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Clinical decision making and information management in the era of managed care

FARRELL J LLOYD AND VALERIE F REYNA

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Current models of managed care impose significant administrative burdens, but their benefits for costs and quality have not been unambiguously demonstrated. We introduce an alternative approach that incorporates providers' decisions as the fundamental unit of analysis, as well as evidence-based practice guidelines, medical outcomes, and measures of efficiency that are tied to clinical indicators of quality of care. Information management can improve outcomes data, but outcomes cannot be interpreted in the absence of information about decision making. Realistic proposals to affect providers' decisions must incorporate research that provides insight into cognitive processes and how these processes affect health care delivery.

INTRODUCTION

The economic infrastructure of medical practice is undergoing rapid change. Recent developments include the emergence of managed care, and its spread from regional enclaves throughout the USA. These changes have subjected medicine to greater scrutiny, especially regarding health care costs and quality. In this chapter, we explore the implications of these economic developments for the practice of medicine. Although the chapter is directed primarily at practitioners, the framework we introduce should also be of practical benefit to health care administrators and policy makers.

We begin with a brief review of the problems that precipitated recent changes in health care. Then, we discuss the nature of these changes, such as the shift from a fee-for-service reimbursement system to capitation, and how they affect the day-to-day practice of medicine. Next, we analyze the assumptions behind these new approaches and introduce an alternative framework that addresses some of the same concerns (e.g. costs and quality of care) but that is without, we believe, some of the drawbacks of current models of managed care and quality improvement. As shall be seen, this alternative framework highlights the importance of clinical information management and decision analysis in providing objective measures of performance for both health care systems and individual practitioners.

BACKGROUND

'Health care crisis' and rise of managed care

Although there is debate about the precise origins of the so-called 'health care crisis', most observers agree that rapidly increasing health care costs were the precipitating factor. Costs, in turn, were related to induced demand (e.g. increasing hospital beds), price inflation, employer-based insurance, rising numbers of uninsured, and government's expanding role in financing health care.[1] By introducing business efficiencies, it was thought that such costs could be contained. Managing care, then, consisted of implementing efficient business practices. A key assumption underlying managed care is that there is 'waste' in the health care system that can be eliminated without jeopardizing quality of care.[2]

Managed care uses a variety of methods to organize providers including preferred provider organizations (PPO), managed service organizations (MSO), provider hospital organizations (PHO), independent practice associations (IPA), group practice plans, and staff models. (Health maintenance organizations, HMOs, are businesses that use managed care and may employ providers in any one of these methods.) These methods can be distinguished according to the degree to which providers have autonomy. For example, physicians in PPOs may be in private practice (with a discounted fee schedule and contracted with HMOs), whereas physicians in staff model organizations typically are salaried employees.

Managed care also uses a variety of methods to control costs. The 'gatekeeper' model, in which primary care physicians constrain referral of patients to specialists, procedures, tests and evaluations, was designed to minimize unnecessary care in order to conserve economic resources (and, ostensibly, to protect patients from overtreatment).[3] In addition to gatekeeping, managed care uses clinical resource management methods, such as referral review, prior approval for admissions and procedures, restricted drug formularies, and case management to reduce length of hospital stays. Clinical resource management includes what is commonly referred to as utilization management (UM),[4] which most often pertains to out-patient referral authorization processes. Utilization review (UR) usually applies to a *post hoc* review of referrals (whereas UM involves a priori review).

Financial methods are also used that establish incentives to providers to reduce costs. These range from discounted fee-for-service to full capitated risk. In the latter, providers are paid a fixed amount per patient over a specified time, usually per month of a contracted period (i.e. per member per month). Thus, costs incurred treating patients are deducted from a provider's predetermined income. Utilization management, therefore, is used to keep providers' expenses within their predetermined budget.

Clinical resource management is defined relative to appropriate care. That is, costs should be reduced only to the extent that unnecessary or inappropriate care is eliminated. Quality assurance (QA) and, more recently, quality improvement (QI) are designed to address underutilization. Quality improvement as an industrial concept is increasingly accepted as a standard in health care delivery.[5] Some health care organizations report success in reducing inappropriate variability by employing industrial quality improvement methods.[6] An extensive description of these methods is beyond the scope of this chapter. The key points relating to health care include:

- concentrating on process rather than individuals;
- breaking down the process to standard data elements and performing statistical analysis to identify variability;
- instituting guidelines to reduce variability; and
- providing feedback to decision makers on their measured variability.[7]

The intent of these efforts is to reduce and ultimately eliminate inappropriate variability in the processes of health care with an assumption that this will lead to better patient outcomes.

Although reports of industrial methods of quality improvement are appearing in the medical literature,[8] most often, QA and QI amount to compliance with external standards such as the Health Employer Data Information Set (HEDIS)[9] established by the National Commission on Quality Assurance (NCQA)[10], and the Joint Commission for Accreditation of Health Care Organizations (JCAHO).[11] Quality improvement standards in health care take different forms depending on the way providers are organized.[12] For example, HEDIS was designed primarily for HMOs for accreditation purposes, and JCAHO is primarily used by hospitals for accreditation purposes but is evolving to include integrated out-patient and in-patient delivery systems. Other delivery systems (e.g. PPOs and IPAs) employ an array of standards that vary with the particulars of contracts and accrediting agencies. These methods of external evaluation tend to emphasize process outcomes (e.g. number of patients immunized) rather than clinical outcomes (e.g. mortality).

Role of protocols and guidelines

Improving clinical outcomes has been a motivating factor in the development of practice guidelines.[13] Guidelines can take the form of recommendations of professional organizations, such as the National Cholesterol Education Program.[14] As the industrial methods of quality improvement have gained favor, guidelines have been regarded as a possible solution to rising costs.[15] The assumption is that, if providers are given the appropriate guidelines, patient care will improve because patients will receive the necessary treatment without the risk of over- or undertreatment. This assumption was the impetus for the federal government's decision to sponsor the development of clinical practice guidelines.[16] The Agency for Health Care Policy and Research (AHCPR) developed a number of these guidelines that are also available on the World Wide Web (now called the Agency for Healthcare Research and Quality; AHRQ). Since 1999, clinical practice guidelines have been available through the National Guideline Clearinghouse (http://www.guideline.gov).

Effects of new demands on clinical practice

What impact, if any, AHCPR and other guidelines have made in actual clinical practice remains unclear.

Empirical evidence of their adoption is lacking.[17] One retrospective analysis indicated that adopting the guideline on the Diagnosis and Management of Unstable Angina would have little impact in actual clinical settings.[18] This conclusion was based on the finding that few low-risk patients were identified and, therefore, that there was little opportunity to decrease unnecessary admissions. However, these results underestimated the number of low-risk patients for whom significant reductions in admissions might have been made.[19]

The ability of physicians and delivery systems to incorporate these guidelines into clinical decision making is also untested. Once implemented, improving the guidelines and updating them is also problematic. Efforts to incorporate guidelines into computer-aided decision support systems are under way. Despite some success in a few health centers,[8] these methods are not routinely used. One problem is that the information systems requirements change as the delivery systems needs change. That is, as delivery systems undergo a transformation to managed care and its various processes, the information needs of the organization can change dramatically, placing new demands on the expectations of automated systems.

The shift from traditional fee-for-service to full-risk capitation reimbursement creates new administrative and clinical demands as well. Documentation and justification of treatment plans is usually required to a much greater extent. Drug formularies may change frequently and physicians are expected to stop therapeutic medication and order new medication on the formulary. The number of patients in a physician panel becomes a critical number because income is increased on a per member basis (not on the basis of services rendered). Increasing numbers in patient panels means that physicians have patients whom they have never seen demanding prescriptions and referrals. These patients are assigned to the provider but have not been seen (ABNS) and may be treated in emergency rooms with instructions to follow-up with their primary physician. Therefore, the primary care physician is responsible for large numbers of patients with whom they are unfamiliar.

As administrative barriers are erected as a result of managed care, patients' calls to medical offices multiply due to patient demands for non-formulary medications, emergency consultations, and referrals. Requested referrals for procedures, tests, and evaluations are usually scrutinized and may be denied after having been discussed as needed with patients. Often, this referral denial is not communicated until considerable time has elapsed from the original encounter. Patients may believe that the physician is the denying party, creating a perception that the physician is no longer an advocate for the patient. Adverse incentives, usually financial, that encourage underutilization of procedures, tests, and evaluations may further undermine the advocacy role of the physician. In practice, physicians are rarely provided feedback by QA and QI about specific instances of underutilization, although feedback is occasionally given about overutilization through UM or UR.[4]

Assumptions of managed care

Although the assumption is that managed care reduces costs,[20] such reductions have not been rigorously demonstrated. For example, the point of diminishing returns, at which economic benefits no longer justify gatekeeping, is poorly defined in practice. Managed-care organizations typically do not perform empirical analyses of the trade-offs between complex approval processes for referrals and their economic returns. The observation that most referrals are approved in most systems does not necessarily imply that costs are not contained by these methods. The procedures, tests, and evaluations that are denied may be among the most expensive (although little evidence exists to support that conjecture). Also, the possibility of scrutiny has been shown to inhibit utilization.[21] However, specific efforts to reduce costs have not been directly linked to documented decreases in costs.

Another major assumption of managed care is that efforts to reduce costs will not adversely affect patient outcomes. Managed care contracts may turn over on a yearly or sooner basis, making long-term health benefits not especially relevant to short-term financial interests. As we have noted, QA and QI are assumed to counteract any tendency to underutilize. However, there is little conclusive evidence on this point. Arguments have been made that restricting access to specialists and advanced technology will deprive patients of timely care and ultimately lead to higher costs.[22] Research indicates, for example, that mortality rates for patients with acute coronary syndrome who are treated by cardiologists are lower than those treated by internists.[23,24] Hence, restricting access to cardiologists might be expected to lead to higher mortality for such patients. A direct comparison of managed care and fee-for-service patients with hypertension and diabetes mellitus found significantly lower subjective well-being for the former group (as measured by the Short Form 36 (SF-36)).[25] As these examples illustrate, however, there is a lack of research relating objective medical outcomes to different reimbursement structures. Thus, although anecdotes have been widely reported, conclusive evidence that managed care yields poor health outcomes is sparse.

Alternatively, the emphasis in some managed care organizations (e.g. many HMOs) on traditional preventive medicine (e.g. cancer screening, immunizations, coronary artery disease risk factor screening) may improve long-term outcomes (although the cost effectiveness of these efforts is in dispute). In addition, lack of access to specialty care in acute situations may offset any potential gains due to traditional prevention efforts. Despite the increased scrutiny of providers, neither

traditional nor newer managed-care approaches currently offer objective measures of quality of outcomes. However, NCQA and JCAHO are beginning to incorporate outcomes management in their accreditation requirements.[11]

These and other assumptions of managed care are shown below:

- no adverse outcomes as a result of UM and UR;
- excess quality in the system;
- physicians are ethical and not influenced by money;
- primary is better than specialty care;
- less technology is better than more technology;
- primary care is better than urgent care, which is better than emergency care;
- specialists are more expensive than primary care physicians;
- adherence to explicit standards results in quality, i.e. ensures good outcomes;
- provide explicit standards and compliance will follow;
- good providers can be distinguished from bad providers in terms of utilization and quality;
- more utilization is bad and less is good;
- case mix can be safely ignored in setting capitation rates and in comparing providers or provider groups despite differences in severity of illness.

In summary, health care delivery is experiencing a comprehensive transition in methods of provider reimbursement and this has created administrative complexities for patients and their physicians. The primary impact occurs when the financing of care changes from fee-for-service to full risk capitation. Managed care attempts to provide appropriate care by instituting administrative processes to reduce overutilization (UM, UR) and processes to prevent underutilization (QA, QI). Organizations and individual physicians have experienced a dramatic change in incentives to see and treat patients based on reimbursement issues. Since the financial incentives to physicians are changing, the question as to whether patient outcomes are better, worse, or no different, based on whether a physician or physician group is paid per case or per member per month has been the subject of recent debate. The question has not been answered definitively. Surprisingly, we have little data concerning the a priori decision making of the physician and the linking of these decisions to patients' medical outcomes.

AN ALTERNATIVE FRAMEWORK

As our discussion indicates, there are obstacles to meeting patients' needs in delivery systems with capitated managed care. Administrators, physicians, and patients require data to navigate these new trends in health care delivery. Administrators need input to deliver cost-effective and efficient care in order to compete in managed care markets. Physicians need information to improve decision making and accountability. Patients need information to help them choose quality health plans and reassurance that their physician is their advocate. A framework that leads to appropriate operational research will facilitate efforts to meet these needs.

In the framework that we propose, clinical decisions that are associated with disease processes are assessed and ultimately linked to patient outcomes. Disease processes consist of a series of clinical events and decisions across related episodes of care, from which outcomes are derived[26] (*see* Fig. 36.1). Knowledge of those processes allows outcomes to be explained and predicted. The nature of the outcomes determines health care costs and quality.

The framework is designed to improve health care by analyzing the practice of medicine with the highest quality as the ideal. We define quality as the best medical decision and the best implementation of this decision.[27] The framework uses information management to relate clinical decisions to patient outcomes. Information management facilitates the measurement and interpretation of both clinical decision making (e.g. clinical assessments and plans) and administrative processes (e.g. UM and QI). The result is a description of the relationships among provider characteristics, patient characteristics, delivery-system characteristics, and patient outcomes (all of which bear on cost and quality). With this description, we can develop tools, such as computer software, to improve areas of deficiency in decisions and in their implementation. Therefore, our objectives include improved measurement, prediction, and intervention without the obtrusive administrative burden of current models of managed care.

Clinical decision making

The current emphasis on assessment of outcomes is a predictable consequence of the increasing scrutiny of medicine. Rising costs and putative 'overtreatment' have been used to justify oversight by business entities, as well as governmental, accrediting, and other regulatory agencies. Outcomes assessment addresses this desire for accountability. Theoretically, public and private expenditures can be rationally traded off against improvements in outcomes. The impact of changes in utilization management can be gauged so that underutilization is avoided. Thus, outcomes assessment can provide an empirical foundation for health care policies, both public and private.

In order to affect medical outcomes, however, it is necessary to understand how they are generated. Medical outcomes are the result of decisions made by patients and physicians in the context of available alternatives.

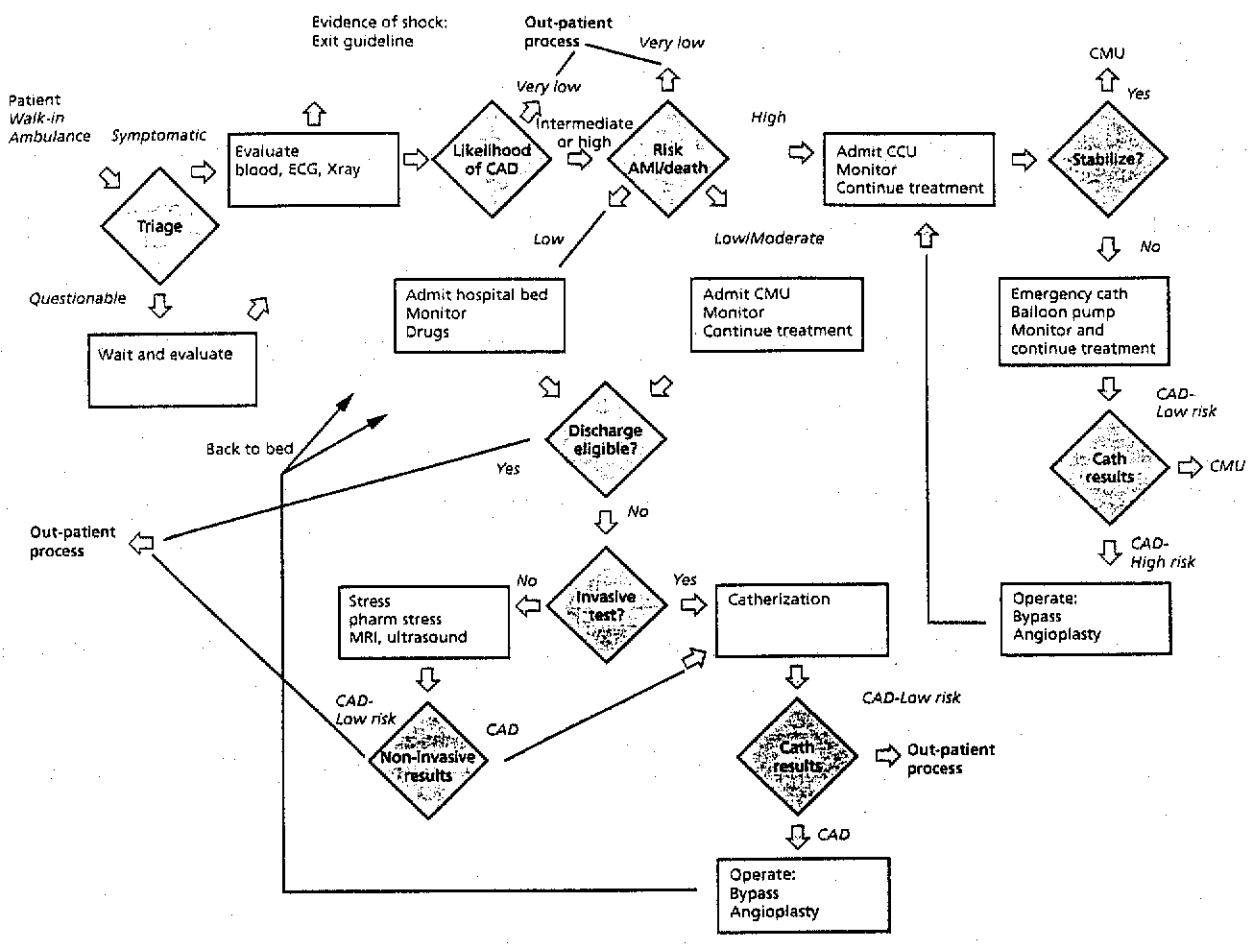

Figure 36.1 *In-patient chest pain process flow. AMI = acute myocardial infarction; CAD = coronary artery disease; Cath = catheterization; CCU = cardiovascular intensive care unit; CMU = cardiac monitoring unit (telemetry); ECG = electrocardiogram; MRI = magnetic resonance imaging; Pharm = pharmacological.*

One way to change medical outcomes, therefore, is to change the available alternatives, for instance, through advances in clinical research or reforms in government policy. The other way to change outcomes – the option that is of greater relevance in this chapter – is through changes in medical decision making.

Indeed, prior research has indicated that 'approximately 80% of health-care costs are associated with physician decision making'.[28] Of course, clinical outcomes are also directly influenced by physicians' decisions. Thus, physicians' decisions are a fundamental unit of analysis in evaluating costs and quality of care. Fortunately, an extensive and empirically grounded research literature exists regarding decision making.[29–32] That literature provides guidance about how the quality of decision making can be rigorously judged, and it contradicts some of the assumptions of the industrial model of quality control (as discussed later).

Moreover, medical outcomes cannot be interpreted in the absence of information about decision making. As is well known, good outcomes can be achieved in spite of poor medicine, and vice versa. The science of decision analysis offers concepts and techniques, used for decades in other fields, that provide a principled basis for judgments about human performance. In general, decision analysis does not impose particular beliefs or values on decision makers, but it does allow them (and others) to judge whether their decisions are consistent with those beliefs and values and with the laws of logic and probability.

Decision analysis can, for example, help physicians select an appropriate diagnostic threshold for breast cancer screening, one that reflects the relative frequency of occurrence of breast cancer and the 'benefits and costs, respectively, of correct and incorrect decisions'.[32] If physicians believe that failing to detect breast cancer is worse than falsely detecting it, their threshold for screening should be low. A low threshold, or lenient criterion, means that more true positives would be detected (at the expense of more false positives). However, the base rate of the positive condition should also influence the screening threshold. When the condi-

tion is common, a low threshold will correctly yield many positive decisions. When the condition is relatively rare, as in the case of breast cancer among women in their 40s, a low threshold will yield many false positives. At the level of clinical decision making, matters are further complicated by the need to incorporate risk factors that alter a priori probabilities for individual patients. The precise implications of clinical decisions may not be fully appreciated without a formal analysis of their potential consequences.

On the other hand, such formal analysis would not be warranted if the benefits to clinical practice were minimal. However, research has amply demonstrated that actual medical decisions can deviate considerably from formal prescriptions.[27,31] A host of systematic biases in information processing have been demonstrated in physicians, including difficulties in incorporating the key base rates noted above into judgments of risk and probability. These findings do not imply that most medical decisions are biased. On the contrary, research has also indicated that human information-processing strategies are generally adaptive.[33–36] It does suggest, however, that when deviations occur, they are likely to be widespread among physicians and to occur automatically and unconsciously. Decision analysis can be used to make these biases explicit.[37]

Decision analysis, then, indicates what the parameters of ideal decision making should be, and it can be used to evaluate actual decision making. In this view, variability in decision making is expected. Surprisingly, some of that variability is principled and, thus, defensible. If, for example, two physicians disagree about the a priori probability of disease, and both probability estimates are consistent with the research literature (or the absence of research), as long as their decision processes are internally coherent, they should not be faulted. Box 36.1 provides a detailed presentation of such a case. As we have seen, however, other kinds of variability indicate biases and cannot be logically defended. Decision analysis makes it possible to discriminate good from bad variability.

The applicability of decision analysis to the development of health care policies and to the establishment of system-wide clinical protocols is, in principle, straightforward. Guidelines concerning the ordering of diagnostic or screening tests, for example, should reflect deliberate choices about tradeoffs among base rates and different kinds of decision errors. Multiple tests should be minimized on the basis of their informativeness, providing superior information to physicians while reducing costs. Utilization management and quality improvement should be consistent with rational constraints on decision making. If such guidelines and protocols were developed, health care systems could then focus on effectively implementing coherent policies. Although these changes are feasible at the system level, there are reasons to believe that the ideal of decision analysis is difficult to implement at the level of individual decision makers.

Consider our earlier analysis of breast cancer screening. Balancing the factors involved in a decision to order a screening mammogram in a 45-year-old woman is cognitively complex. As noted, that process is fraught with reasoning biases that have little to do with level of knowledge or training.[31,33] If we assumed that human information processing is analogous to machine computation, then we would design tools and interventions that helped physicians process more information more thoroughly and more quantitatively.[38] However, recent research indicates that human reasoning is primarily qualitative.[33–36] Qualitative reasoning has been shown to underlie judgment and decision making even in quantitatively sophisticated populations, such as statisticians.[31] In fact, increasing the detail and precision of thinking has been shown to increase human error.[39] Reasoning seems to compensate for weaknesses in verbatim memory and processing by relying on intuitive gist-like mental representations of information. Thus, it is impractical to assume that physicians will base day-to-day decisions on formal analysis, and errors might be exacerbated if they did.

Research also shows, however, that interventions can be designed that are compatible with humans' intuitive decision making and that improve performance. Thus, realistic proposals to affect physicians' decisions must include research that provides insight into the measurement and interpretation of cognitive processes, as well as into how these processes affect systemic aspects of health care delivery. Our framework is designed to capitalize on such research, especially about intuitive decision processes, and to translate it into recommendations for practice.

Some progress has been made without an awareness of the research in this area, however. Based on efforts to teach formal decision analysis, observers have concluded that this kind of analysis is time consuming and not likely to be readily embraced by physicians. Decision analysis techniques, which are based on Bayes' theorem and other probabilistic models, may predict patient outcomes acceptably but these techniques may not be incorporated into clinical decision making at the individual patient encounter because of predictable cognitive barriers. For example, empirical evidence exists that humans make systematic errors when information is presented in different, though equivalent, formats.[40,41] This leads to questions that are not addressed in decision analysis alone, but that concern those cognitive characteristics of decision makers that determine decisions and, therefore, patient outcomes.

Implications of the framework for managed care

Although biases are somewhat disturbing, cognitive research also has the potential to lead to important inter-

ventions that may improve patient outcomes by improving the decision making of providers. In addition, a framework that incorporates the important aspects of human decision making is likely to lead to better health care delivery systems. Unlike many industrial products like a computer chip, our patients' health care may never be standardized, even with ideal non-variable implementation processes, because of the relative unpredictable nature of biologic systems and the inherent and appropriate variability in human decision making.

In the industrial model of quality improvement, the process, not individuals, is the object of interest. The variability of outcomes is measured as a performance indicator. In our framework, in contrast, the decision processes of individuals must be taken into account and these are seen as a source of outcomes. As we have discussed, diagnosis and management in many clinical scenarios results in practice variability. The industrial assumptions about variability may hold in, for example, well-defined surgical procedures and pre- and post-surgical management[8] but, in other areas, such as evaluating patients with chest pain, variability is likely to be refractory.

Using the industrial model, health care systems are attempting to measure practice variability, as well as physician productivity and patient outcomes. The example in Box 36.1 illustrates the difficulty of these tasks. If the administrators of an emergency room (ER) had a guideline which placed the patient in Box 36.1 at high/intermediate risk and the emergency physician discharged the patient to home, the hospital may believe the physician is in error. Conversely, if the guideline rated the patient as low/intermediate and the ER physi-

Box 36.1 *An example of decision making in clinical cardiology*

Clinical scenario

Two physicians are discussing a patient that was evaluated in the emergency room recently for a chief complaint of chest pain. Ms G. is a 49-year-old premenopausal female who reported sharp chest pain under her left breast and radiating to her left arm. The pain occurred while running the cash register at her business and has re-occurred on exertion and at rest. The pain resolved after taking her husband's nitroglycerin. On evaluation Ms G. has hypertension treated with a calcium-channel blocker, she smokes one pack of cigarettes per day and has for 20 years, her cholesterol is 180 mg/dL, her triglycerides are normal and high-density lipoprotein is 55. She has no history of diabetes. Her mother died at the age of 72 of an acute myocardial infarction. The emergency room physician, after noting that the electrocardiogram was normal and Ms G's physical examination was non-diagnostic, placed Ms G. on aspirin and a nitroglycerin patch, and sent her to the medicine out-patient clinic for further evaluation and management of possible unstable angina.

Clinical impressions of physician A and physician B

Physician A acknowledges there is some risk but believes it to be low. Physician B is concerned that Ms G. is at high risk for acute coronary syndrome. When asked to quantify their subjective probability estimates, physician A reports 30% or less and physician B reports 80% or more. Which physician is correct? What is the correct test to order: an exercise tolerance test (ETT), stress sestamibi or thallium, dipyridimole sestamibi, dobutamine echo, positron emission tomography scan, cardiac catheterization? An important point is that both physicians may be correct based on published data on prevalence of coronary artery disease.[47–50]

Diagnostic test ordered

The physicians agree that an ETT is the appropriate next step. Ms G. achieved 85% of expected heart rate and exercised for a total of 12 minutes with no ST or T-wave abnormalities noted. Physician A is satisfied but physician B is not, and is considering a nuclear stress test or possibly a cardiac catheterization. Which physician is correct?

Examination of positive and negative predictive values

Based on their a priori probability estimates, the negative predictive value of an ETT for physician A would be above 85%; however, for physician B it is below 45%. (Given a positive test the predictive values would be just the reverse: 46% for physician A and 89% for physician B.) When examining these numbers, we may begin to see that both physicians have evidence to support their point of view. The ETT was a good test for physician A because of the relatively high negative predictive value (given physician A's a priori probability). However, physician B is not so sure given the relatively low negative predictive value (given physician B's a priori probability). For this physician the correct initial test may have been a stress sestamibi, stress echo, or a cardiac catheterization. For example, the negative predictive value would approach 80% for the stress sestamibi, and if the test were negative, the physician may have more confidence in the result. This example is illustrative of the range in possible pretest probabilities given present clinical research.

Assumptions analyzed

This example illustrates physicians' use of probability calculations to order diagnostic tests, which is possible but not very probable. In fact, there may be systematic bias in the subjective estimates of pretest probabilities and there are likely to be systematic errors in interpretation of diagnostic tests. This has been demonstrated in cognitive research, and empirically confirmed in medical decision making, and may have profound effects on patient outcomes.

cian admitted the patient the physician would also be considered in error. The clinic physician who orders a stress sestamibi may be considered an overutilizer because he did not order the cheaper exercise tolerance test (ETT) when in fact the sestamibi may be the appropriate test given the physician's a priori risk estimate.[31] This expected and appropriate variability, if unaccounted for, could lead to administrative rules that produce systematically worse patient outcomes in terms of both cost and quality.

The example in Box 36.1 can also be used to illustrate the linking of physician decision making and utilization of clinical resources. Measuring appropriate utilization, then, depends not only on patient characteristics but on decision making characteristics.

There are three standard ways to evaluate decisions.[42] One is to compare the decision to some externally derived standard such as a guideline. Preferably the guideline has been validated empirically with at least a preponderance of strong evidence, such as medical outcomes, to support it. Another method would be to compare decision makers – that is, to compare one physician's decisions to that of the group (the so-called 'consensus' method or 'standard of care'). A third would be to evaluate the decision based on internal coherence, which is a minimal expectation that a decision maker agrees with his or her own estimations of risk.

Implementation of the decision

In our framework, quality of care includes decision making and the implementation of the decision. Implementation of a decision as part of a traditional quality improvement methodology involves improving performance of the delivery system's administration of services. This kind of industrial model is now commonly employed in health care delivery. Efficiency and effectiveness in terms of customer satisfaction have been the targets of NCQA and JCAHO, as well as numerous reengineering efforts of health care delivery systems.[43] Important components of these efforts are that the health care organizations employing these methods must measure efficiency, effectiveness, and cost appropriately. Again, variability is the key to most quality improvement efforts with the assumption being that reducing variability will lead to higher quality.

Our framework also incorporates measures of efficiency and effectiveness, and of customer satisfaction. However, in our view, efficiency and effectiveness must be tied to clinical indicators of quality of care. Health care systems should be judged by the timeliness and accuracy with which they implement the best medical decisions. Those aspects of customer satisfaction that are more closely tied with good patient outcomes should receive greater weight. Evaluations of administrative systems' delivery of services should be based on reliable data that is appropriately analyzed so that it accurately reflects cost and quality. For example, the evaluation of an electronic medical record should not depend solely on case histories from other institutions or on a site visit at which anecdotes about effectiveness are traded. Instead, performance should be assessed by such measures as the time taken for encounters before versus after adoption, or the availability of chart information and its effect on adherence to clinical guidelines. Thus, our framework includes measurement of the performance of providers and of the systemic aspects of health care delivery. To employ the framework, accurate indicators of cost and quality must be analyzed, such as patient outcomes. The framework takes into account patient outcomes and links these outcomes to patient and provider characteristics.

In summary, the framework allows analysis of the relationships between cost and quality. Specifically, the framework is designed to facilitate the ability of health care systems to:

1 provide measurably appropriate care to patients;
2 generate reliable estimates of costs and accurate measures of quality;
3 establish contracts that are outcomes-based, thereby shifting the emphasis from care at the lowest cost to the lowest-cost best care provided;
4 identify, collect, and analyze the data needed to provide information, ensuring (1), (2), and (3), above;
5 obtain the tools to perform (4) above, that will facilitate cost and quality improvements.

Application of the framework to clinical practice

Consider how points (1)–(5) are reflected in gatekeeping. Physicians, physician assistants, and nurse practitioners all see patients and are referred to as providers in managed care plans. As described above, in many instances the plans encourage a gatekeeper system. The primary care provider then is responsible for referring patients to specialists, and for special examinations such as magnetic resonance imaging, positron emission tomography, sestamibi, cardiac catheterization, physical therapy, etc. Several questions have been raised about this system including: is quality reduced, improved, or no different from standard fee-for-service; are primary care providers diagnosing and managing patients more efficiently; are fewer patients receiving high-technology care; does the physician reimbursement scheme influence ordering behavior; and are patient outcomes affected?

According to the framework, these questions could be addressed by studying providers as gatekeepers and comparing their decision making to non-gatekeeper providers. Disease processes could be mapped across episodes of care for different providers using information systems to track related episodes. After measuring the provider's decisions, the effect of decision making on outcomes can be assessed. To accomplish this, we must link disease-specific patient episodes of care and measure the clinical and cost outcomes.

As an illustration of how such a framework would apply in practice, consider a patient, Mr Jones, a 77-year-old member of a senior care HMO. He began experiencing substernal chest pressure that awoke him from sleep. It went away with three sublingual nitroglycerin spaced 5 minutes apart. The next morning Mr Jones called his primary care provider's (PCP) office. He was transferred to the triage nurse in the PCP's clinic who advised Mr Jones to go to the emergency room. Upon arrival at the emergency room, the physician evaluates Mr Jones and makes a determination of risk of coronary artery disease and of the possibility of acute myocardial infarction. She may decide to admit Mr Jones or discharge Mr Jones with out-patient follow-up. She also may decide to order diagnostic tests. If she admits Mr Jones, she may order a cardiac intensive care, telemetry, or regular ward bed.

Assume that she sent Mr Jones home with instructions to follow-up with his PCP. Mr Jones calls to get an appointment and is told that his PCP's next available appointment is in 2 months. He tells the scheduler that he needs an earlier appointment and is transferred to the clinic triage nurse who schedules a same-day or urgent-care visit with another doctor. (Mr Jones's doctor has no available slots.) When Mr Jones is seen in the clinic, his chart is unavailable but the physician assesses Mr Jones, who has had two similar episodes in the last 2 days. The physician decides to add a calcium-channel blocker and writes a referral for an ETT. He also tells Mr Jones to make an appointment with his PCP. Mr Jones leaves the clinic with instructions to call back 'in a few days' to see if the ETT is approved and to schedule the test. He is given an appointment with his PCP (to be seen in 2 months).

How can the framework help identify whether appropriate decisions were made? First, we identify all of the medical decision makers: the triage nurse, the emergency physician, the urgent-care physician (note that the PCP may or may not be aware of the situation). Were appropriate decisions made? Were the decisions implemented appropriately? What is the patient's expected outcome(s)? The patient may be at high, intermediate, or low risk of death or acute myocardial infarction, and he may have high, intermediate, or low likelihood of coronary artery disease. Clinical decision makers estimate these probabilities, if only implicitly. We can expect that if he is at high risk of acute myocardial infarction and he is not admitted to the hospital with unstable angina he is at increased risk of poor outcome(s).

In addition, an elderly person negotiating through this process may have difficulty complying with the requests for a 'call back in a few days'. Given that decisions were made without the benefit of a chart, did the patient's memory serve him well enough to recall medications or past work-ups?[44] Did the patient's providers have access to alternate forms of information, such as shadow charts or automated information? Did the providers caring for the patient page the PCP and discuss the case? Was the referral processed and approved efficiently? Was an appropriate appointment made for the ETT? Were the results conveyed to one of the patient's providers? Was the calcium-channel blocker on the HMO's formulary?

Databases and information management

The above example is meant to serve as 'grist for the mill' in forming hypotheses that the framework can test. The data gathering, analysis, and linkage, i.e. operational research, requires sophisticated information systems. The technical capability is present to perform these tasks but they have yet to be tested. With the framework in mind, two questions should be asked of any information system. Does the technology improve clinical decision making? Does it improve implementation of the decision? A database that was formed as a result of this operational research would be valuable in forming contracts. Because such a database would link episodes of care (e.g. from emergency room to out-patient clinic to the cardiac stress testing laboratory), it would contain the key information for predictions in terms of cost and quality.

For example, HMOs may be considering contracting with a multispecialty physician group and hospital for all chest pain service. A disease management strategy could be seen as a way to improve economic efficiency. In order to manage the contract well, the physician group should collect data on presentation to the emergency room that allows the prediction of cost and quality over the following year. The physician group then can negotiate from a much better position when determining whether the HMO's capitation rate is advantageous. The HMO will be interested in such data as well because this will quantify any cost-quality gaps that may be real or perceived, and could help improve the HMO's market share.

The electronic medical record is touted as having solutions to many of the problems we have discussed.[7,38] Unfortunately, empirical evidence of its utility is sparse. There are, however, reports of success with certain processes such as order entry and hospital management. A major issue is the shift in emphasis from hospital to out-patient care. Many of the out-patient systems are only months from initial testing in actual clinical

environments. Order entry systems have been shown to improve physician compliance with minimal standards of quality.[28] These systems also may be helpful in the referral management process but this remains untested as well.

Information systems should be compatible with human information processing, which research shows is intuitive, i.e. qualitative and gist-based. Therefore, large amounts of precise detail should be eschewed in favor of information displays that do not create confusion or information overload. Thus, an information system in the era of managed care should have the following characteristics:

- referral management;
- documentation capabilities that comply with practice standards;
- ability to manage and display order entry, and results of procedures, tests and evaluations;
- clinical assistance, such as dealing with multiple formularies;
- tools such as e-mail and access to information sources, such as Medline;
- implementation issues, such as maintenance and security, are known upfront;
- technical capabilities are consistent with an open architecture to ensure accurate and reliable reporting capabilities.

FUTURE DIRECTIONS

Implications for physicians in the emerging medical market place

Physicians are being asked to serve in a number of new roles in the emerging medical market place. For example, physicians will be serving on committees to develop clinical guidelines, establish policies for utilization management, review provider decisions regarding procedures, tests and evaluations, implement NCQA and JCAHO requirements, manage new delivery systems, reduce costs and re-engineer clinics and hospitals, select electronic medical records, and advise/consent on negotiated contracts. Using the framework described above, physicians can generate critical questions that will address the cost and quality implications of proposed changes. These questions fall into two categories: those concerning the physician–patient relationship, and the system-level operations.

In dealing with patients, physicians should ask whether their decisions are consistent with high-quality practice guidelines, peer groups, and the laws of logic and probability. The best decisions, however, will lead to poor outcomes if they are ineffectively implemented. Therefore, physicians should demand that operational infrastructure, including information systems, facilitate implementation of their clinical decisions. Information systems, such as electronic medical records, hold promise since disease processes could be mapped from decisions across episodes of care to outcomes. Therefore, physicians must inquire about the capability of systems to perform these important linkages.

Physicians' input to operations will often occur in the context of their service on utilization management and quality improvement committees. In reviewing other physicians' decisions, the usual assumption is that variability is undesirable. Given the same patient, two physicians should reach the same decision. As an abstract ideal, this assumption is correct. However, uncertainty in the clinical literature and differences in experience (e.g. with different patient populations) justify some variability in judgments. By analyzing decision processes for internal coherence, this kind of justifiable variability can be identified. Thus, most diagnostic decisions are inherently uncertain. Simply providing protocols or guidelines cannot eliminate this uncertainty. Guidelines can play a useful role, however, in reducing uncertainty when combined with information about decision processes and patient outcomes. This 'three-legged stool' of guidelines, decision processes, and patient outcomes provides a foundation to measure quality of care. Appropriate utilization, then, depends not only on patient characteristics but also on decision-making characteristics.

As delivery systems seek to comply with accreditation and re-engineering efforts, physicians will be asked to help implement clinical components, and they can expect audits by internal and external reviewers. Quality standards that focus on service requirements should be distinguished from standards that have direct implications for clinical outcomes. For example, NCQA's requirements on timely appointments may be considered a direct indicator of clinical efficiency but an indirect indicator of clinical quality. That is, new patients who are not given appointments within a few weeks of the request (efficiency) should be distinguished from patients with high risk of coronary artery disease or high risk of acute myocardial infarction who are not admitted to the coronary intensive care unit (quality).

Concerns about quality have arisen because, with capitation, organizations have financial incentives to withhold care. In fact, incentives in managed care are often the mirror image of those in fee-for-service reimbursement where there are financial incentives to overtreat. The difficulty lies in determining whether over- or undertreatment has occurred. According to our framework, adherence to evidence-based guidelines is one indicator of decision-making quality. For example, a guideline might indicate that a patient should be admitted to a hospital but the patient was actually discharged and vice versa. Undertreatment would correspond to failure to admit (when indicated by the guide-

line) and overtreatment to unnecessary admission. In a fee-for-service system, failure to admit leads to a loss in revenue and unnecessary admissions may increase revenue. In a capitated system, failure to admit prevents short-term revenue loss. Unnecessary admissions, of course, are a financial loss. Therefore, although treatment of patients incurs costs in both systems, reimbursement incentives are different.

The obvious financial loss associated with failure to admit in fee-for-service systems may also apply to capitated systems, however. The long-term costs of undertreatment may outweigh any short-term gain. For example, a high-risk patient for acute coronary syndrome who is discharged from the emergency room inappropriately may develop an acute myocardial infarction leading to cardiogenic shock with placement of a balloon pump after admission to the cardiovascular intensive care unit (CCU). If the patient had been admitted on first presentation and received a cardiac catheterization with resultant percutaneous transluminal coronary angioplasty, the CCU admission would likely have been prevented. The cost of the CCU admission is assessed against the capitated budget as are any out-patient evaluations. These costs are frequently overlooked in capitated systems and may not be fully recovered in fee-for-service systems.[45] Thus, short-term decision making, and resultant cost shifting, should be discouraged to reduce overall health care costs.

Regardless of the health care system or reimbursement mechanisms, over- and undertreatment are indicative of poor quality. Health care organizations and policy makers should measure the frequency of these errors.[46] Their interpretation, however, requires a decision analytic framework that incorporates clinical outcomes. Such a framework provides explicit definitions of quality and empirical measures of errors. A scientific approach to understanding the cost of quality health care will allow policymakers to focus on those issues that are likely to have the greatest impact on patients.

SUMMARY

- The shift from a fee-for-service reimbursement system to capitation is changing the day-to-day practice of medicine, subjecting physicians to greater administrative oversight.
- Utilization management is used to conserve resources within a capitated budget; quality improvement is an industrial concept used to ensure that care does not fall below an acceptable standard.
- Protocols and guidelines are being developed in an attempt to standardize processes of care.
- Fundamental assumptions of managed care have yet to be tested including the tradeoffs involved in gatekeeping.
- An alternative framework is necessary that incorporates clinical information management and decision analysis to provide objective measures of performance for health care systems and practitioners.
- Quality of health care can be defined as the best medical decision and its best implementation.
- Guidelines, patient outcomes, and provider's decisions form the basis of quality measurement; outcome data are ambiguous without decision analysis.
- Clinical information systems can be used to link episodes of care, to generate reliable estimates of costs and accurate measures of quality, and to provide technological interventions that improve decision making.

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