Chapter 6

Quality of Care

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INTRODUCTION

Medicare's prospective payment system (PPS) has intensified concern with the complex relationship between cost and quality of medical care. Although in ideal terms the best care is that which is most effective, in practical terms some tradeoff between cost and quality is unavoidable. The possibility of such a tradeoff has been anticipated in many quarters, prompting attention to the quality-of-care issue from the General Accounting Office (GAO), OTA, Prospective Payment Assessment Commission, and the Health Care Financing Administration (HCFA). One manifestation of this concern was the establishment by Congress of utilization and quality control peer review organizations (PROS) as the successors to professional standards review organizations (PSROs).

Assessing PPS impacts on quality of care is critical for several reasons. First, if PPS succeeds in containing expenditure growth for the Medicare program, its effect on the quality of care will be a deciding factor in the program's continued survival. (Another will be its effect on access to care, as discussed in ch. 7.) Second, PPS incentives for the amount and mix of inpatient services provided to the elderly differ markedly from the incentives of cost-based payment, yet the Nation has little experience with the effects on quality of such prospective payment systems. [1] Third, widespread concern among professional groups, including physicians', nurses', and hospitals' associations, and among representatives of the elderly that PPS might pose a substantial threat to quality of care has made quality a highly visible issue (280,302, 310,381).

Complicating the task of evaluating PPS impacts on the quality of care is the fact that PPS impacts vary along at least four dimensions: their seriousness, their timing, their measurability, and their distribution among the elderly. These dimensions vary in ways that make evaluating PPS, and particularly its effects on quality, very difficult to plan and carry out.

Highly visible or easily measured effects on quality of care are likely to be the most serious, especially if they involve deaths, inappropriate readmissions, and the like. They are also likely to be concentrated in a few groups of patients. More subtle effects, such as effects on the quality of life for Medicare beneficiaries, are likely to be both more difficult to measure and less serious.

How effects on quality of care will emerge over time is difficult to predict, but the more serious effects may not appear for a number of years. Indeed, PPS may not have much discernible effect at all on quality of care for 2 to 3 years. Initially, PPS impacts on quality may be small because many hospital management efficiencies may have no appreciable impact on clinical practice; such efficiencies may even enhance outcomes for Medicare beneficiaries. As slack in the system is taken up, however, PPS could force economies that are inconsistent with maintaining quality of care as now known. Some problems may arrive sooner for hospitals with low financial reserves, for those in areas of high labor or nonlabor costs, or for those facing other problems external to PPS. In short, although some PPS effects on quality of care may surface relatively early, others that ultimately are equally or more important may take some years to be detected or documented.

Most important to understand is that PPS is likely to change the quality of care in both positive and negative ways. More skillful hospital management may lead to desirable administrative or clinical efficiencies, such as improved choices of diagnostic or therapeutic interventions (87). Nevertheless, PPS incentives for hospitals to reduce inpatient services are strong enough to raise fears that the lives or health of at least some Medicare beneficiaries could be endangered.

[1] Several States had prospective hospital ratesetting programs before PPS, but they differ in structure from each other and from the current national program; in any event, a report on the impact of these State programs on quality of care (and other topics) has not yet been released (59).

The remainder of this chapter is organized into four sections. The next section examines the concept of quality of care, highlighting the difficulties of both definition and measurement. The third section describes how PPS may affect the quality of care, and the fourth section sets out the critical evaluation questions in this area, with attention to what data sources are or might be available t support evaluation activities. The final section reviews strategies for evaluating PPS effects on quality of care.

DEFINING AND MEASURING QUALITY OF CARE

Definitions of Quality of Care

Medicare is expected to purchase quality health care for its beneficiaries, but what constitutes "quality" remains poorly defined. One definition is ".. . the kind of care that maximizes an inclusive measure of patient welfare after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" *(86).* The term "benefit" could easily replace "welfare" in this definition without markedly changing the essential meaning. Hence this definition has intuitive appeal, for it is consistent with the benefit and cost framework for PPS evaluation laid out in chapter **2.**

Two terms frequently used in the literature on health care quality —''quality assessment" and "quality assurance' '—need to be distinguished from one another, "Quality assessment" refers to the measurement and evaluation of quality of care for individuals, groups, or populations. "Quality assurance" refers to integrated programs that attempt to protect or raise quality of care by conducting assessments, taking action to correct problems found, and following up corrective actions.

Quality assurance programs historically focused on changing the behavior of individual providers through educational interventions or payment sanctions. The major quality assurance efforts for Medicare have been the PSRO program and its successor, the PRO program.

Because quality assurance programs rest on assessments of the care delivered to individual patients, the terms quality assurance and quality assessment are sometimes used synonymously. In this report, however, the two terms are used quite differently. A major focus of this report is on the assessment of changes in the quality of care due to a health care financing program, namely, Medicare's PPS. This report is only indirectly concerned with the ability of PROS to assess and assure quality. Quality assessment data developed for quality assurance programs, particularly the PROS, are of interest in this report primarily for their potential usefulness in evaluating the impacts of PPS (including the PRO program) on the quality of care.

Measures of Quality of Care

Measures of quality of care fall into three categories: structure, process, and outcome (85). "Structure" refers to the relatively fixed and stable parts of the medical care delivery system, such as numbers, types, and qualifications of professional personnel, physical facilities, and medical technologies. Criteria for such structural factors, which may be set by professional associations, regulatory bodies, or legislation, are often used for accreditation, licensing, and Medicare certification purposes.

"Process" measures reflect what is done to and for the patient: the application of medical procedures, drugs, nursing care, counseling, and the like. Typically, the process of care is evaluated against implicit or explicit criteria that reflect professional norms of practice; often such criteria are stated in terms of particular diagnostic or therapeutic practices at specific points in an episode of illness. Ultimately, however, assessing quality in terms of process gives an incomplete picture of patient benefits. The reason is that links between much of the process of medical care and eventual patient outcomes have not been clinically demonstrated (46).

"Outcomes," the results of patient care, are more direct reflections of patient benefits. They are measures of changes in the patient's actual

health status. Health status itself has many dimensions: the level of functioning in daily or usual activities, capacity for physical activity, emotional health, physiologic functioning of body organs, perceptions of and expectations of one's own general health, and even satisfaction with care. Most broadly, health status has been defined to include the physical, mental, and social well-being of individuals, not just the absence of disease (400).

Ideally, the benefits of medical care should be viewed in terms of effects on patients' outcomes—i.e., health status. At a fairly crude level, health status can be evaluated in terms of death or presence of serious illness or disability. Health status can also be assessed with respect to short-term physiologic factors, such as the presence or absence of fever or infection, or the level of functioning of a specific organ (e.g., kidney). These are relatively unambiguous measures, but they tend to be insensitive to small or incremental changes in medical practice.

A wide array of health status scales and indexes has been developed over the past 15 years (31,47, 378). Health status indexes typically focus on the physical and mental aspects of health and are constructed from separate items or measured by direct examination, interview, or self-administered questionnaires. Many have been shown to be highly reliable and valid, meaning that they will give reproducible results when administered more than once and that they provide information about the aspect(s) of health status they are purported to measure, not something else. Nonetheless, no one set of health status indexes currently available will comprehensively measure health outcomes for persons in the Medicare population.

Despite the fact that patient outcomes are the most desirable benchmark against which to assess quality of care, outcome measures have several drawbacks. One is that outcomes need to be evaluated over time: the patient's health status at the time of discharge from hospital may or may not indicate his or her health status in a week, a month, or a year. Another is that the collection of data on outcomes may be very expensive and intrusive, if, for instance, patients must be interviewed or examined directly.

Although process measures are more tentative indicators of quality, some do correlate directly with outcomes. Handwashing reduces infection, so use of surgical scrubs will improve surgical outcomes. Immunizations reduce the threat of communicable diseases such as influenza. Pap smears improve the likelihood of detecting and adequately treating cervical cancer. Followup of abnormal laboratory tests such as serum glucose levels may have dramatic implications for eventual patient outcomes. Administering an appropriate antibiotic based on a bacterial urine culture usually cures a urinary tract infection. Nursing care can prevent or reduce bedsores and skin ulcers. In these and other cases, explicit criteria for judging the quality of the process of care can be (or have been) developed through either the consensus of experts (usually physicians), the accumulation of evidence from clinical practice, or clinical trials and research.

For every example of a probable process-outcome link, however, there is one for which the evidence is equivocal. Hospital length of stay is a case in point. A recent OTA study concluded that variations in length of hospital stay for five diseases had not been shown to be related to differences in health outcomes (57), Patients with acute myocardial infarction or elective surgery who were discharged "early," for instance, fared no worse than those with traditionally longer lengths of stay. For psychiatric disorders, the evidence favoring shorter lengths of stay was strong. The medical literature, however, does not provide clear clinical criteria for *appropriate* lengths of stay (57). In this situation, judging quality by the process measure (i.e., length of stay) provides no indication of likely outcomes.

Previous evaluations of quality impacts of health care have used specific measures in all three categories (structure, process, and outcome). In-hospital mortality rates by specific patient condition or severity of illness are frequently used outcome measures in studies of the quality of hospital care (107,108,403). Population-based mortality rates by age, sex, and race have been used in broader analyses of the effects of health care programs (47,125). Other outcome variables have

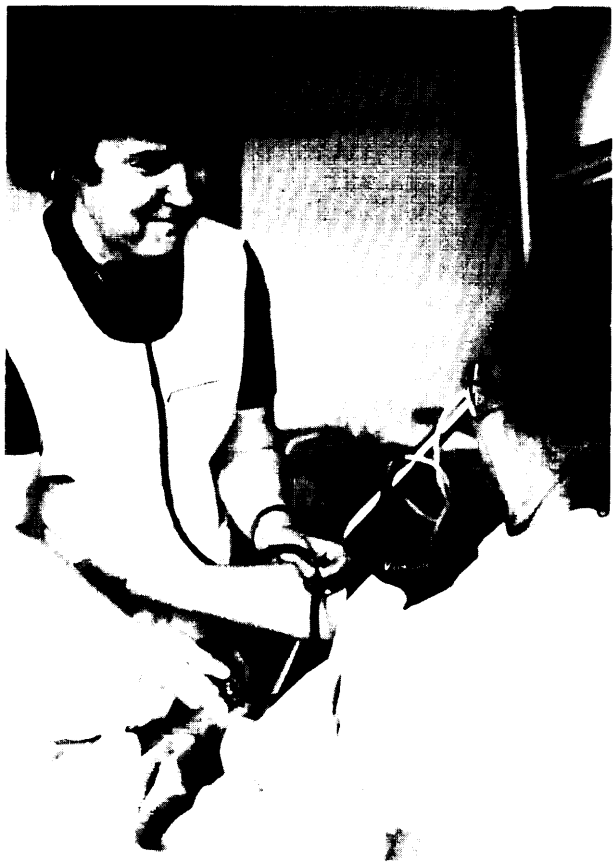

Photo credit Fairfax Hospital Association

Determining the impact of changes in nursing care on patient health outcomes is an important component of evaluating the impact of PPS on quality of care, yet this impact is difficult to measure.

included health status indexes (44,47), patient satisfaction (44,47), and hospital readmission rates (403). Typically, these analyses are conducted for specific "tracer" conditions, identified as medical conditions whose outcomes are likely to be sensitive to the administrative or clinical decisions of health care providers (44,313,403).

Structural variables and process criteria have been used in some evaluations of health care programs but with a great deal of caution. Structural quality measures, such as accreditation status, staffing levels, or availability of specific services, have been used occasionally (403). Process criteria have been used more often (225,313,403). The method of selecting process criteria and validation of process criteria against outcomes takes on great importance in studies using these quality indicators. For example, in a study of the quality impacts of State-level hospital ratesetting programs, the intensity of ancillary service[2] utilization and length of stay were selected as process measures of quality (403). Yet, documentation of either increases or decreases in these variables says little about the ultimate quality of care. Indeed, if there were substantial evidence of a strong relationship between general measures of intensity of care and patient outcome, the ratesetting programs under evaluation, whose primary purpose is to reduce service intensity, would probably not have been initiated in the first place.

To summarize, a balanced assessment of quality of care requires attention to both process and outcomes; this may be especially true for any evaluation of Medicare's PPS. PPS will change medical and hospital care in as yet unknown ways and to unknown degrees. Focusing exclusively on process means learning very little about the impacts of PPS on Medicare patients, Conversely, measuring only outcomes means learning very little about which changes wrought by PPS had good, bad, or neutral impacts—information that will be critical in planning or implementing further changes in the Medicare program.

[2]Ancillary services are technologies used in the hospital that are typically billed separately from routine services. They include diagnostic radiology, radiation therapy, clinical laboratory, and other special services.

POTENTIAL IMPACTS OF PPS ON QUALITY OF CARE

This section explores the potential effects of PPS on the quality of care for Medicare beneficiaries through an analysis of the financial incentives inherent in PPS. As the section will demonstrate, some effects are likely to be positive, others deleterious to quality. And some people may benefit from PPS in the quality of care they receive, while others suffer.

This section also examines the ways in which the PRO program can be expected to enhance or moderate the basic effects of PPS. Because PROS are an integral part of PPS, charged both with containing Medicare outlays through the review of hospital admissions and with assuring the quality of hospital care for Medicare beneficiaries, they are likely to have strong direct and indirect impacts on quality. Appendix G contains a detailed discussion of the current role and potential effects of PROS in this regard.

PPS Incentives That May Affect Quality of Care

Table 6-1 presents the major financial incentives of PPS that may affect the quality of care received by Medicare patients. The eventual net impact of these incentives depends heavily on physician practice patterns, preexisting levels of inefficiency in hospital care, current levels of quality in hospitals and other medical care delivery sites, and physicians' and hospital managers' willingness to respond to financial incentives given their competing goals and constraints.

Specific PPS financial incentives (e.g., to lower length of stay, increase admissions, specialize in particular services, or induce unprofitable patients to seek care at other sites) will have both positive and negative effects on quality of care. The main goal of PPS is to encourage hospitals to adopt more efficient ways of delivering patient care. Chief among these ways is to reduce the number and kinds of services provided to patients. As shown in table 6-1, quality might well be improved through such cutbacks. With earlier discharge from the hospital, for instance, patients may face a lower risk of iatrogenic events[3]; they may also enjoy a more comfortable and psychologically beneficial recuperation at home or in a short-term nursing facility.

However, quality of care could be affected negatively by PPS. Premature discharges may necessitate readmission (or cycles of discharges and readmission); illnesses treatable at an early stage could progress undetected to a much more serious degree; patients could be forced to acquire followup care in inappropriate settings, with ramifications for both their physical and mental well-being. If total PPS expenditures are constrained to a point where adequate care simply cannot be rendered, outcomes could be seriously compromised.

Photo credit: Fairfax Hospital Association

The fact that PPS may spur specialization in particular types of services may increase quality of care, especially for surgical procedures (e. g., coronary surgery) where high volume is correlated with high quality.

Distribution of PPS Effects on Quality of Care

Some regions or institutions will undoubtedly find it harder than others to cope under Medicare's PPS; in these regions or institutions, quality of care is likely to be more severely affected. Under PPS, Medicare payments to hospitals for patients in specific diagnosis-related groups (DRGs) are based on average resource use, and the dispersion around that average can be very wide. Within any DRG, elderly patients may require resources close to the average, well above the average, or well below it. Hospitals that admit mostly patients whose needs are at or below the average, even inefficient hospitals, may make money. Those that admit patients whose needs are mainly at or above the average may lose money.

[3]Iatrogenic events are misadventures occurring because patients are hospitalized. They include broken bones from falls (either out of bed or because elderly ambulatory patients are unattended), decubitus ulcers from insufficient nursing attention (turning, bathing, and the like), infections from bacteria indigenous to hospitals, and problems related to drugs or medications (interactions of incompatible drugs; improper dosages, etc.).

Table 6-1 .—Potential Effects of Provider Financial Incentives Under PPS on Quality of Care

Financial incentive	Behavior depends on	Possible positive effects	Possible negative effects
To reduce length of hospital stay	• Physician practice patterns • Hospital management practices	• May increase psychological benefits for patients • May lessen chance of iatrogenic events	• May lead to discharge of sicker patients (may lead to pattern of admission/discharge/ad mission)
To increase admissions	• Physician practice patterns . Ratio of DRG price to cost	• May build specialty in particular DRGs in a hospital	. May increase psychological costs for patients • May increase possibility of iatrogenic events
To avoid admitting "unprofitable" patients	• "Unprofitable" DRGs • Ability to identify severely i l l patients at admission	• May increase specialization by eliminating some services	• May decrease access for some patients
To decrease use of services or change mix of services	• Physician practice patterns • Hospital management practices . Hospital purchasing decisions	• May decrease use of unnecessary services • May decrease risk from diagnostic tests and invasive procedures	• May decrease use of necessary technologies . May increase use of cheaper and less effective materials, devices, and supplies • May decrease use of specialized personnel where needed
To shift patients to nonhospital sites of care	. Physician practice and patient acceptance	• May lessen chance of iatrogenic events • May increase access to other appropriate types of care	. May decrease access to appropriate hospitalization
To increase hospital specialization	• Physician specialties within the hospital • Ratios of DRG price to cost	• May increase volume in specific services (high volume often correlates with high-quality outcomes)	• May decrease access for certain patients (locations may not be accessible) or for particular diseases (no hospital will want to specialize in a DRG that loses money overall)

SOURCE Off Ice of Technology Assessment, 1985

Hospitals feeling little or no financial threat from PPS may thus be in a good position to maintain or even improve the quality of care rendered, especially if by doing so they can attract more cases into DRGs that are "profitable" for them. Improvements in quality of care may well spill over to all patients admitted into these institutions. In contrast, hospitals with patient populations that put them in serious financial straits under PPS may have to cut back on services to a degree that compromises quality of care, not just for those patients with higher-than-average needs but for all their patients. In the absence of some form of balancing, this phenomenon can become a self-perpetuating downward cycle for some hospitals and for the patients served by those institutions.

Some DRGs are very heterogeneous, with numerous diagnostic and treatment options that may differ widely in cost. For instance, the two DRGs concerned with gastrointestinal bleeding (DRGs #174 and #175) include patients who are bleeding from anywhere in the gastrointestinal tract, and appropriate diagnostic and therapeutic options range very widely (152). Care that is correct for the average patient with gastrointestinal bleeding, if adopted as the standard for patients admitted in these DRGs, may produce poor outcomes for those patients with both more and less serious problems.

Even efficient hospitals can lose money when DRGs consistently do not cover the costs of needed services. This may happen if a DRG has been priced incorrectly or when the average level of severity of illness within one DRG increases without a corresponding drop in severity of illness within a similarly priced DRG. It may also occur if the natural evolution of medical practice leads to more outpatient management of patients who formerly would have been admitted, leaving only the more severely ill to be hospitalized without corresponding changes in DRG prices. Recalibration of DRG prices that occurs only infrequently may not forestall the negative impacts on quality imposed by these problems,

The Influence of PROS on Quality of Care[4]

The PRO program was established by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) as a direct successor to the PSRO program; it was modified the following year by the Social Security Amendments that inaugurated PPS (Public Law 98-21). PROS, which are administered by HCFA, have substantial responsibilities for monitoring and controlling changes in hospital admissions, readmissions, and transfers that are predicted to increase in response to PPS incentives; PROS are also expected to carry out quality-of-care review. They are not required to review the quality of care delivered by nonhospital providers.

Most of the responsibilities delegated to PROS by HCFA pertain to the review of hospital admissions and use of invasive procedures, largely for cost-containment purposes. However, PROS are also required to identify and meet specific objectives in five general areas relating to quality of care. [5]

Several admissions review activities required of PROS have stringent numerical objectives, as do all five quality-of-care areas. The general quality objectives for the first 2-year contract period, which are common to all PRO contracts, were defined by HCFA. Within them, however, PROS were given flexibility to identify local problems and devise local approaches to solve them. The actual quantitative objectives were arrived at during contract negotiations with HCFA.

[4]This section is based on app. G, which is taken from K.N.Lohr, "Peer Review Organizations (PROS): Quality Assurance in Medicare, " prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, July 1985.

[5]The five quality-of-care areas are: 1) reducing unnecessary hospital readmission due to previously substandard care; 2) reducing the risk of mortality associated with selected procedures and or conditions requiring hospitalization (211) (recently changed by HCFA from "decreasing avoidable deaths"):3) lowering unnecessary surgery; 4) curtailing avoidable postoperative or other complications; and 5) assuring provision of medical services which, if not given, would have significant potential for causing serious patient complications,

The direction in which the PRO program influences the quality of care depends not only on the extent to which PROS make appropriate choices in the selection of specific quality assurance issues, but also on how they carry out admissions review functions. Some critics have argued that PROS may treat both the quality and admissions objectives as quotas for limiting Medicare hospitalizations irrespective of whether or not they are appropriate. In that case, PROS could actually reduce rather than enhance the quality of care rendered to some Medicare beneficiaries. Thus, despite the explicit recognition of a quality assurance role for the PROS, the simultaneous existence of other cost-containment objectives and HCFA'S reliance on numerical objectives for the evaluation of PRO contracts leaves the net impact of PROS on quality of care largely unpredictable.

The limitations of PROS as a quality assurance mechanism are heightened by funding issues. PROS have a sizable budget—$339 million for the first 2-year cycle—but it is small in proportion to the $100+ billions that may be spent by Medicare just for hospital care in the equivalent 2 years. Furthermore, the portion of the PRO budgets directed to quality assurance may also be small because of the large number of other required functions and the uncertainty about the importance that will be placed on quality of care when contract performances are evaluated. If even as much as 25 percent of PRO budgets were spent for quality reviews, a miniscule proportion of the amount spent on inpatient care would be going for quality assurance,

APPROACHES TO EVALUATING THE IMPACTS OF PPS ON THE QUALITY OF CARE

Critical Evaluation Questions

Medicare's PPS for inpatient hospital services clearly has the capacity to alter the quality of care delivered to the elderly in both good and bad ways. Some of the changes are likely to be dramatic, others subtle and difficult to detect. The importance of maintaining an acceptable level of quality of care while reforming the payment system suggests that evaluation of PPS impacts on quality of care should occur on two levels: first, the identification of major negative impacts of PPS on quality of care; and second, a more balanced assessment of the less dramatic changes that are likely to take place in both directions. The first level of evaluation is of the highest priority, but it need not, and perhaps should not, occur earlier than studies in the second category. Because some serious negative consequences of PPS may take years to develop, a plan for evaluating quality impacts must have a long-run perspective.

Evaluation of PPS quality impacts also must consider effects on both the quality of hospital care and the quality of care received in other settings. PPS will have its most immediate impacts in the hospital itself, but over time, as access to care in different settings changes, the impacts on quality will shift to the entire medical care delivery system.

These considerations lead to three critical evaluation questions:

- What, if any, negative effects has PPS had on the quality of hospital care for Medicare beneficiaries?
- What is the net effect of PPS on the quality of hospital care for Medicare beneficiaries?
- How has PPS affected the quality of care in nonhospital settings of care?

Each of these questions is examined in greater detail below.

Evaluating Serious Negative Effects of PPS on the Quality of Hospital Care

Several outcome measures can be used to detect serious negative effects of PPS on the quality of hospital care. Among them are: 1) in-hospital and postdischarge mortality rates; 2) rates of occurrence of complications or iatrogenic events or illnesses; and 3) readmission rates. Most of these data items are reasonably accessible from

Medicare databases, but because they are relatively rare events, large samples will 'be needed for precise estimation.

In-hospital and postdischarge mortality rates can be measured as total death rates across institutions or for specified types of facilities, rates specific to patient populations (e.g., the very elderly), and rates specific to diagnosis, surgical procedure, or DRG (and combinations thereof). Postdischarge death rates can be measured at various intervals following discharge (such as 1 week or 1 month). Of course, increases in in-hospital and postdischarge mortality rates are to be expected if the less seriously ill patients are shifted to outpatient settings due to PPS incentives or PRO admissions review. Thus, attention needs to be paid to the question of whether elderly patients with given medical conditions or with similar levels of severity of illness are dying in the hospital or shortly after discharge at rates demonstrably above those of the pre-PPS era.

Iatrogenic events are infections, drug reactions, or other mishaps due to treatment in the hospital, These and other preventable problems, sometimes called "sentinel events, " can be a signal that quality of care has declined (254). They will help in distinguishing between very bad care and adequate care, so they can serve as useful screening indicators of the direction that inpatient quality of care may be taking. They will not be as useful in distinguishing between satisfactory and excellent inpatient care, and they are not especially pertinent to ambulatory care.

Iatrogenic problems may already be more common than is sometimes recognized; the question is whether the rates of such problems increase as PPS incentives to reduce services and personnel begin to take hold. '

Readmission are defined as admissions to the hospital following a prior hospitalization within a specified period of time (PROS will review any readmission within 7 days of a prior admission). For a variety of reasons, readmission can reflect a deterioration in the quality of care, so these merit early and close attention. They will occur for several reasons, and care must be taken to attribute to PPS only those that are likely results of the incentives inherent in PPS.

Some patients will require rehospitalization for unrelated problems (e. g., elective surgery followed by admission for an acute problem such as a fracture or a fall). Readmission can also occur if routine testing or specialized consultations are curtailed, so that unsuspected problems are not detected or confirmed on a first admission, Thus, it is important to determine if PPS incentives for curbing length of stay, routine testing, followup of diagnostic tests, and specialty consults seem to be associated with a rise in readmission of this sort.

Readmission can also be prompted by complications arising from surgery. Some complications may be relatively unavoidable, of course, but whereas in the past the patient may have had a long length of stay in a single hospitalization, under PPS the patient may be discharged and later return to the hospital, Other complications may be direct outcomes of poor surgical, medical, or nursing care due to PPS changes in procedures or personnel. Complications may occur for patients who are relatively poor risks for surgery; because PPS incentives favor surgical over medical care for certain types of patients (221,273), this may be an especially difficult area to assess, [7]

Readmission may also occur because of inappropriate care or inadequate recuperation before discharge (without any overt complications). This phenomenon of "premature" discharge is especially hard to detect or evaluate: early discharges may be quite beneficial for some patients, but they do not return to the hospital and are thus not easily incorporated into a balanced evaluation,

Finally, one form of "readmission" arises from sequencing of admissions, one for diagnostic testing and workup and a second for surgery or other definitive therapy. In general, return to the hospital in such circumstances may be undesirable,

[6] In one pre-PPS study in a university hospital, 36 percent of 815 consecutive patients on a general medical service had an iatrogenic illness; most of these were related to drugs (278).

[7] Examining changes in the proportions of patients in medical surgical "pairs" of DRGs may he instructive Such pairs include DRG #243 (medical back problems) and DRGs #214 and #215 (back and neck procedures) or DRGs #235 and #236 (fractures of the femur, hip, and pelvis treated nonsurgically) and DRGs #209 to #211 (surgical procedures on major joints, hip, and femur).

because of the possible increase in out-of-pocket costs to the patient and the probable rise in anxiety and family disruption. Certainly, the last pattern appears to be less likely to be in the patient's interest than in the hospitals.

In all the areas just mentioned, the crucial evaluation question to be addressed first is whether mortality rates, rates of preventable complications, readmission rates, and the like for patients with similar conditions, are higher in the PPS period than previously, independent of any underlying trends. If they are not, the Nation might be reasonably assured that PPS has not induced provider behaviors seriously inimical to the health and well-being of the elderly. If they are, thorough evaluation efforts must be directed at determining and rectifying the cause(s) for apparently harmful effects of PPS.

Evaluating the Net Effect of PPS on the Quality of Hospital Care

An important limitation of mortality rates, readmission rates, or sentinel events is that such rates alone are poor measures of more subtle changes in inpatient care for the elderly. Even if death or readmission rates show little or no change, PPS may have effects in terms of time to full recovery, chronic impairments, or emotional well-being. Moreover, because they are relatively rare events, relying on them to appear in sufficient number to trigger corrective action means that some patients may be harmed.

Examination of the processes of care and "proximate" (i. e., short-term) outcomes of care rendered in the hospital will provide balanced evidence of PPS effects (or lack of them) that is far more convincing to the medical profession, the policymaking community, and the Medicare population than studies based on crude outcome measures. Only medical record audit is likely to provide pre- and post-PPS data with the requisite reliability, validity, and clinical detail.

Such studies would require abstracting medical records (for two time periods, such as 1981 and 1985) for condition-specific process and outcome variables related to medical and nursing care in a nationally representative sample of hospitals within the four census regions (or, better, within the nine census divisions). Important aspects of such studies are that they account for patient complexity (sociodemographic variables such as age and income, level of severity of illness for which the person is hospitalized, and underlying levels of health status and comorbidity). They should cover a range of conditions reflecting medical and surgical reasons for admission. The conditions should be ones for which the medical literature provides consensus on appropriate processes of care and expected patient outcomes, for which information is readily available in the hospital chart, and that account for a large fraction of medical admissions.

Evaluating the Effects of PPS on Quality of Care in Nonhospital Settings

The predicted reductions in lengths of hospital stay, increases in patient transfers, and increases in the use of outpatient care (both for surgery and for postdischarge followup) all argue for study of the quality of care prior to admission and the outcomes of care after discharge. PPS' emphasis on reducing hospital use also calls for special attention to the subset of patients who are never admitted, either because their conditions can be treated adequately on an ambulatory basis or because their poverty or severity of illness makes them "undesirable" patients. With more (and sicker) elderly patients obtaining care in ambulatory settings, from home health and other community agencies, and in long-term care facilities, the need for greater attention to quality of care from those sources is apparent.

The first line of inquiry, of course, is to monitor population-based mortality rates in the elderly population by age, sex, and race. But these measures are likely to be relatively insensitive to the influence of PPS. Hence, they are not likely to provide much insight into this important question. Study of the broader effects of PPS requires longitudinal studies of panels of patients or cohorts of Medicare beneficiaries whose course of diagnosis, treatment, and recovery can be tracked through an entire episode of illness, regardless of whether care was rendered in a physician's office, a freestanding or outpatient surgical clinic, a hospital, a skilled nursing home or intermediate care facility, or the like. Patient outcomes such as

physical functioning, emotional well-being, and capacity for independent living, as well as effects on family members, are all critical dimensions of care to be evaluated. These are more amenable to targeted research efforts than to broad statistical analyses based on routine databases.

Data Sources

Data for addressing the critical evaluation questions in the area of PPS impacts on quality of care can be obtained from a variety of sources. The basic sources of information, listed in the order of feasibility and ease of use in evaluation, are: 1) Medicare claims; 2) discharge abstract data sets; 3) medical records; 4) patient surveys; and 5) findings from patient examinations and patient or family interviews and questionnaires.

By and large, data from Medicare claims and discharge abstract data sets tend to be cheaper to obtain and thus available for a larger number of individuals. Information on Medicare program claims, for instance, is essentially automatically available (albeit with a delay of several months from date of service). These data sources tend to suffer more from unreliability (missing data, poor coding of key information such as diagnosis or procedures, inconsistency across sources) and from poor validity (i.e., what they reflect about processes of care may correlate only poorly with patient outcomes). They also tell little about problems related to underservice (needed tests or procedures not performed, drugs not administered) or delay in obtaining care.

Data from patients' medical records, patient surveys, and findings from patient examinations are more expensive to collect, with a corresponding drop in the number of persons who can be studied.[8] They are likely to be both more reliable and more valid. They provide a mechanism for learning about relatively subtle aspects of health status, such as physical functioning *or emo*tional well-being, as well as a means of understanding relationships between process and outcome. Finally, they are a direct way to document the extent and effect on quality of reduced access and underservice.

Table 6-2 summarizes and compares the contents of five national databases on patient characteristics: Medicare Part A and Part B claims, the PRO Hospital Discharge Data Set (PHDDS), the Hospital Discharge Survey (HDS), and Commission on Professional and Hospital Activities **(CPHA)** data. These and other sources of data that could be used to evaluate PPS impacts on quality of care are described in detail below.

Medicare Claims

Claims filed on behalf of Medicare beneficiaries pertain mainly to inpatient stays in short-stay acute hospitals (Part A) or to care received in ambulatory settings (Part B). Such claims, which are processed and reported to HCFA by fiscal intermediaries and carriers, form the Medicare Statistical System data files. The Part A and Part B files are generally not integrated; linking the inpatient and outpatient files for all individual Medicare patients has been considered until recently a prohibitively difficult task.[9] The Medicare History Sample has demographic and utilization data since 1974 for both Part A and Part B services for a continuing 5-percent sample of beneficiaries (see app. E), but the lag in availability of this file reduces its usefulness for evaluation.

Part A claims-based data on hospital stays are submitted to HCFA by fiscal intermediaries (contractors that administer Part A payments) and are compiled in the Hospital Stay Record. The Stay Record includes the following elements: beneficiary identification number (usually Social Security number); demographic information such as age, sex, and State of residence; hospital where admitted; up to five diagnoses for the admission; up to three procedures performed during the admission; status (alive or not) and destination (e. g., home, nursing home, intermediate care facility, home health care) upon discharge; dates of admission and discharge; days spent in intensive or coronary care units; and aggregate dollar charges

[8] For example, abstracting new data directly from patients' medical records could cost as much as $40 per case (188,224). For a study using 1,000 records in each of three conditions, abstracting costs alone would be $120,000.

[9] HCFA has recognized the need to use parts of the Medicare Statistical System simultaneously and is currently trying to develop a sample file that merges Parts A and B data. This file, the "Medicare Automated Data Ret Rertieval System (MADRS), is described in app. E.

Table 6-2.— Data Elements in Patient-Based National Databases

	Medicare claims		Discharge abstracts		
Major data elements	Part A billing records	Part B billing records	PHDDS	HDS	CPHA
Medicare beneficiary identifier	X		X		
Patient name	X	X	X		X
Date of birth (or age)	X	X	X	X	X
Sex	X	X	X	X	X
Race	X	X	X	X	
Marital status				X	X
Zip code of residence	X		X	X	X
Medical record number	X			X	
Hospital identifier	X		X[a]	X	
HDS number				X	
Date of admission	X		X	X	X
Type of admission (emergency, urgent, elective)	X		X		
Source of admission	X		X		
Date of discharge	X		X	X	X
Disposition of patient (home health care, nursing home, home/self care, etc.)	X		X	X	
Diagnoses:					
Admitting diagnosis	X		X		X
Principal diagnosis	X		X	X	X
Up to four secondary diagnoses	X		X		X
Procedures:					
Principal procedure and date	X		X		X
Up to two secondary procedures and dates	X		X		X
Abnormal tissue indicator					X
Number of days in special care units	X				X
Attending physician	X	X			X
Operating physician	X				
Expected principal source(s) of payment	X				X
Type of PRO review and action (e.g., preadmission/preprocedure review, admission review, outlier review; approval or denial)					
Actual dollars paid	X	X			
Current DRG assigned	X				
Original DRG assigned	X				
Pricer action code	X				
Billing and payment dates		X			
Medicare eligibility status (e.g., aged, disabled, end-stage renal disease)		X			
Outpatient psychiatric charges		X			
Reasonable medical (nonpsychiatric) charges		X			
Place of service (e.g., office, home, independent laboratory)		X			
Type of service (e.g., medical care, surgery, diagnostic X-ray)		X			

ABBREVIATIONS CPHAS - Commission on Professional and Hospital Actlv!tles
HDS = Hospital Discharge Survey
PHDDS = PRO Hospital Discharge Data Set

aRecent additlon to the national database

SOURCES U S Department of Health and Human Services, Health Care Financing Administration, *Meal/care Sfaf/sf/ca/ Files* &fanua/ (Balt!more, MD" HCFA, September 1983), National Academy of Sciences Institute of Medicine, *Reliability of National Hospital Discharge Survey Data* (Washington, DC: NAS, 1980), U S Department of Health and Human Services, Health Care Financing Administration, "PRO Hospital Discharge Data Set Tape Layout, " Baltimore, MD, 1984, and Commission on Professional and Hospital Activities, "PAS Case Abstract"' form, Ann Arbor, MI, 1984

for various hospital services and departments such as pathology, radiology, or physical therapy.

Part B claims-based data are submitted by Medicare carriers (contractors that administer Part B payments) on payment records following their payment of Medicare bills. There are 36 items reported on each Part B payment record, many of them for administrative purposes within HCFA. Data elements from Part B payment records that could be useful in quality of care assessments include the following: patient's name; Medicare status; expense period dates; outpatient psychiatric charges; reimbursement amount; reasonable medical charges (nonpsychiatric); deductible applied; physician or supplier identification code; sex; place of service for the largest charge (e.g., office, home, outpatient hospital, independent laboratory, independent kidney disease treatment center); type of service (e. g., medical care, surgery, consultation, diagnostic X-ray, radiation therapy); physician or supplier specialty code; beneficiary date of birth; and race.

One drawback to using Medicare billing data for quality studies is the lack of comparability and compatibility between the Part A and Part B databases. For instance, the coding systems differ: Part A procedure codes since 1980 have been based on the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) (and before 1980 were based on the International Classification of Diseases, Adapted, 8th Revision), whereas Part B procedure codes are based on the Current Procedural Terminology (CPT). Although CPT codes can be classified in the ICD system, the ICD codes cannot be put into CPT. Worse, by the time Part B data reach HCFA, they no longer contain any diagnostic or procedural information, meaning that tracking shifts in the sites of care or changes in the processes of care for specific illnesses is infeasible from these sources alone.

Other major parts of the Medicare database that could be used in quality studies are the Provider of Services File, which gives detailed information about hospitals and nursing homes, and the Health Insurance Master Enrollment File, which is a cumulative file on all individuals ever eligible for Medicare benefits. The latter includes dates of death.

Discharge Abstracts

Most hospitals use some medical records abstracting scheme to process patient care information. Although specific items may vary by abstracting service, the common core of information usually includes items specified for the Uniform Hospital Discharge Data Set (UHDDS) as defined by the U.S. Committee on Vital and Health Statistics: patient identification, date of birth, sex, race and ethnicity, residence, hospital identification, admission and discharge dates, identifiers for admission and operating physician(s), principal diagnosis, procedures and dates done, disposition of patient, and expected source of payment.

PROS compile a more complete version of UHDDS for Medicare known as PHDDS (the PRO Hospital Discharge Data Set), adding data regarding various review activities and more detailed information about the admission (see table 6-2). Some of this information (e.g., patient's name and names of physicians) is never reported to HCFA. PHDDS thus provides a stream of information quite similar to, but completely independent of, the Medicare claims data that are *re*ported to HCFA by the fiscal intermediaries and that constitute the Part A Hospital Stay Record files .'"

[10]In years past, the forerunner to PHDDS, the PSRO Hospital Discharge Data Set, was considered to have much more reliable, valid, and complete data, especially for diagnosis and procedure, than the corresponding Part A files, Unlike the Part A file, however, this data set was not necessarily a full enumeration of Medicare admissions because not all areas of the country had an operational PSRO, Because of the extreme sensitivity of DRG-based payments to diagnostic and procedural information, most observers expect the Part A files now being compiled to be considerably improved compared to the pre-PPS era. These improvements in recording and coding, although clearly welcome, complicate studying changes in medical practice (and quality of care) over time with just HCFA Medicare data,

Exactly how much improvement will be realized, and how quickly, are being monitored. Early in PPS, the HCFA central data processing office was alerted to an unexpectedly high error rate in DRG assignment, and 15 million PPS claims were rerun to check DRG assignments for all Medicare patients under PPS from Oct, 1, 1983 through Dec. 31, 1984. Checking the internal consistency of the data, HCFA found that the error rate dropped from 5.48 percent for the first PPS quarter (October 1983 through December 1983) to 1.59 percent in the fifth PPS quarter (October 1984 through December 1984), This indicates a fairly rapid improvement. At this time, reasons for the errors and whether they are random or systematic are unknown (265).

HDS is a federally supported abstract system begun in 1964 by NCHS and carried out by the Bureau of the Census. HDS is based on a set of hospitals selected from a stratified sample of hospitals; patient records are then systematically sampled within selected hospitals. Most items in the HDS come from the face sheet of the medical record (see table 6-2). Most have been collected consistently over time, although some changes in definitions of certain items mean that trends must be interpreted carefully; this is especially true of principal diagnosis (214).

CPHA administers **a** private sector abstracting service. CPHA is a voluntary nonprofit organization to which over 1,500 hospitals provide a set of data in return for various interinstitutional comparative analyses and internal medical cost analyses. The data collected by CPHA contain all of the data elements of the UHDDS, as well as indicators for abnormal tissue and the number of days in care units (see table 6-2). A subset of 250 to 300 hospitals provide data on costs and various diagnostic tests. Although data are available over a period of years for a national, representative sample of hospitals, the data are confidential and cannot be linked to identify hospitals, so all analyses must be done by CPHA staff on a contract basis (105).

The Hospital Cost and Utilization Project (HCUP) of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR&HCTA) is another Federal database that contains discharge abstract data. The information for HCUP comes from 12 major discharge abstract services, the American Hospital Association's Annual Survey of Hospitals, and Medicare cost reports. These data files link abstracted clinical information on patients with hospital cost information and community characteristics. Data are available for over 300 short-term, general, non-Federal hospitals for 1970 through 1977. New data are to be collected for 1980 through 1987 from an enlarged sample of about 500 hospitals. Although some of the patient-level charge data are incomplete, HCUP is a potential source of linked quality and cost data (351).

Medical Records and Medical Record Audits

A considerably richer source of quality of care data is the patients' medical records. The content of most hospital medical records in this country reflects standards set forth by the Joint Commission on the Accreditation of Hospitals (JCAH): "The medical record shall contain sufficient information to identify the patient, to support the diagnosis, to justify the treatment, and to document the results accurately. " Detailed requirements for the following elements are published by JCAH (155): identification data; medical history of the patient; report of a relevant physical examination; diagnostic and therapeutic orders; evidence of appropriate informed consent; clinical observations, includin, results of therapy; reports of procedures, tests, and their results; and conclusions at termination of hospitalization or evaluation / treatment.

Medical record data do have some limitations. Some quality-related information will be absent from even the most detailed records, including information relating to postdischarge outpatient care, longer term outcomes such as length of time to full recovery and functioning (or death out of hospital), and patient satisfaction. The reliability and validity of abstract data taken from medical records have been questioned (212,213,214). Finally, collecting evaluation information through medical record abstracting ("audit" or "chart review") tends to be more costly than using insurance claims data.

In general, the accuracy and comprehensiveness of medical record data, especially when collected by trained medical record abstracters, far surpasses that of insurance claims or discharge abstract data. An evaluation of PPS that examines changes in in-hospital processes of care and their relationship to outcomes for the aged would require data collected directly from medical records. Any PPS evaluation that is extended to out-of-hospital impacts, for which almost no adequate claims data exist, would also have to rely in part on medical record data.

Patient Surveys and Direct **Data** Collection

As noted earlier, measures of patients' health status, often based on self-administered questionnaires, are available to be employed in or adapted for an evaluation of PPS effects on quality of care. No one set of measures will serve the full range of PPS evaluation needs, because some indicators

pertain more to outcomes of ambulatory than inpatient care and some are more appropriate for nonelderly populations than for the elderly. Furthermore, these types of indexes or indicators relate more to patient outcomes, such as long-term physical functioning or mental health, than to actual processes of care.

Nonetheless, most of the currently available health status measures would provide adequate bases for devising measures related to what effect PPS may have had on quality of care *over* the longer run or for more subtle changes of health. Highly reliable and valid measures of patient satisfaction are also readily available.

CONCLUSIONS

Because the issues that can be identified in the area of PPS impacts on quality of care are so numerous and complex, some priorities as to the most critical evaluation questions must be set. This chapter has outlined the following points.

First, inarguably negative effects of PPS on quality must be anticipated by monitoring changes in the following: deaths; postoperative or other complications; "sentinel events" that reflect preventable negative outcomes such as infection or drug reactions; readmission (including "second" or "sequences of" admissions); and discharge destinations. Often, this monitoring can be accomplished using administrative data such as Medicare insurance claims files and by agencies such as PROS. This type of assessment can be (and some is being) done in the near term.

Second, PPS assessments must examine processes and outcomes of hospital care and their relationships. Critical questions are whether changes in in-hospital processes of care are taking place, whether any such process changes are related to expected patient outcomes, and if so, in what ways patient outcomes are being affected. These types of assessments rely less on administrative data and more on costly direct data collection methods such as medical record audit, patient and family interviews, and health status measurement survey instruments. The advantage of these kinds of evaluations is that they provide stronger evidence of both positive and negative ramifications of prospective payment on quality of care.

Third, PPS can have far-reaching ramifications, especially for long-term care and for outpatient services. Investigating how the outcomes of care are changing in the post-PPS era, with evidence strong enough to link such changes at least provisionally to PPS, will be a third critical evaluation issue before the end of the decade.

Congress recognized the potential threat to quality of care of PPS and built at least two safeguards into relevant legislation. PROS have responsibility for monitoring the quality of care in addition to numerous activities relating to cost containment. And, for the first **4** years, HCFA must report to Congress annually on the broad impacts of PPS, including quality of care (see ch. 10). Yet the question remains whether these arrangements will provide adequate information on the quality impacts of PPS.

PROS are responsible for protecting against certain extreme effects of PPS on inpatient care, but their responsibility stops at the hospital door; severe funding constraints and uncertainty about priorities will restrict PROS' attention to quality of care. They also have cost-containment objectives that, under certain circumstances, could counter the quality assurance efforts.

HCFA has generally been accepted by the Administration as the agency to conduct major PPS evaluations (see ch. 10). As the source of the major routine databases (e. g., Medicare claims and beneficiary history files), this agency is most familiar with the potential strengths and weaknesses of the data. The fact that HCFA is not entirely disinterested in the outcome of such studies, however, may pose questions of bias. External (extramural) research would lessen concerns that any evaluation performed by the agency that has administrative responsibility for PPS will lack full credibility, but congressional oversight of HCFA's role in supporting such evaluations could help

protect the integrity of these research efforts. A second problem is that present or contemplated HCFA Office of Research and Demonstrations budgets and staff for PPS research and evaluation, especially in the quality-of-care area, are inadequate (see ch. 10); this is certainly true if longer term patient outcomes are to be monitored or the linkages between processes and outcomes are to be documented and understood.

Other organizations and agencies within DHHS could also carry out substantial parts of the PPS evaluations. Both the Office of the Assistant Secretary for Planning and Evaluation and the NCHSR&HCTA have considerable experience with funding and managing large and lengthy studies of this sort done by outside contractors and grantees. Because they are external agencies with respect to the administration of PPS, questions about credibility and integrity of the research effort would be minimized. Reliance on these agencies, however, would require coordination with and cooperation from HCFA for access to data.

As with HCFA, however, current funding levels for these agencies would not sustain very comprehensive evaluations, almost certainly not ones requiring medical record abstraction or direct data collection from elderly patients or families. Furthermore, any PPS evaluation done by a DHHS agency will be subject to an additional level of control, expense, and delay by the Federal bureaucracy if the Office of Management and Budget requires detailed clearance of data collection materials, questionnaires, medical record audit forms, and the like.

Any evaluation of the effects of PPS on quality of care will be costly, but actual funding requirements will vary depending on the degree to which the evaluation attempts to be comprehensive (i. e., to cover all the critical evaluation questions). The least expensive evaluations will rely nearly exclusively on existing data systems, largely Medicare claims files, but such evaluations will be subject to the limitations and restrictions inherent in those databases.

Selecting ways to assess PPS impacts on quality does not imply choosing one strategy or database to the exclusion of all others; the optimal approach will probably be one that incorporates some work along all the lines discussed. The high cost of in-depth studies reinforces the need for careful specification of process and outcome (health status measures). Allocation of resources to the development of a consensus about the quality measures to be evaluated would be prudent.