factors. It calls for careful observation of balance and gait and review of previous fall situations. Based on such assessment, a combination of medical, rehabilitative, and environmental interventions may help prevent hip fractures without compromising functioning and morbidity. Intervention strategies to reduce the severity of falls should also be considered.

Bone Mass and Osteoporosis

Fracture pathogenesis is complex and involves abnormalities that are intrinsic and extrinsic to the skeleton. Low bone mass is the most critical skeletal abnormality relating to hip fracture. Osteoporosis is the gradual loss of bone mass with aging. Although the pathophysiology of osteoporosis is incompletely understood, it may arise from disorders of the physiologic systems that regulate calcium balance.

Risk factors associated with osteoporotic fractures include white race, female sex, post-menopausal status, low body mass index (weight over height squared), sedentary life-style and physical inactivity, and possibly alcohol and tobacco use. Diet and nutrition, especially calcium intake

during rapid growth, climate, and genetic factors may also influence bone mass. Continued research is needed on these and other risk factors.

The major determinant of bone loss among early post-menopausal women is estrogen deficiency; osteoporosis can be retarded and bone loss largely prevented with estrogen replacement therapy. Late in life, calcium deficiency may develop because of insufficient calcium intake and calcium malabsorption. Common wisdom has been that the prevention of osteoporosis must begin early in life because available therapies can preserve bone mass but cannot replace lost bone to any great extent. The protective effects of instituting osteoporosis prevention measures for women in their 40s and 50s, especially estrogen replacement therapy, may be dramatic in reducing the incidence of hip fractures among women in their late 80s and 90s.

Medications have complex effects on bone mass. As implied above, estrogen replacement therapy decreases the risk of hip fracture in newly menopausal women, but whether it has similar benefits for women age 65 and older is unknown. Thiazide diuretics, which decrease urinary calcium loss and which are used commonly, have been associated with increased bone mass and decreased hip fracture risk in people aged 65 and older. For some individuals, however, thiazide diuretics may cause orthostatic hypotension (especially in the initial phase of therapy) resulting in fainting when rising from a seated or horizontal position and hence raising the risk of falls. Other potential therapies include the antiresorptive agents calcitonin and biphosphonates. Anticonvulsants, corticosteriods, and replacement thyroid hormone may increase bone loss and, thus, increase fracture risk. Clinical trials and other research efforts are needed to quantify the risk of hip fractures associated with use of these medications, assess potential prophylaxis, and identify less hazardous alternative therapies.

Surgical Issues

Several different treatment options exist for each type of hip fracture, and professionals are uncertain as to which technique consistently offers the best outcome. Before 1930, the treatment options for a patient with a fractured hip consisted of bed rest with traction, cast immobilization, or simple mobilization with disregard to the fracture. With the advent of internal fixation in the 1930s, operative management became the preferred method of treatment unless the risks of surgery were prohibitive. Surgical approaches at the time consisted of a single nail or multiple pins for treatment of a fractured femoral neck or a nail-plate combination for intertrochanteric and subtrochanteric fractures. These approaches led to earlier mobilization of the patient and lowered mortality significantly.

Failure of the fracture to heal, a source of continued complications, prompted the development of a prosthesis to replace the femoral head. Use of this prosthesis allowed immediate weight-bearing without requiring the lengthy convalescence needed for union of the bone itself. Nevertheless, in the 1950s and 1960s, complications with femoral head replacement persisted, including unexplained postoperative pain in the hip and a high infection rate.

With the advent in the 1970s of total hip replacement techniques (sometimes called total hip arthroplasty, which is a procedure in which the acetabulum and the femoral head are both replaced), yet another treatment became available for the management of fractured hips.[5] The advantages of total hip replacement included, as before, early weight-bearing without the need to wait for bony union, more consistent relief of pain, and elimination of the acetabular erosion that occasionally occurred with the simple femoral head replacement. The disadvantages included a more complex operation and considerably more expensive implantable devices.

Surgical Treatment Options

Although several surgical treatment options are available, clinicians generally agree that open reduction and fixation of the fracture fragments are the appropriate treatments for intertrochanteric and subtrochanteric fractures. A major controversy relates to defining objectively the appropriate treatment options for femoral neck fractures. The options are briefly described below.

Intertrochanteric Fractures

Intertrochanteric fractures are nearly always treated with some form of internal fixation and an implanted device such as a pin and plate or intramedullary rods (rods that run along the center of the bone and that stabilize the fracture fragments). Because this is frequently a difficult fracture to manage, multiple surgical approaches are used, but in virtually all cases the patient's own bone stock is preserved. The most commonly used fixation device for an intertrochanteric fracture is a collapsible nail plate or screw plate device that allows bone impaction (i.e., the bone being pressed together by ambulation after surgery into a stable position).

[5] Total hip replacement is performed for reasons other than fractures, for instance, to reduce severe pain or significant constraints on physical mobility owing to problems with the hip joint and, perhaps, to forestall possible falls should the hip joint give way suddenly secondary to severe deterioration. Although the appropriate indications for total hip replacement are themselves a matter of controversy, the focus of this report is on the clinical condition of hip *fracture* and the relationship of total hip replacement as a therapeutic intervention for that clinical event.

Subtrochanteric Fractures

The use of intramedullary devices is now recommended for treatment of the true subtrochanteric fracture. This requires open reduction and internal fixation of the fracture. More complex approaches such as interfragmentary fixation (screwing multiple fragments together) or cerclage wiring (tying fragments together) are often needed to reconstruct a stable bony situation to prevent subsequent shortening of the leg. In certain severe cases, bone grafting is recommended.

Femoral Neck Fractures

Fractures of the femoral neck are classified on radiographs in four "Garden stages"[6] (in ascending order of severity): I, incomplete or impacted fracture; II, complete but nondisplaced fracture; III, complete and partially displaced fracture; and IV, complete and totally displaced fracture. Different treatment options exist, depending on the stage. Although clinicians agree that most of these fractures should be treated surgically, they do not agree about the type of surgery.

The original approach to femoral neck fracture was to use some form of internal fixation device such as a nail or a nail and plate. This technique is still used, but the incidence rates of non-union (failure of the fracture to heal) and of avascular necrosis of the femoral head (i.e., decay and death of bony tissue owing to the lack of needed blood supply)—well over 20 percent—are significant. Furthermore, both problems, singly or in combination, produce a poor result and may require further surgery, leading to replacement of the femoral head. For these reasons, many orthopedic surgeons elect to treat femoral neck fractures of the Garden III and Garden IV stages almost routinely with some form of prosthetic replacement.

Anatomic reduction and stable internal fixation produce the best long-term outcome (in terms of bone strength) when healing occurs primarily. This is the most common way to treat Garden stage I and II fractures and is associated with a high rate of success. The shift of the bone fragments is very little and the blood supply is usually intact. If reduction is necessary, it is achieved by closed means if possible. If not, open reduction is carried out. Although two-and three-point fixation with multiple pins appears to offer better stability and long-term outcomes than the use of one large pin

[6] This classification system is different and more detailed than the taxonomy presented in Figure 1. Garden stage I is an incomplete fracture—a so-called impacted fracture. Garden stage II fractures are complete but undisplaced. Garden stage III fractures are complete and displaced but the fragments remain in contact with each other. Complete displacement occurs in Garden stage IV.

(according to some orthopedists), excellent results have been obtained with either method of fixation.

Controversy exists in use of the treatment options available for the more severe Garden stage III and IV fractures. Few useful criteria exist to assist a practitioner in determining when and under what circumstances a particular displaced femoral neck fracture should be reduced and internally fixed, treated by primary hemiarthroplasty (replacement of the femoral head with a prosthesis as the primary procedure), or treated by primary total hip arthroplasty.

One disadvantage of internal fixation of the fractured femoral neck has been the need for the gradual resumption of full weight-bearing. Elderly patients have difficulty with balance, with manipulation of crutches or walkers, and with understanding the concepts of partial weight-bearing and bone healing. For that reason, the alternatives of femoral head replacement or total hip replacement have certain advantages. Specific indications for the last two treatment options are present in individuals with Parkinson's disease, Alzheimer's disease, or severe osteoporosis.

Two major questions arise about treating femoral neck fracture. First, is internal fixation or replacement of the femoral head the best treatment method? Second, is total hip replacement being carried out in patients with appropriate indications? With respect to internal fixation, issues include the extent of healing, non-union rates, avascular necrosis, and other complications. For prosthetic replacement, issues include complications such as dislocation, infection, loosening, and need for reoperation. Although at the extremes of the distribution of femoral neck fractures the indications for appropriate treatment may be fairly clear, there are no data to guide treatment selection for the large majority of fractures. Most physicians elect to treat femoral neck fractures based on their own personal experience. The utility of this approach needs to be evaluated.

Managing Postoperative Complications and Ambulation

Historically, better postoperative management of patients with hip fractures has helped to reduce death rates from hip fractures. In the past decade, however, despite advances in treatment, the one-year mortality of 12 to 25 percent over the norm has remained high and unchanged. The practice of ambulating patients as soon as possible after surgery has significantly lowered the incidence of thrombophlebitis and consequent pulmonary embolism (clots that obstruct blood circulation); the latter can be life-threatening. Early mobilization probably remains the single most effective method for reducing the incidence of these complications. Various other prophylactic measures are also employed, including the use

of antiembolism stockings, continuous passive motion of the hip, and antiblood-clotting medications such as coumarin and heparin. Special attention to the nutritional status of patients may also be important.

Early ambulation has a direct impact not only by forestalling certain medical complications but also by increasing the potential for the individual patient to return to his or her prefracture environment. Limited ambulation can force an elderly individual who enjoyed independent living to be admitted to a managed living environment.

Nonsurgical Treatment Issues

With the many advances in medical care and technology over past decades, physicians are now confronted with a group of very elderly, infirm patients with moderate to severe mental and functional impairments who sustain hip fractures. These injuries frequently occur in protected environments such as nursing homes and hospitals. Orthopedic surgeons have continued to apply the accepted standard of care to patients with these injuries—that essentially all such patients should operated upon.

Although firm data are not available, experienced clinicians believe that the results of surgery in these debilitated patients are usually poor and that complication rates are high. Many of these patients die within a short period of time, although not necessarily during the acute hospitalization. Further, patients in this category may continue to suffer from significant postoperative symptoms, remain severely impaired functionally, and frequently never return to their prior functional level. Epidemiologically, such patients tend to include:

- very elderly patients
- patients residing in nursing homes or other protected environments
- patients with moderate or severe mental impairment or dementia
- bedridden or severely physically disabled patients
- patients with severe or progressive comorbid conditions.

Given the poor expectations for many of these patients, it is appropriate to ask whether they should be treated surgically at all. Instead they might be given nonsurgical care that focuses on alleviation of pain, prevention of complications, and ease of care-giving. The problem from an ethical point of view is that the outcome in unoperated patients is almost always predictably poor, with multiple complications, continued pain, and possibly death occurring in a short period of time. One question is whether it is possible to identify a group of patients in whom the outcomes of surgery are virtually certain to be so poor that nonoperative support treatment only should be rendered. This question involves measurement of the medical

and functional aspects of treatment and attention to the patient's and family's desires (e.g., the right to refuse surgical treatment).

Rehabilitation

The goal of rehabilitation is to return an individual to as normal a life as possible. For elderly people with hip fractures, the goal is to return them to the same level of independence and activity that existed before their injury. Rehabilitation addresses not only the ability of individuals to walk and perform other activities requiring mobility. It also concerns their opportunity to live independently; to function within the community; to participate in social activities; and to continue other activities they might wish to perform.

Many services can be offered: effective limb and joint mobilization and alignment; passive resistive exercises of nonaffected joints; other physical therapy and occupational therapy to regain mobility and independence; restorative nursing services (e.g., range-of-motion exercises) as a follow-up phase to active rehabilitation; training in major areas of life function (such as mobility and self-care); physician monitoring of care or progress; and psychological support when indicated. The optimal setting to provide these rehabilitation services for a particular patient depends on four factors: the number of problems needed to be addressed to achieve full rehabilitation; the severity of functional deficits; the severity of any comorbid conditions; and access to alternative services and settings.

Rehabilitation programs can vary significantly by the type of institution, comprehensiveness of services, intensity of program delivery, and rehabilitation goals. Institutions include acute-care hospitals, rehabilitation hospitals or units, long-term-care facilities (skilled nursing and intermediate care), outpatient facilities, and homes. Some address only mobility through physical therapy services. Others address mobility, self-care, community activities, social and psychological adjustment, recreation, and other goals through the services of a wide array of professionals—physicians, nurses, psychologists, physical therapists, occupational therapists, social workers, recreational therapists, and others.

The goals of a given rehabilitation program determine its comprehensiveness and intensity. Some individuals with hip fracture may receive monthly physician visits in association with biweekly physical therapy treatments. Other patients receive services from multiple therapists twice a day during the initial period of their rehabilitation. These needs, in turn, usually influence the setting in which the services are delivered. Some individuals may go directly home from the hospital and receive home or outpatient rehabilitation care. Others may go through a series of institutions, such as

the rehabilitation hospital or unit or the skilled nursing facility, or both, before receiving services in the home setting.

Because of the enormous variation in these aspects of rehabilitation, decisions regarding the site and intensity of rehabilitation services should be determined through an assessment of the needs of the individual that establishes clear rehabilitation goals. However, the availability of insurance (or the extent of covered benefits in Medicare), the desire of the patient, and the preferences of individual physicians who manage the acute phases of injury of the individual with a hip fracture may influence these decisions. Nevertheless, both historical and clinical experience suggests that active rehabilitation that focuses broadly on the various needs of an individual results in better outcomes than does more limited services. At present, most rehabilitation professionals believe it is preferable for an individual to receive comprehensive services in a setting somewhat more intense than necessary, rather than risk having a patient fail to receive comprehensive services because of efforts to reduce short-term costs.

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

Hip fracture was selected for the Effectiveness Initiative research program because of its high concentration among elderly people and strong relationship to age; its high mortality, morbidity, and disability rates; considerable disagreement about surgical approaches in at least some classes of hip fracture; appreciable concern about whether the standard therapy—surgery—is appropriate in all cases (especially for patients whose prefracture status was poor); wide variation in approaches to rehabilitation; and high costs of care that will increase in the future as the population ages.

The committee agreed, in principle, that the HCFA data banks should be used to develop preliminary information on the costs and effectiveness of prevention, treatment, and rehabilitation of hip fracture. It also endorsed the general concept that analysis of variations in patterns of care and outcomes by geographic area, institution, type of provider or practitioner, and other factors could be a useful component of any effectiveness research program. Finally, it concluded that separate studies to determine the outcomes of care provided to the Medicare population will be valuable, especially if those analyses advance the understanding of the effectiveness of prevention strategies, clarify whether interventions offered to the elderly reduce the incidence of hip fracture at any given age, and identify preferred patient management regimens.

SELECTING PATIENT MANAGEMENT ISSUES

Several factors affect the selection of patient management issues for effectiveness research into hip fracture. Although not equally well documented in the clinical or health policy literature, the committee believed

that all these factors deserved to be considered in choosing specific study topics:

- epidemiologic aspects of hip fracture (e.g., the relative incidence of osteoporosis, falls, fractures, and repeat fractures in particular subgroups)
- health status and quality of life aspects of both the illness itself and different treatment options for elderly people
- different treatment options characterized by the likelihood of prolonging survival, producing major impairment and disability, or improving the patient's physical functioning and mobility, emotional well-being and social interaction, and independence
- high degree of professional and clinical uncertainty or disagreement about alternative strategies for managing the care of hip fracture patients
- substantial variation across geographic areas in the per-person use of services for hip fracture, including those for prevention and management of risk factors, beyond that explained by differences in patient characteristics or health resources
- substantial variation across geographic areas or institutions in the outcomes of care for patients with hip fractures, beyond that explained by the differences in the severity or type of fracture or the sociodemographic characteristics of patients
- relatively high costs to the Medicare program for the services to prevent hip fractures and to treat and rehabilitate hip fracture patients
- relatively high out-of-pocket costs to Medicare beneficiaries for hip fracture prevention, treatment, and follow-up care.

SELECTING RESEARCH TOPICS AND ACTIVITIES

Content, Conduct, and Use of Research

For high-priority hip fracture research, the committee raised three additional points. First, it endorsed four generic subjects identified by the October 1988 workshop: prevention, generation and use of outcomes measures that include functional status and quality of life, analysis of mental and emotional dimensions of an illness (cognitive functioning, anxiety and depression), and clarification of the difference between efficacy and effectiveness.

Second, the research strategy adopted should be the one that is most appropriate for the specific question being asked. For effectiveness research, the choice of strategies include monitoring through analysis of administrative data; observational (cross-sectional, case-control, or longitudinal-cohort) studies; quasi-experimental studies and demonstrations; and, potentially, RCTs. The choice is often determined by the research question, but if the question can be addressed by more than one

approach, then the complexity, rigor, and expense of alternative research designs should be examined. Plans to use more than one strategy either simultaneously or sequentially should also be considered.

In addition, projects based on newer, more sophisticated, nonexperimental techniques, such as meta-analysis and cost-effectiveness analysis, should be included among the research options. Furthermore, the Medicare claims databases might yield information that is useful for developing decision-analytic methods (which incorporate data-based probabilities). In short, the committee concurred that all these approaches should be considered potential investigational methods for effectiveness research and cautions that there is no single appropriate strategy. The committee also wishes to emphasize the importance of evaluating beforehand the trade-offs implicit in selecting one approach over another and in mounting combined approaches.

Third, the committee stressed the contributions that studies of particular illnesses can have as prototypes for examining other conditions. Hip fracture research should be seen as an opportunity to address conceptual and methodologic issues relevant to other conditions or functional impairments that are prevalent in the Medicare population and that call for attention to prevention, rehabilitation, or situations in which standard therapy (e.g., surgery in a patient who suffers from dementia or is bedridden) may not be in that patient's best interest.

Data Issues

The October 1988 workshop committee questioned the adequacy and availability of data to investigate key effectiveness questions through HCFA's existing (or anticipated) administrative data files. As effectiveness research proposals depend on the quality of the data collected and used, the hip fracture committee reiterated this general concern with respect to hip fracture.

First, adequate data on health and functional status of patients with hip fracture must be available before any longitudinal studies of alternative therapies (surgical and rehabilitative) are undertaken with the Medicare files. Second, accurate case identification and coding must be assured. Problems with the Medicare files include inaccurate descriptions of race, discrepancies in numbers of identifiable cases based on diagnosis versus those derived by summing over appropriate procedures, inability to identify reliably the type or stage of fracture, and inability to differentiate left from right hip fracture (meaning that it is also difficult to distinguish a reoperation on one hip from a first operation on the other). To the extent that information about hip fracture from the administrative data

bases lacks reliability and validity, data analysis and interpretation will be severely restricted; this limitation must be acknowledged and overcome.

Third, extensive and high quality data are necessary for the analysis of comorbidity (or case mix). Analyses of hip fracture, for instance, should not combine (or confuse) patients who were healthy before the fracture with those for whom the fracture is a culmination of numerous chronic conditions. Adequate case mix data are needed both for interpreting practice variations and, more critically, for investigating outcomes (especially those with strong quality of life components).

Notwithstanding the above caveats, the committee endorsed the view that the existing administrative data sets even now can provide information on several important topics, such as the site of service, shifts in the choice of procedures over time (e.g., from pinning to total hip replacement), and geographic variations in broad patterns of care. They can also be used to evaluate in hospital survival, time-based survival (30 days, six months, one year), readmissions, some complications, and other simple outcome measures. Thus, although the discussion emphasized the necessity of obtaining richer clinical and patient outcome data through, for instance, Medicare PROs or primary data collection, the potential of the existing data sets to answer some questions was acknowledged.

Key Patient Management Topics for Effectiveness Research in Hip Fracture

PRELIMINARY DISCUSSION AND SELECTION OF MAJOR TOPICS

The high-priority patient management topics nominated by the committee—primary prevention, treatment selection, and rehabilitation—remained essentially unchanged from a homework exercise conducted before the workshop (see the appendix). Specific study topics within each group, however, were quite broad in scope. In addition, prevention and management of secondary complications of hip fractures were noted by a few committee members as patient management topics suitable for effectiveness research. Issues of cost, cost-effectiveness, and cost-efficiency were noted with some frequency across all categories. In the second round of voting, a consensus by the committee to focus on prevention of hip fracture, selection of treatment alternatives, and rehabilitation was virtually unanimous.

Table A.2 of the appendix summarizes the topics listed by the committee in the preworkshop homework exercise. Methodologic and data issues related to the study of these topics are discussed in the next section of this report.

SUMMARY OF RECOMMENDATIONS

The workshop discussion did not propose testable hypotheses or specific research questions. Rather, it was meant to arrive at a broader set of issues whose exploration would depend critically on the data that might be available through the Medicare files or that could be collected by independent effectiveness research projects. Even with this limitation, many useful subjects might be addressed, and the major questions that the committee thought belonged in an effectiveness research agenda are discussed here.

The committee made recommendations that were specific to HCFA's existing capabilities as well as those related to the larger, evolving DHHS program of effectiveness and outcomes research. The administrative databases, by themselves, are limited in the type of effectiveness research questions that they can address, but they provide some unique opportunities when combined with other data sources and research efforts.

The committee recommended that explicit attention be given to four methodologic issues in hip fracture effectiveness research:[1]

1. **health and functional status assessment;**
2. **definitions of outcomes and comparability of outcome measures;**
3. **the need for longitudinal data; and**
4. **risk stratification and classification by comorbidity.**

A methodologic issue that was not addressed by the hip fracture committee explicitly but was judged by the core committee to be integral to effectiveness research was:

5. **patterns of care and variations in those patterns.**

The committee also recommends three clinical or patient management topics for initial study in an effectiveness research program:

1. **prevention of hip fracture;**
2. **treatment options for hip fracture, particularly as a function of age, frailty, comorbidities, and provider characteristics; and**
3. **rehabilitation, particularly as a function of type and intensity of service, site of care, and provider characteristics.**

Finally, the committee noted that age cuts across all effectiveness and outcomes research affecting elderly people. In hip fracture, as with many other clinical conditions, age and the degree of frailty have profound implications for treatment choice and outcome. These issues are discussed below and mentioned throughout the report.

METHODS ISSUES

Health and Functional Status Assessment

Recent work in measuring health status and functional capabilities is quite extensive. There is little consensus, however, as to formats that should be adopted by a government agency or by private researchers to measure

[1] All four methodologic issues noted in this report pertain as well to breast cancer and acute myocardial infarction research strategies, and they are discussed in the companion reports with modifications pertinent to the diseases under consideration.

either prognostic indicators or outcomes in effectiveness research. Many current measures are too long and are not specific to the clinical condition under consideration.

To move forward in effectiveness research, the recent work on health and functional status assessment must be synthesized; the committee cautioned against "reinventing the wheel" in this area. The use of "generic" health status measures (e.g., the Sickness Impact Profile, the Visual Analogue Pain rating scales, or the Index of Independence in Activities of Daily Living), augmented by selected "disease-specific" measures (e.g., the Arthritis Impact Measurement Scale), is increasingly recognized as an appropriate research strategy (see the citations in the bibliography). The committee noted, for example, that the concept of frailty must be incorporated into health and functional status assessments of patients with hip fractures. The committee supports funding of methodologic research that would construct a geriatric assessment instrument that includes the concept of frailty.

Effectiveness research on hip fracture will require that baseline and follow-up data on health status be collected for several purposes: prognostic risk stratification, physician and patient decision making about treatment options, defining and understanding short-and long-term outcomes, and appropriate characterization of the patient populations being studied. Standard patient-based measures of acceptable reliability and validity should, in the long run, become an integral part of the effectiveness research program.

Regarding data sources, much health and functional status information will have to be obtained directly from patients (or their proxies); existing HCFA databases lack measures of functional status.[2] **The committee recommends that HCFA develop health and functional status measures that can be linked longitudinally to the Medicare Part A and Part B files and to medical record data.** Health and functional status information is needed on a broad population base and should be assessed periodically. Studies must be funded to determine the most effective way to implement such questionnaires to obtain consistent, reliable, and valid data. Eventually, this database could serve as a source of information for predicting future events (i.e., determining risk) and for measuring response to interventions.

The committee further recommends that HCFA consider introducing a health assessment mechanism or questionnaire to patients on their entry to the Medicare system—before any illness—even for a limited sample of

[2] At the time of the workshop, HCFA was attempting to add a physician-based functional status measure to the Medicare insurance claims forms. Depending on the adequacy of any such measure, appropriate information for hip fracture (or for the other conditions recommended for the Effectiveness Initiative) may still need to be obtained directly. Presumably the reliability, validity, and cost-effectiveness of adding functional status information to the claims forms will be evaluated, but these issues were not addressed by the committee.

beneficiaries.[3] As implied above, this additional information should include physiologic parameters and risk factors as well as the health and functional concepts noted above. This registry, if implemented over time, could reveal information about change in health status in the Medicare population as people age and the prevalence of chronic disease increases.

Ultimately, a component of this health status assessment would describe very high risk individuals. These individuals are called frail for the purposes of hip fracture, but other categories might emerge from population-based health status assessments. Such a data set would be valuable to effectiveness and outcomes research across many clinical conditions important in the Medicare population. It may also provide insights into clinical issues that emerge in late middle age and that ultimately impinge heavily on the Medicare program.

It was beyond the charge of this committee to specify components of a geriatric health and functional status assessment instrument suitable for hip fracture research. In general, however, the committee believed that this assessment instrument should include components of what has classically been called functional capabilities (including Activities of Daily Living [ADLs] and Instrumental ADLs [IADLs]), cognitive functioning, sociodemographic variables, physiologic parameters, and prognostic indicators. A comprehensive assessment incorporating these various perspectives might aid in defining a category of people considered to be frail. This frailty index could be factored into treatment decision making. Incorporating a frailty dimension into assessment of elderly people is one aspect of recognizing the heterogeneity of the elderly population for purposes of research and patient care.

Because hip fracture seems to be so intimately tied to the development of mobility and cognitive problems that come under the rubric of frailty, this clinical condition can potentially be used to understand and perhaps separate disease processes from the process of aging. The interest, energy, and financial resources that are focused on the study of hip fracture will therefore carry over to effectiveness research of other clinical conditions.

Outcomes

The committee recommends that HCFA focus on two outcomes issues, (1) a more comprehensive definition of outcomes, in line with recent developments in health status assessment and quality of life measurement,

[3] At the time of the workshop, very preliminary plans were being discussed at HCFA about developing a Medicare "registry" perhaps involving a 5 percent sample of newly enrolled Medicare beneficiaries. This recommendation was meant to support further exploration of this idea.

and (2) techniques for acquiring data that cross the full spectrum of care delivery sites.

Mortality rates are often used as outcome measures. Although the mortality rate at one year for hip fracture is substantial, mortality alone is not the only appropriate outcome measure for hip fracture. The 30-day mortality rate for hip fracture, for instance, is 7 percent and does not reflect the often rapid decrease in functional and health status that follows injury. Various clinical and surgical outcomes are important, such as stability of the joint, healing of the fracture, and prevention of acetabular erosion. The committee wishes to emphasize that for hip fracture (more than for breast cancer or acute myocardial infarction), health and functional status assessment *before* the adverse clinical event is necessary to interpret these and other outcome measures appropriately.

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. Adequate ascertainment of these health and functional status levels should affect the choice of surgical procedure (or, in a subset of frail elderly people, the decision to treat the fracture nonsurgically) and may determine the type and site of rehabilitative services needed and offered. Thus, it is important to differentiate between outcomes and patient preferences for outcomes and to encourage the acquisition and use of information on patient preferences for different outcomes.

The committee recommends that HCFA continue to seek expert assistance to develop outcome measures other than mortality, including guidance for selecting the instruments for general effectiveness use as well as for hip fracture. This committee draws special attention to the emerging evidence that the use of "generic" health status measures augmented by selected "disease-specific" measures is an appropriate, desirable, and practical research strategy. The committee does not, however, advocate that a single outcome measure (or even a single set of measures) be mandated for effectiveness research; the goal is to obtain comparable information across studies by using measures whose elements can be mapped to one another.

For hip fracture, a definition of poor outcome would include several variables: increased length of hospital stay (not explained by provision of comprehensive rehabilitation services), increased rates of institutional placement, continued pain, lower health and functional status along several dimensions (mobility and physical activity, mental distress, reduced social interaction, inability to conduct activities of daily living), and premature mortality. Short-and long-term outcomes for patients with hip fractures (controlling for the type of surgical procedure and comorbidity at admission) must be determined.

One outcomes assessment strategy, cited by the committee as a potential model for a multifaceted assessment, is Ellwood's Outcomes Management approach. HCFA has funded Quality Quest to work with the PROs in three states to assess systematically outcomes of large groups of people using information in addition to billing data. The research instrument includes measures of functional status, patient satisfaction, and other indicators of health status. The committee recommends that HCFA continue to support this kind of effort.

Longitudinal Follow-up

The committee recommends that hip fracture outcomes be measured longitudinally, for instance, at the time of hospital discharge and at six weeks, six months, and one year after discharge. As noted earlier, prefracture health status should also be obtained. Outcomes as a function of living arrangements should, for example, be examined in detail to determine the variables that permit individuals to return to the community (e.g., utilization of a skilled nursing facility, living with family or a paid caretaker, Medicare home health service). Short-, mid-, and long-term outcomes can be contrasted with prefracture status and correlated with type of treatment, length of stay, and type, site, and intensity of rehabilitation.

Research currently being conducted on hip fracture outcomes by investigators at the University of Minnesota School of Public Health was identified as an example of a follow-up study that will yield health and functional status information across various settings. In that study, prehospital functioning was assessed retrospectively; functional status was measured at the time of discharge and at two weeks, six weeks, six months, and one year after discharge. Patients are followed as they move from hospital to rehabilitation facility to nursing home to a community setting, sometimes all within the span of six weeks.

Risk Stratification and Classification of Comorbidities

The committee recommends that case mix indices for hip fracture be developed (including a measure of prefracture frailty), to predict, for example, cost, mortality, and ADL functioning six months postfracture. Attention should be given to the minimum clinical data needed and the procedures for acquiring such data. The importance of good risk stratification is obvious; a vigorous 70-year-old tennis player who breaks a hip, for instance, is in a very different category than a 70-year-old resident of a nursing home.

Categorizing patients in terms of prognosis becomes very critical in understanding the effectiveness of treatment. Risk stratification, for example,

may suggest that the intervention that will achieve the "best" outcome for some patients is nonsurgical management. This difficult ethical question can only be addressed satisfactorily with accurate risk stratification. Again, for HCFA, this type of analysis will depend on linking administrative data to primary data collection by the PROs or other research efforts.

Information about the presence of comorbid conditions is also important, such as kidney failure secondary to atherosclerotic cardiovascular disease, diabetes with severe peripheral vascular disease, or stroke with cognitive impairment or neurologic conditions. Knowing the medications the patient was taking before the hospitalization can also contribute significantly to the risk stratification and classification process. A scale could be developed that would enable researchers to stratify (or grade) the patient population into various classes reflecting their baseline functional status. If four or five different classes of patients were identified, more realistic outcome goals for each class of patient could be developed.

Patterns of Care and Variations

Analysis of the change of patterns of care over time and as a function of epidemiologic, clinical, and health care factors has emerged as a major dimension of effectiveness research. This is true because evidence has revealed (1) wide variations in rates of use of services (in hip fracture, primarily surgery and rehabilitation), (2) variations in use and site of services (especially for rehabilitative care), and (3) differences in practice styles that appear to reflect professional disagreement. The committee supports the use of the HCFA databases, augmented as appropriate by information from patient records, to analyze patterns of care for hip fracture. This could be done partly for policy and epidemiologic purposes and partly to help design good follow-up studies of groups of hip fracture patients.

Patterns of care studies should be linked expressly to issues of prevention, treatment options, and rehabilitation. Several variables should be a part of a comprehensive set of analyses of patterns of care and variations. *Geographic region* (even at the level of major census divisions) may prove to be a crucial element in understanding who experiences hip fractures and what type of treatment option (e.g., surgical or nonsurgical; type of surgical intervention) is chosen. Small-area analysis should also yield useful information on different patterns of care. Differences by *institutional providers* (e.g., types of hospitals; rehabilitation settings) and by *professional characteristics* of physicians and various types of therapists should also be studied, as they may shed light on differences in organizational factors or professional training and practice styles that might be used to explain or to change performance patterns. Other variables (e.g., prepaid versus

fee-for-service practice) may also prove to be important, especially for the frail elderly population.

PATIENT MANAGEMENT ISSUES

Prevention

Prevention of hip fracture was identified as a priority patient management issue because of the high social costs and grim personal consequences for elderly victims in terms of pain, disability, functional limitations, and displacement from community living. Prevention is a very promising area of study. For the person 65 years of age, the incidence of hip fracture doubles every five to seven years, with the risk increasing 8-fold to 16-fold between the ages of 65 and 85. Even from the time that a person enters the Medicare system, certain preventive interventions may modify the risk. If the onset of a hip fracture could be delayed five years, the incidence of hip fracture could be reduced by as much as 50 percent, with considerable savings in patient suffering and costs.

The committee identified osteoporosis and falls as priority targets for prevention research, because they are major risk factors for hip fracture. Prevention research for falls should include preventing falls per se and reducing fracture risk for falls that do occur. Studies on medications should also be pursued as corollary to understanding prevention issues.

Osteoporosis

Because of the intricate relationship of osteoporosis, bone strength, falls, and hip fracture, the committee recommends that osteoporosis be made a focus of prevention research. Several prevention strategies for this risk factor are probably most effective if they are implemented before the person enters the Medicare system (i.e., reaches age 65). Consideration should be given to the impact that third party payer denial of preventive services before age 65 has on shifting costs of these sequelae after age 65 onto the public sector.

One example of work that might be done in this area involves medications that are believed to have a protective effect. Observational studies suggest that thiazide diuretics reduce the risk of hip fractures if they are used for a period of several years; this is consistent with their known effects on reducing calcium excretion. Replacement estrogens are protective for newly postmenopausal women; it is unknown if starting these medications for women age 65 and older will delay osteoporosis. Calcium supplements, calcitonin, biphosphonates, and coherence therapy are all potential drug treatments for osteoporosis whose efficacy for preventing hip fractures is

unknown.[4] Life-style changes such as an increase in the level of physical activity may also preserve bone mass. There is an urgent need both for efficacy and effectiveness research to clarify the clinical utility of these potential preventive measures.

Thus, because this topic is clinically, epidemiologically, and administratively important, we advise that those planning the effectiveness research programs reach beyond the Medicare eligible population and ask what studies can be done now for those 65 years of age and older and what can be initiated for those under 65.

Falls

Falls are the leading cause of death from injury in the United States for people age 65 and older. As noted earlier, approximately 260,000 hip fractures occur among the elderly each year, with an associated medical cost estimated at over $6 billion, and falls are clearly a major factor in this picture.[5]

The committee recommends that effectiveness research efforts address pathophysiologic processes, the primary aging processes, and behavioral and environmental factors associated with falls. Outcomes and the cost-effectiveness of various prevention strategies must be evaluated. The mechanisms of falls and their role in hip fracture etiology should also be addressed.

Administrative databases can make only limited contributions to these questions, but certain uses should not be overlooked. For instance, such data might be used to evaluate programs to prevent falls, such as a demonstration project comparing an intervention in one community (a city- or state-wide program in which benefits include assessment of the home environment for hazards such as throw rugs on polished floors, inadequate lighting, and lack of handrails on stairs) and no intervention in another.

Another potential contribution that the HCFA data might make is to develop a risk profile for fall-related fractures. Differences in fracture related to race, body weight, and the like can be examined. The validity of this kind of analysis requires that the presence or absence of comorbidity be explicitly recognized. Although this type of analysis is not currently possible, diagnosis-related group (DRG) data will become much more useful if the codes account for the presence or absence of complications or comorbidities. This change, if implemented by HCFA, would help

[4] Coherence therapy is a cyclic combination of therapies stimulating the rate of bone remodeling and depressing resorption.

[5] A relatively small proportion of falls in old people result in fracture (4-6 percent), but nearly all hip fractures are consequent to falls.

researchers obtain a clean sample of patients, that is, one with similar complications or comorbidities; this risk stratification would then permit useful comparisons.

Medication Usage

Effectiveness research should include work on medications thought to be helpful in preventing osteoporosis (and, hence, falls and fractures) and on those believed to be harmful.[6] One example of the former—thiazide diuretics—was noted earlier. Possibly more important, however, is improvement in the understanding of which medications (including combinations of medications) may foster osteoporosis (and indirectly increase the risk of fractures) and which may affect balance or cognition and, thus, more directly increase the risk of falls and fractures.

Psychotropic medications are a class of drugs that constitute a significant risk factor for falls and fractures. Certain psychotropic medications (e.g., hypnotic-anxiolytics with long elimination half-lives, tricyclic antidepressants, and antipsychotics) produce about a twofold increase in the risk for hip fracture. An estimated 20 percent of Medicare beneficiaries are currently being prescribed psychotropic medications (although the Medicare program will not provide reimbursement for them when they are prescribed on an outpatient basis). The potential for effective prevention intervention by changing practice patterns and refining indications for drugs is great. Thus, clarification of how widely and how appropriately these agents are used and their role in falls or fractures is badly needed.

Treatment Options

The committee recommends that three questions be addressed concerning choices of treatment: (1) effectiveness of selected surgical interventions, (2) appropriateness of nonsurgical (medical and supportive) management, and (3) other treatments that pose high costs of care.

[6] Medicare does not cover outpatient prescription drugs at present. The Medicare Catastrophic Coverage Act, which would have instituted an outpatient drug provision, was repealed in late 1989. The committee noted, however, that the absence of outpatient medication information will limit effectiveness research that otherwise might be conducted using the Medicare insurance claims files. That is, HCFA databases currently offer little assistance in this area because Medicare does not cover outpatient prescription drugs. One possible way around this might be to link Medicare data to Medicaid data for those states that provide ambulatory medication information for the subsample of Medicare patients dually covered by Medicaid (i.e., the poor and disabled elderly population). By and large, however, effectiveness research directed at issues involving medications, which for hip fracture may be fairly important, will have to be done based on data collected through means other than the HCFA files.

Effectiveness of Surgical Interventions

The committee recommends that effectiveness research on hip fracture treatment alternatives develop scientifically based indications to determine which patients should have the following: (1) open or closed reduction with internal fixation, (2) prosthetic replacement of the femoral head, or (3) primary total hip replacement.

Nonsurgical Management

Many questions remain unanswered in the treatment of hip fracture for the oldest old and the frail elderly populations. Anecdotal experience suggests that a category of patients exists for whom standard care (i.e., surgical treatment) may not be indicated. Those who were minimally functional before the fracture often remain so afterward. They undergo a major operation at a very high cost (in physical, mental, and perhaps financial terms), yet they return to their previous functional status and face an extremely high probability of death within three to six months. Research is needed to determine whether there is a subset of patients who sustain hip fractures who are so disabled that the usual operative intervention offers little if any functional gain. Recommendations for the treatment of the frail elderly population, therefore, must be developed consistent with the purposes of treatment. These include return to previous function, control of pain, ease of nursing management at the site to which the patient will be discharged, and the speed with which mobilization can be accomplished.

Current predictors of hip fracture treatment by nonsurgical means appear to include: inability to walk three months before the fracture, low ADL status before admission, an impacted (i.e., compressed) fracture, and cancer of the hip.[7] It is possible now to analyze the HCFA administrative databases (mainly in terms of mortality and some simple morbidity variables) to generate hypotheses regarding this ethical question. Information not available from these existing files might be obtained through medical record abstraction or other activities of the Medicare PROs. In the future, health and functional status information should be matched with Medicare Part A and Part B data.

[7] These factors for predicting selection of nonsurgical treatment options are based on preliminary results of a study being conducted by investigators at The RAND Corporation. Approximately 2,800 patients with hip fractures were selected from the Medicare files and their medical records were abstracted to obtain information to clarify treatment selection factors. Approximately 5 percent of the patients with hip fracture were managed nonsurgically.

Other Treatment Issues

The committee recommends that HCFA address four other clinical treatment effectiveness issues: impact of comorbidity, patient predictors of excessively long lengths of stay or high costs of care, better clinical data sets, and payment incentives affecting clinical decision making. First is the question of comorbidity and its observed effects on treatment choices and outcomes. As noted elsewhere in this report, work is needed on patient classification and risk stratification problems. One instrument cited by the committee that might be used in effectiveness research to monitor the impact of comorbidity is the Gonnella disease staging system. This severity-of-illness classification system, which is based chiefly on the presence of comorbid conditions, uses data that already appear in the HCFA Medicare Part A files; thus, it might be useful now for risk stratification purposes. Stratification by comorbidities may enable researchers to pose more precise questions regarding timing and intensity of rehabilitation.

Second, work should be done to identify the clinical and demographic variables that predict cost and utilization outliers, that is, those patients who greatly exceed the average costs or institutional lengths of stay for treatment of their hip fractures. Such research may provide important clues to treatment effectiveness.

Third, the committee recommends that HCFA continue its efforts to establish a valid and reliable clinical data set[8] for use in effectiveness research. Additional mechanisms should be developed by which all data sets (i.e., the administrative claims files and the files containing inpatient clinical information) might be linked. Survey data, containing functional and health status information, when linked to inpatient and outpatient data, may ultimately provide an additional powerful input into treatment effectiveness and outcomes research. The barriers that exist to linking person-specific data bases from different sources are very great, however, and issues of confidentiality and privacy must be addressed. In the near future, therefore, the likely "linkage" will be on a population basis.

Finally, many committee members expressed concern that the payment system may drive decision making for treatment choice. Monitoring utilization trends can highlight odd or perverse patterns of use and direct policy attention in such a way that treatment decisions will in future be made on the basis of desired outcomes and not on the level of reimbursement.

[8] The need for a minimal data set shared by all effectiveness research is implicit throughout these recommendations. The appendix contains additional information on the Uniform Clinical Data Set.

Rehabilitation

The committee recommends that three rehabilitation questions receive priority consideration in effectiveness research because of their importance to health status and quality of life:

1. **What are the appropriate rehabilitation programs for different kinds of hip fractures?**
2. **What rehabilitation programs are most appropriate for different kinds of patients?**
3. **Which sites for delivery of rehabilitation services are most effective in outcomes and cost?**

Professional uncertainty exists in matching rehabilitation programs to type of fracture. There is no firm consensus on extensiveness, for example, intensity of physical or occupational therapy or emotional counseling as a function of type of fracture.

Rehabilitation after hip fracture is highly sensitive to cognitive, physical, and functional status before the fracture. Some elderly people who fracture a hip are healthy and have no ADL or IADL impairments; others have numerous problems that predispose them to falls and fractures. The increased prevalence of chronic conditions in those most at risk for hip fracture make the issues of data reliability, validity, and comprehensiveness particularly important. Certain coexisting ailments (e.g., dementia, depression, and chronic infections) may also inhibit the rehabilitation process. Assessment must not only determine the presence and severity of these conditions but also monitor their impact on the outcome of hip fracture treatment. The proper management of coexisting illnesses is potentially as important in rehabilitation as the type of fracture or the surgical procedure elected.

Again, information on cognitive and physical function is generally not available from the administrative data set and often not from the medical record. The committee noted that a long-range goal for HCFA should be to incorporate this information into the medical record and claims data. In the short run, primary data collection will be required.

Rehabilitation outcomes may also depend on the availability and utilization of appropriate services following acute care. The density of available rehabilitation beds per population, the availability of appropriate personnel in home health agencies, and access to outpatient physical and occupational therapy are all important.

The committee recommends that HCFA concentrate its effectiveness research for rehabilitation on four areas: (1) minimal data set, (2) timing and intensity, (3) longitudinal follow-up across settings of care, and (4) hypothesis generation.

Establishment of a Minimal Data Set

Section 9305(h) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 mandated the development (but not the implementation) of a uniform needs assessment instrument by the Secretary of DHHS. Its content will include measures of functional capacities, nursing care requirements, and the social and family supports that are available. The instrument would be used to evaluate the needs of patients for posthospital extended-care services, home health services, and long-term-care services of a health-related or supportive nature, and the data would be used by hospital discharge planners, home health care agencies, other health care providers, and Medicare fiscal intermediaries and carriers. It might also be used to determine whether payment for long term care should be approved. A different requirement item from OBRA 1987 is for a uniform minimum data set for nursing homes.[9] The committee strongly supports these developmental efforts and further field testing.

Timing and Intensity Issues in Rehabilitation

Medicare currently covers 100 days of rehabilitation services and nursing home care when a potential for improvement can be demonstrated. Effectiveness research could help define appropriate services and time frames for benefits that are effective in terms of both health status and cost. Sites appropriate for analysis include acute care hospitals, rehabilitation hospitals, extended-care facilities, home settings when the care is rendered through home health agencies, and other settings delivering relevant outpatient care. Medicaid files might also be used to capture intermediate care facility utilization.

Longitudinal Follow-up

A major deficit in the knowledge of hip fracture rehabilitation is outcomes over time. Detailed health status information before fracture is not usually available. The current Medicare benefit structure permits tracking of patients across only a limited number of settings, for example, in acute and rehabilitation hospitals but not skilled nursing facilities after 100 days.

[9] An advisory panel appointed by the Secretary of DHHS has developed a draft of the uniform needs assessment instrument that was reviewed by interested organizations, associations, and providers. As of November 1989, a final instrument had been prepared but not yet transmitted to the U.S. Congress by the Secretary of DHHS. Both this effort and the uniform minimum data set for nursing homes are being coordinated by the Office of Survey and Certification, Health Standards and Quality Bureau, HCFA.

Nevertheless, the results of rehabilitative care should be examined in different settings to determine whether Medicare program operations and coverage benefits limit those outcomes. Such outcome information obtained over time is critical if appropriate and effective alternatives for rehabilitation are to be identified. Put another way, this information is needed to decide what services should be made available to Medicare beneficiaries, and to avoid policies that may make outcomes worse. Governmental behavior, as well as provider and patient behavior, need to be critically evaluated in this regard.

Hypothesis Generation

The possibility that the HCFA databases can be used to generate hypotheses should not be overlooked. Often, a hip fracture signals a rapid decline in health status and functional capabilities. Through the HCFA data, variations within geographic areas and among different practitioners might be examined to generate hypotheses regarding type, site, and intensity of rehabilitation services; for instance, about the relative merits of providing rehabilitation in the acute setting, a rehabilitation hospital, or at home. These hypotheses could then be examined by linking HCFA data files to other data bases or by funding experimental and quasi-experimental studies.

Hip Fracture in the Context of Aging

Few data are directed specifically to understanding what a hip fracture actually represents biologically, that is, in terms of aging per se. If hip fracture represents the accumulation of risk factors and therefore is a clinical manifestation of decline, then it may be inappropriate (if the rate of decline is moderate or rapid) to expect many individuals to return to prefracture levels of functioning. If, on the other hand, the fracture is an acute injury that itself can precipitate a major decline in an otherwise intact individual, then treatment strategies must be developed to minimize side effects or inadequate rehabilitation. Some experts suspect that, for some people, hip fracture is a precipitating event and that, for others, it signals a decline that is well in progress. Research is needed to determine how to classify individual patients and how to apportion resources so that the maximum recovery level for each person suffering a hip fracture can be achieved at a reasonable cost.

Conclusions

Aside from the recommendations already cited, the hip fracture committee reached three main conclusions. First, as in the breast cancer and acute myocardial infarction clinical workshops, the committee believes that the HCFA data sets, as presently constituted, can be best used to describe, track, and compare broad patterns of care for hip fracture according to subgroups of providers, practitioners, and patients. The committee fully supports these goals of the Effectiveness Initiative.

The patient management areas identified as highest priority for effectiveness research—prevention, treatment options, and rehabilitation—reach beyond the capacity of the current HCFA databases. The scarcity of outcome measures (other than mortality) and of health and functional status information (both pre- and post-fracture) in the Medicare administrative databases makes them inadequate to adjust for case mix, to ascertain risk, or to determine the effectiveness of prevention, treatment, or rehabilitation interventions. These limitations, among others, emphasize the importance of developing strategies to acquire needed outcome and health and functional status data, either for the standard data sets themselves or for special projects and studies.

Second, the Medicare files pose problems of data reliability and validity. These limitations include inadequate descriptions of race, the impossibility of expressing which one of a paired body part is involved in a procedure, and discrepancies between the numbers of identifiable cases based on the diagnosis and those identified by summing over the appropriate procedures. These and other difficulties obligate external users of these files to consult experts within HCFA during extramural research projects and to incorporate validity studies in all effectiveness research.

Third, the committee emphasized the need for coordination among DHHS agencies that are responsible for effectiveness research. This should minimize duplication of efforts and maximize current knowledge (e.g., in the development of a health and functional status measure that includes the concept of frailty). DHHS should develop a mechanism (e.g., a task force, requests for proposals, contracting, and grants) to accomplish this coordination. DHHS should also consult widely and continuously with clinicians and technical experts in these efforts. To this end, DHHS might empanel a high-level advisory committee of experts to provide oversight for effectiveness and outcomes research.

This workshop represents an important step in hip fracture effectiveness research. Problems of patients, practitioners, and payers are addressed from a very broad perspective. Effectiveness research, done well, will have several benefits beyond its immediate scope: it will generate hypotheses for clinical and biomedical studies; it will provide a focusing mechanism for such research that is derived from the epidemiology of disease and its treatment, not simply from the science base; and it will stimulate a more comprehensive orientation to research that will in turn support clinical practice.

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Appendix: Background and Conduct of the Workshop

STRUCTURE OF THE WORKSHOP

This appendix describes the hip fracture workshop project and documents the materials developed or used as background for the committee discussions. Before the workshop, the Institute of Medicine (IOM) staff distributed a set of background materials to the committee to familiarize them with the Effectiveness Initiative and the issues to be discussed. These materials included information on the Medicare data files; current research funded by the National Institute on Aging, the Centers for Disease Control, the National Center for Health Services Research, and the Health Care Financing Administration (HCFA); and abstracts from recently published articles and presentations on hip fracture research relating to the use of services, risk factors, prevention interventions, reimbursement, and efficacies of various treatment regimens (see Bibliography, this volume).

In addition, IOM staff developed a brief exercise, which the committee completed and returned before the workshop, to determine the committee's views about high-priority research questions for hip fracture. Before the workshop, committee members were asked to list three patient management topics that should be given highest priority and, for each of the topics nominated, to specify the types of studies that should be undertaken or sponsored. The results of this exercise were presented at the outset of the meeting.

The committee also received estimates on the incidence of hip fractures in the elderly population of the United States and case-fatality rates for those people. These data were compiled, in part, from the HCFA Medicare

Provider Analysis and Review (MEDPAR) files and taken from preliminary results of an ecologic study of factors associated with hip fracture.[1]

The workshop featured four background presentations: Rose Connerton of HCFA, on the Medicaid/Medicare Decision Support System; Alfred A. Rimm of the Medical College of Wisconsin, on risk factors and incidence rates obtained from the administrative databases; Kenneth I. Shine of UCLA (chair of the committee), on factors that the committee should consider in recommending patient management topics; and Kim A. Heithoff of the IOM, on the results of the homework exercise. After extensive discussion, the committee selected (by voting) the priority patient management and methodologic issues and further delineated the primary research strategies related to those issues. The executive session refined the final recommendations of the committee.

HCFA DATA

Medicare/Medicaid Decision Support System

The description of the Medicare decision support system included a simplified version of the flow of data into the Medicare systems. That flow starts with entitlement and demographic data for about 33 million Medicare beneficiaries that are obtained initially by the Social Security Administration (SSA). Health care providers and contractors are the primary sources 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 on to the system. These utilization data are merged with the SSA demographic information. 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 care agencies, independent laboratories, ambulatory

[1] Requests for copies of these preliminary findings should be directed to Alfred A. Rimm, Medical College of Wisconsin, Milwaukee.

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

MEDPAR is a 100 percent file of Part A inpatient care (about 10 million admissions a 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 hip fracture. 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; it currently exists for 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 contains 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 latter are coded using 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 the existing basic record groups might be used to conduct analyses related to hip fracture (especially to monitor trends and examine variations in use of services). First, researchers would select the ICD-9-CM code for hip fracture 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

(i.e., MADRS). 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 Peer Review Organizations (PROs) as part of the proposed Uniform Clinical Data Set.

In 1987, HCFA's Health Standards and Quality Bureau 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 was heretofore available in the 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 ensure the quality of care delivered to Medicare beneficiaries, 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 hip fracture, 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 these, about 3 percent are a truly random sample of admissions, and the remainder are cases mandated for review for various reasons.) 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 1,600, although not every datum 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. Recovery Phase
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 hip fracture, see Table A.1.

As of July 1989, the pilot-test phase was complete. Field testing of the whole approach was under way and was expected to continue through the summer and fall of 1989. An assessment and recommendation as to whether to go forward with this approach was expected early in 1990. HCFA is also working to develop mechanisms to collect quality of life and other patient outcomes data more directly.

Hip Fracture Analyses Illustrating the Use of Medicare Data

Examples of the use of Medicare data in the analysis of hip fracture were given by a designated representative of HCFA. Preliminary results of a study designed to provide population-based estimates of the incidence of hip fractures by age, sex, and race among the elderly population of the United States and to estimate case-fatality rates for those people were discussed. The study uses discharge data, obtained from HCFA and the Department of Veterans Affairs, from all short-stay hospitals from 1984 to 1987.

These estimates are considered unique in that for the first time in this country they will be based on an enumeration of essentially all hip fractures occurring among the elderly in all regions of the country. Further, estimates will include age-specific rates for the very old (age 85 and older). With these estimates, detailed maps of the incidence of hip fracture will be developed and combined into an atlas depicting the geographic variation in incidence across the country. Further, seasonal variation will be assessed through the detailed examination of dates of admission for 1984 to 1987.

PREWORKSHOP HOMEWORK EXERCISE

In a preworkshop homework exercise, which was conducted as a modified Delphi process, the committee members first nominated three major

patient management topics and then recommended research activities for those specific topics. The committee reached considerable consensus in the first round of this process. Nearly 75 percent of the responses fell into the categories of *prevention* (identification and modification of risk factors, dissemination of preventive practice information, and timing of preventive interventions); *treatment options* (determinations of treatment modality and need for meaningful outcome measures); and *rehabilitation* (timing, intensity, and site of service; structure and process of a prototypical program; and linkage to outcome measures). Other topics mentioned at least once were related to postoperative management, emotional components of recovery, and identification of potential sites of care and their relation to cost and outcome. A second round of voting was held at the workshop itself. The committee reaffirmed prevention, treatment options, and rehabilitation as the three priority patient management issues in those with hip fractures that it would recommend to HCFA. Table A.2 provides a summary of these topics.

Tables A.3 through A.9 present the results of the second part of the exercise, in which committee members specified potential research strategies for seven main categories of priority patient management topics. The information in these tables represents the views of skilled clinicians, some of whom specialize in the care of patients with hip fracture, and experts in research and other disciplines needed for successful effectiveness research. The workshop format did not permit a full discussion of all the issues raised by these committee members, but the breadth of topics included here provides guidance for a rich research agenda for future years.

TABLE A.1 Selected Data Elements Related to Hip Fracture Recorded for the Proposed Uniform Clinical Data Set

OPERATIVE EPISODES

This section refers to operating room procedures. Operative episodes are those that occur in the operating suites under anesthesia or that would generally be performed in the operating suites but were not because of emergency or patient condition.

One operative episode may involve more than one operative procedure. For example: Laparotomy and Cholecystectomy and Splenectomy = 1 operative episode = 3 procedures = 3 procedures codes.

2. For each operative episode, record the month and day. If the surgery occurred around midnight, record the date that anesthesia began.

Date: _____ _____
(month) (day)

3. You are required to enter the procedure codes (ICD-9-CM) that apply to each operative episode. To access the computer screen to enter these codes, change F to T and enter all procedure codes which apply per operative episode.

7. Surgical Wound Classification (SWC)

You are required to enter the surgical wound classification (SWC) as assigned in the operating room utilizing the following numbers.

Operating wound, clean	1
Operating wound, clean contaminated	2
Operating wound, contaminated	3
Operating wound, dirty	4
Not documented	9

TREATMENT INTERVENTIONS

3. Professional Services

If any of the following professional services were utilized at any point in this hospitalization, change F to T and record all applicable services.

Physiotherapy	F
Occupational therapy	F
Clinical nutrition	F
Respiratory therapy	F
Speech therapy	F
Social work	F
Clinical pharmacist	F
Vocational services	F
Palliative care (of hospice type)	F
Prosthetics/orthotics	F
Pastoral care	F
Psychiatric counseling/care	F
Patient education	F

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.

TABLE A.2 Patient Management Topics Nominated by the Hip Fracture Committee in Round One of the Preworkshop Homework Exercise

A. General (4 percent of responses)
- Balancing post operative management, outcome, and cost
- Consideration of emotional components in recovery
- Consolidation of hip fracture research information

B. Prevention (27 percent of responses)
- Identification of and modification strategies for risk factors: frailty, osteoporosis, falls, and hip fracture
- Dissemination of preventive practice information
- Timing of preventive interventions

C. Treatment Options (18 percent of responses)
- Need for additional information on the most effective type of surgery for specific type of fracture
- Need for improved outcomes research
- Nonsurgical option for the very disabled patient

D. Prevention/Managment of Secondary Complication (9 percent of responses)
- Prophylaxis of phlebitis and pulmonary embolus
- Use of readmission data to assess and improve quality of care
- Use of geriatric assessment to prevent secondary complications
- Adapting the hospital structure to meet the needs of the frail elderly

E. Rehabilitation (27 percent of responses)
- Timing, intensity, and site of rehabilitative services
- Classifying patients for appropriate level and type of rehabilitative services
- Prototype rehabilitation program: structural and process components
- Outcome measures: the need to determine effectiveness of rehabilitation services

F. Site of Care (7 percent of responses)
- Identification of potential sites of care and appropriate type of service per site
- Relationship of site of care to outcome

G. Outcome Measures (4 percent of responses)
- Identification of relevant and meaningful patient and provider outcome measures

TABLE A.3 Summary of Research Issues and Activities Recommended for Hip Fracture (general category, not classified elsewhere)

I. Emotional Well-Being

A. Determine how and under which circumstances emotional well-being (especially level of depressive symptoms) can be treated with resultant improvement in rates and degree of recovery achieved by 2 or 12 months

Research Strategies:

A. Design and conduct observational treatment outcome studies

B. Undertake randomized trials of different mental health programs and approaches with homogeneous groups of depressed individuals (those with major depression and those having symptoms of depression but not reaching diagnostic criteria)

II. Linking Information

A. Determine the best method to provide linkage or integration between hip fracture-related studies and activities

TABLE A.4 Summary of Research Issues and Activities Recommended for Prevention Activities in Hip Fracture

I. Determination of Risk Factors

A. Determine which factors contribute to the incidence of hip fracture

Research Strategies:

A. Conduct randomized, controlled trials designed to:
   1. Prevent frailty in elderly people at risk
   2. Reduce frailty in those who already are frail

B. Fund large scale studies (possibly, multi-center collaborative studies), combining behavioral and social interventions with physical interventions
   1. Examine *pre- and postfracture* for possible effects on incidents
   2. Determine prevention options that arise from this analysis

II. Cost and Effectiveness of Prevention Interventions

A. Determine the effects of patient's health, life-style and socioeconomic circumstances pre- and postfracture on cost and effectiveness of treatment

B. Determine effective methods (i.e., system changes, economic incentives, education) for incorporating efficacious preventive practices (i.e., prescribing estrogen therapy for women at risk for osteoporosis) into the everyday routine of all community-practicing primary care providers

C. Determine whether improvements in flexibility, cardiac endurance, and muscle strength for the frail elderly can be carried over to function in everyday life thereby reducing the incidence of hip fracture
   1. Determine duration of these effects on functional status
   2. Determine what personal and environmental factors enhance such interventions
   3. Determine the most effective method of preventing hip fracture (i.e., estrogen therapy versus calcium replacement versus both versus nothing)

Research Strategies:

A. Conduct demonstration studies designed to change practice styles of community practicing physicians
   1. Population of interest: practicing primary care physicians from *all* settings
   2. Evaluate methods for influencing this change - via prospective trials
   3. Design studies to evaluate effectiveness of "efficacious" practices of prevention

III. Using the Administrative Data Bases to Predict Fracture

A. Determine whether the frequency of trauma predicts fracture (i.e., if you can prevent trauma can you prevent fracture?)
   Hypothesis: Those with frequent trauma are more likely to have a subsequent fracture

B. Determine whether the frequency of claims predicts fracture (i.e., are fractures a marker for deterioration?)

Research Strategies:

A. Historical-prospective studies to:
   1. Examine link between soft tissue injuries and subsequent fractures
   2. Explore the relationship of claims for treatment to hip fracture

TABLE A.4

IV. Prevention of Falls

A. Determine effective interventions for the prevention of falls in people age 65 and older
   1. Identify persons at greatest risk of fall and fracture
   2. Identify fallers at greatest risk for fracture

Research Strategies:

A. Develop risk profile for fallers who fracture their hips
B. Test multifactorial interventions to reduce risk of fall in large cooperative studies
C. Design etiologic studies to elucidate risk factors for falls
D. Implement focused interventions to demonstrate that individual risk factors can be modified
E. Use HCFA data to create population-based injury surveillance systems to identify fall-related fractures

V. Prevention of Osteoporosis

A. Determine whether estrogen replacement or supplementation reduces the risk of hip fracture in the elderly Medicare or Medicaid population of women
B. Determine whether thiazide diuretics, which decrease urinary calcium loss, reduce bone loss and hip fractures in people age 65 or older. Determine how long preventive therapy/intervention should be applied to maximally reduce the incidence of fractures
C. Determine the benefit of starting preventive therapy for osteoporosis *before* the menopause

Research Strategies:

A. Design case-control studies of patients on Medicaid who suffer hip fractures (stratify by age, race, and home status). Compare patients who have had treatment with estrogen as documented in Medicaid prescription drug records
B. Conduct clinical trial in small sample (200-300 subjects) to determine whether thiazide diuretics decrease loss of bone mass at the proximal femur in people age 65 and older
C. Conduct larger clinical trials to determine whether thiazide diuretics decrease the incidence of hip fractures in this population
D. Collect data on estrogen replacement therapy in a large cohort to determine how long it must be administered to reduce the fracture incidence maximally

TABLE A.5 Summary of Research Issues and Activities Recommended for Treatment Alternative Selection in Hip Fracture

I. **Develop Guidelines for Selecting Treatment Alternative**
   - A. Determine under what circumstances a patient with a hip fracture should be treated by a surgical procedure other than nailing
   - B. Determine whether patient outcomes are clearly better for patients with fracture of the femoral neck treated with reduction and fixation *or* endoprosthesis
   - C. Determine whether there is a subset of patients who sustain hip fractures who are so disabled that the usual operative intervention offers little functional gain; and therefore, nonoperative supportive treatment only should be considered
   - D. Determine the differences in long-term functioning of total hip replacement compared with that of head replacement compared with that of internal fixation; determine the mortality implications
   - E. Determine the best approach for surgical management of the patient with femoral neck or intertrochanteric fractures

Research Strategies:

- A. Patient stratification by specified fractures (subcapital, neck, intertrochanteric) for surgical procedure selection
  1. Open or closed reduction with internal fixation
  2. Prosthetic replacement of femoral head
  3. Primary total hip replacement
  4. Non-operative supportive treatment

  Controlling for:
  a. Prefracture health status
  b. Prefracture physical and cognitive functioning
  c. Access to community care

- B. Convene physician consensus panel:
  1. To determine which patients should be treated by a surgical procedure other than nailing
  2. To determine whether outcomes are clearly better for patients with fracture of the femoral neck treated with reduction and fixation *or* endoprosthesis
- C. Design observational, prospective studies and randomized clinical trials to follow patients with fracture of the femoral neck treated with reduction and fixation *or* endoprosthesis to assess outcomes
- D. Conduct a randomized study of parallel groups of operated and nonoperated patients (severely disabled) to assess outcomes
- E. Conduct randomized clinical trials with mortality, ambulatory status, and functional status as outcomes to determine the optimal hospital regimen for hip fracture care
- F. Use chart review and follow-up studies after hospital treatment to measure outcomes of patient subgroup for which nonsurgical treatment was selected and compare them with a matched sample for which surgical treatment was selected
- G. Monitor data bases and determine by type of fracture
  1. Time to surgery
  2. Type of surgery
  3. Postoperative rehabilitation services
  4. Use of services
  5. Length of stay
  6. Postoperative complications
  7. Cost of care
  8. Prefracture health and functional status
  9. Short- and long-term outcomes

TABLE A.5

H. Analyze Medicare database to assess available outcomes of a very elderly patient group with severe comorbidities and dementia
I. Monitor trends in the population for individuals receiving different forms of therapy; establish the relationship of the type of surgery performed to subsequent hospitalizations, recurrent fractures, length of stay in nursing homes, or time to death
J. Monitor geographic variation and trends in procedures to determine the advantage in long-term functioning and mortality of total hip replacement over that of head replacement over that of internal fixation
K. Monitor trends in the population for individuals receiving different forms of therapy to determine the best approach for surgical management of the patient with femoral neck or intertrochanteric fractures
L. Analyze the relationship of the type of surgery performed to subsequent hospitalizations, recurrent fractures, length of stay in nursing homes, and time to death
M. For specified fractures (subcapital, neck, and intertrochanteric) and surgical treatments (internal fixation, replacement of femoral, head and total hip replacement), determine the differences in length of stay, readmission change in premorbid home status, survival, and use of hospital
N. Link MEDPAR/BMAD-relevant tape to the Medicaid files to analyze factors related to:
    1. Nursing home placement
    2. Home health utilization
    3. Ambulatory treatment
    4. Medication utilization

Outcomes of interest include:
    a. Mortality-early and late
    b. Morbidity
    c. Second operation
    d. Secondary complications
    e. Readmission
    f. Functional recovery (short and long term)

II. Feedback and Education to Practicing Physicians

TABLE A.6 Summary of Research Issues and Activities Recommended for Prevention/ Management of Secondary Complications in Hip Fracture

I. Complications of Interest
- A. Phlebitis
- B. Pulmonary embolus

II. Patient Management Issues
- A. Determine whether a geriatric assessment or consultation procedure early in the course of a hospital stay has an impact on the rate of secondary complication postfracture
- B. Determine whether examination of readmissions data is a valuable method of judging quality of care; can readmission data identify specific links to correctable problems in performance?
- C. Determine whether hospitals and institutions that are basically organized for efficient care of younger adults, can be adapted to support the functional recovery of frail elderly people
- D. Determine the structural and process components of a model geriatric program

Research Strategies:
- A. Literature review
- B. Randomized controlled trials
  1. Implement randomized controlled trials to determine the impact of a geriatric assessment on secondary complications by matching patients and hospitals and using hospitals as the unit of study (controlling for geographic variation in surgical practice)
  2. Develop and evaluate model geriatric patient care units randomizing patients to usual care or experimental setting; such studies should be preceded by modest pilots of care strategies which attempt to match patient factors (including cognitive impairment) to care strategies; studies should control for prefracture function
  3. Design randomized controlled trials to assess the efficacies of various prophylaxis therapies
  4. Conduct trials of effectiveness of current prophylaxis therapies in various clinical settings (especially small and rural hospitals)

  Controlling for:
  - a. Practice setting
  - b. Prefracture health and functional status
- C. Using HCFA data
  1. Analyze database to assess or determine
     - a. Effectiveness and efficacy of prophylaxis therapies
     - b. Occurrence of phlebitis and embolus (and the resulting mortality and morbidity)
     - c. Geographic variations in use of services and outcome
     - d. Access to services
     - e. Utilization of services
     - f. Readmissions
  2. Analyze database for available information regarding occurrence of phlebitis and embolus, including mortality
  3. Analyze database for geographic variations in the occurrence of phlebitis and embolus, including mortality
  4. Monitor trends and geographic variations in readmissions as an indicator of secondary complications
  5. Through examination of medical records, determine whether the coded diagnosis indicates a problem readmission; compare readmissions to diagnosis mistakes found in abstracted medical records as a way to pinpoint problems

III. Feedback and Education to Medical Profession

TABLE A.7 Summary of Research Issues and Activities Recommended for Rehabilitation Services in Hip Fracture

I. Standards for Rehabilitation in Hip Fracture

A. Determine effectiveness of various structural and process components of rehabilitation by:
1. Type of service
2. Site of service
   a. Acute setting
   b. Rehabilitation unit
   c. Rehabilitation hospital
   d. Skilled nursing facility
   e. Intermediate care facility
   f. Ambulatory programs
   g. Home health services
3. Timing of services
4. Duration and intensity of services
5. Cost of service

Stratified by:
1. Prefracture health and functional status (including cognitive dimensions)
2. Type of fracture
3. Prefracture place of residence (community versus institution)
4. Socioeconomic factors

Outcomes measured over time (i.e., 6 weeks, 6 months, 1 year) including:
1. Health and functional status (including cognitive dimensions)
2. Rehospitalizations
3. Placement in long-term-care facility
4. Return to community
5. Length of stay in nursing homes
6. Quality-of-life variables
7. Mortality

Research Strategies:
1. Monitoring of time trends of use of services
2. Analysis of geographic (population-based) variations in use of services and in outcomes of care - Link MEDPAR, BMAD, and tape-to-tape files
3. Clinical demonstrations and observational studies
   a. Define "ideal situation" programs for various levels of expectation
   b. Implement "model" programs to test feasibility of defined programs
   c. Study a selected population of individuals with hip fracture to determine whether their outcomes differ on the basis of rehabilitation program intensity and comprehensiveness
   d. Study a selected population of individuals with hip fractures, by observing their return to the home setting as a function of the intensity of rehabilitation services and any effect differences in intensity may have on later quality of life (1 year)
4. Randomized clinical trials, to test those factors identified above.

II. Coordination of Services

A. Examine methods to better coordinate services inpatient to outpatient
1. Determine optimal length of service (i.e., hospital and nursing home stay, or home care)
2. Study the effects of programs that involve family, friends, or paid caregivers and whether they should be included in the rehabilitation process

Stratified by:
1. Prefracture health and functional status
2. Comorbidity
3. Social economic factors

Research Strategy:

A. Medicare waivers to evaluate alternative benefit options (e.g., longer hospital stay or nursing home or home care)

TABLE A.8 Summary of Research Issues and Activities Recommended for Site of Service Issues in Hip Fracture

I. Impact of Site on Rehabilitation

- A. Determine whether a rehabilitation unit attached to a community hospital can be adapted to the special needs of the geriatric hip fracture patients
- B. Examine the potential role of a day hospital in the rehabilitation of the hip fracture patients
- C. Determine whether the length of hospitalization for hip fracture should be uniformly long, with rehabilitation and physical therapy undertaken in the hospital, or whether hospital stays should be shorter (even than the current diagnosis-related group allowance), with almost universal discharge to a rehabilitation hospital for a lengthy stay (if necessary)
- D. Determine in cases of uncomplicated hip fracture requiring extended inpatient rehabilitation, determine whether the type of facility materially affects long-term outcomes
- E. For comparable outcomes, determine whether one form of post-acute-care rehabilitation costs less to deliver
- F. Determine the relative costs and effectiveness of these sites for comparable cases

Research Strategies:

- A. Heterogeneous nature of patients with hip fractures must be recognized

  Stratify by prefracture:
  1. Cognitive function
  2. Physical function
  3. Emotional well-being
- B. Design prospective studies of recovery from hip fracture in different settings to identify person and environment (social, psychological, and physical) factors that are associated with good recovery and poor recovery.
  1. The physical site must be stratified by:
     a. Type of personnel
     b. Competence of personnel
     c. Management policy
  2. The populations must be stratified by:
     a. Age
     b. Sex
     c. Prefracture variables noted above

     Individuals would be randomly assigned to hospital care or early discharge and transfer to the rehabilitation unit or hospital for rehabilitation
- C. Existing Medicaid data could be linked to Medicare Part A and Part B data to examine outcomes in nursing home settings
- D. Analyze differential length of hospitalization in terms of:
  1. Cost implications
  2. Outcome implications
  3. Quality of care
- E. Compare utilization of different forms of post-acute care over rehabilitation time (i.e., possibly compare 1984 and 1988 data [sample of Medicare data])
- F. Analyze geographic differences in post-acute-care utilization and outcomes in terms of differences in service utilization (sample of Medicare data)
- G. Analyze costs and outcomes through different patterns of post-acute-care rehabilitation using patient-specific studies

TABLE A.9 Summary of Research Issues and Activities Recommended for Outcome Issues in Hip Fracture Not Included Elsewhere

I. Defining Outcomes

A. Determine measures that represent relevant and meaningful (to patients as well as providers) outcomes of the care of hip fractures

Research Strategies:

A. Conduct meta-analysis of existing literature
B. Convene consensus panels of experts in orthopedic surgery, geriatrics, ethics, and rehabilitation medicine
C. Survey patients before and after fractures

II. Prognostic Stratification

A. Determine the relationship between length of stay (LOS) and outcome in hip fracture (hypothesis: correcting for severity and comorbidity, length of stay predicts outcome)

Research Strategy:

A. Using HCFA Medicare files, identify the population of all individuals with hip fractures that were treated surgically; for a sample of these individuals, using case-mix severity adjusters, determine
   1. Length of stay
   2. Vital status at 30 days, 3 months, 6 months, 1 year, and 2 years
   3. Functional status (as measured by interview)