Medical Error and Patient Safety: Understanding Cultures in Conflict*

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Evidence documenting the high rate of medical errors to patients has taken a prominent place on the health care radar screen. The injuries and deaths associated with medical errors represent a major public health problem with significant economic costs and erosion of trust in the health care system. Between 44,000 and 98,000 deaths due to preventable medical errors are estimated to occur each year, making medical errors the eighth leading cause of death in the United States. However, the recent prominence of the issue of safety *or* error *does not reflect a new phenomenon or sudden rift in the quality of health care (although it is a system fraying at the edges). Rather, the prominence of the issue reflects a radical change in the culture of health care, and in how relationships within the health care system are structured and perceived. In this paper, I discuss the multiple factors responsible for the change in the culture of health care. First, the culture has shifted from a clinician cantered system, in which decision making is one-sided, to a shared system of negotiated care between clinician and patient, and, often, between administrator or payer. Second, the nature of quality in health care has changed due to the geometric increase in the availability of technological and pharmaceutical enhancements to patient care. Third, the health care culture continues to rely on outdated models of conflict resolution. Finally, the regulatory structure of health system oversight was set in place when fee-for-service care governed physician–patient relationships and where few external technologies were available. In the current health care culture, that structure seems inadequate and diffuse, with multiple and overlapping federal and state regulatory structures that make implementation of patient safety systems difficult.*

I. INTRODUCTION

Evidence documenting the high rate of medical errors to patients has taken a prominent place on the health care radar screen. The term may more accurately be described as *unintended adverse medical events*. However, for purposes of this paper, I use the term *error*, although the term is not intended to indicate specific blame. In response to the growing recognition

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of the widespread occurrence of accidental patient injury or unintended adverse medical events and their impact on patients in the course of treatment, the Institute of Medicine (IOM) released a report in 2000 entitled *To Err is Human* (Kohn, Corrigan & Donaldson 2000). The IOM report noting that "as health care and the system that delivers it become more complex, the opportunity for errors abound," urged that the traditional clinical boundaries that discourage disclosure of adverse events be broken, and that the existing culture of blame be redirected.

The injuries and deaths associated with medical errors represent a major public health problem with significant economic costs and erosion of trust in the health care system. The IOM report estimated that between 44,000 and 98,000 deaths due to preventable medical errors are estimated to occur each year, accounting for more deaths than motor vehicle crashes, breast cancer or acquired immunodeficiency syndrome, and making medical errors the eighth leading cause of death in the United States. These data are controversial, but whether the number is high or low (and both claims have been made), the point was well-taken that, even in a country where the highest level of medical technology is available, both too-frequent lapses in the level of care and the effectiveness of numerous oversight systems lead to unintended adverse events. These events affect the ability not only of those with limited resources to engage with the health care system, but also those who receive the most sophisticated and expensive care**.** In 2001, the IOM followed with another report, *Crossing the Quality Chasm* (Institute of Medicine 2001), which concluded that errors are only the tip of the iceberg in the larger story about quality care. It noted that America's health system is a tangled, highly fragmented web that often wastes resources by providing unnecessary services and duplicating efforts that leave unaccountable gaps in care and fail to build on the strengths of all health professionals. The report recommended a revamped system that centered on the needs, preferences, and values of patients, and increased use of information technology.

This paper discusses the multiple factors responsible for the change in the culture of health care in the United States and elsewhere in the industrialized world. First, the culture has shifted from a clinician (usually physician)-cantered system in which decision making is one-sided, to a shared system of negotiated care between clinician and patient, as well as, often, between administrator or payer (health plan or insurance company). Second, the nature of quality in health care has changed due to the geometric increase in the availability of technological and pharmaceutical enhancements to patient care. Third, the health care culture continues to rely on outdated models of conflict resolution, either passive acceptance or malpractice litigation for the patient, and *the culture of blame* for the clinician. Finally, the regulatory structure of health system oversight was set in place when fee-for-service care governed physician-patient relationships, and where few external technologies (medical devices and pharmaceuticals) were available.

In the current health care culture, this structure seems inadequate and diffuse, with multiple and overlapping federal and state regulatory structures that make implementation of patient safety systems difficult.

II. INTERNATIONAL PERSPECTIVES ON PATIENT SAFETY

A. THE SCOPE OF THE PROBLEM

1. *Patient Safety Across National Boundaries*

Patient safety was initially perceived as a uniquely *American* problem, however, following the 2000 IOM report, other countries joined the discussion exposing errors within other health systems (Charatan 2000; Wilson et al. 1995; Quebec. Ministère de la Santé et des Services Sociaux de Québec 2001). These disclosures make clear that the prominence of the issue of *safety* or *error* does not reflect a new phenomenon or sudden rift in the quality of health care (although it is a system fraying at the edges). Rather, the prominence of the issue reflects a radical change in the culture of health care, and in how relationships within the health care system are structured and perceived.

2. *Health Care System Organization and Fragmentation*

(a) *Access to Care*

A number of factors have intensified the scope of the issue in the United States health care system, or at least have caused a louder and more aggressive response. Health care in the U.S. is fragmented, with the large majority of people receiving health care through a variety of private and employer-based insurance structures that offer vastly differing levels of care. For example, is it an error, when one person with a top-of-the line health insurance policy receives top-of-the line medication for a condition, while someone with a less generous policy receives a less expensive and possibly less effective medication? Or, what about differences in the quality of care in long-term care facilities accepting only privately paid patients compared to those accepting the much lower level of payment authorized by Medicaid? These issues might not exist in countries with universal health care.

(b) *Rationing and Equity*

Other issues do exist, and again might or might not be considered error (Davies & Nutley 2001). For example, if a U.S. hospital refused dialysis for an otherwise eligible person who is over age seventy, this action would be considered overt rationing and probably illegal. Such a practice might be considered appropriate, and even recommended, in another health care system where fewer dialysis machines may justify overt rationing on the

basis of age (Weale 1998). But in the U.S., subtle rationing on the basis of ability to pay, such as the medication differential described above, happens with impunity. At what point should this be considered *medical error* (Loewy 2001)? Moreover, a failure to exercise a community *standard of care* can be used as evidence of malpractice in the U.S. medical system which has extensive malpractice litigation structures that far exceed those of other countries. Proof of what is a *standard of care*, however, is based on the testimony of practicing physicians, and not necessarily on specified standards of safe practice (Bovbjerg 1998).

(c) *System Complexity*

The 2000 IOM report noted that "as health care and the system that delivers it become more complex, the opportunity for errors abound," and urged that the traditional clinical boundaries that discourage disclosure of adverse events be broken and the existing culture of blame be redirected (Kohn 2000:ix). The report was based on extrapolations from several studies documenting errors ranging from serious medication errors in 6.7 out of every 100 patients (Brennan et al. 1991) and injuries (i.e., *adverse events*) in 3.7% of hospital admissions, 13.6% of which led to the patient's death (Leape et al. 1998). As a result of the 2000 IOM report, and similar reports by the health departments in the United Kingdom, Australia, and Canada (Department of Health 2000; Quebec 2000; Agency for Healthcare Research and Quality [AHRQ] 1999), the issue of medical error or patient injury has become a prominent focus of health system discussions and is considered a major threat to public health (Gostin 2000).

3. *The Prevalence of Medical Error*

(a) *Historical Data*

Studies documenting a high prevalence of medical errors have appeared in the literature for more than fifteen years with varying degrees of specificity (Chassin 1998), including the greater likelihood of unreported (and unprotested by patients) error in hospitalized poor and elderly patients (Burstin 1993). The 2000 IOM report and the cited statistics are also supported by the public's perception of health care safety. According to a national poll conducted by the National Patient Safety Foundation at the AMA (NPSF 1997), 42% of respondents had been affected by a medical error, either personally or through a friend or relative, and 32% of the respondents indicated that the error had a permanent, negative effect on the patient's health. The vast majority of health care professionals – 95% of physicians and 89% of nurses in one survey – report having witnessed at least one serious medical mistake (Kohn, Corrigan & Donaldson 2000; Alberti 2001).

The recent prominence of the issue of safety or error does not reflect a new phenomenon or sudden rift in the quality of health care. Rather, the prominence of the issue reflects an underlying shift in the culture of health

care and how relationships within the health care system are structured and perceived. In this paper, I discuss the multiple factors responsible for the change in the culture of health care.

(b) *The Validity of the Data*

The data cited by the 2000 IOM report and the United Kingdom's Department of Health (which relied essentially on the same data) have been criticized as extrapolations of limited chart reviews and vagueness in how error is characterized (Cook, Woods & Miller 1998). Moreover, it is not clear whether the rate of medical error has increased, or whether it is the *reporting* of error that has increased. It is hard to tell since statistical compilations are relatively recent and most errors remain unreported (Cooper 2001). Are patients less safe than before? More procedures and more medications probably do lead to increased risk of injury, but without these technological advances, fewer patients would successfully be treated.

III. THE CULTURE OF DECISION MAKING

A. SYSTEM STRUCTURE AND RULES

1. *From Physician Benevolence to Patient Autonomy*

There is a broad assumption that the nexus of decision making in health care has shifted away from individual clinicians to individual patients, and that patients, as a result, are empowered. (The term *patient*, here, stands for the consumers of health services – families, professional caregivers, and friends who advocate for the patient and articulate patient concerns). In classic medical ethics terminology, this represents a shift away from the classic value of benevolence to a modern recognition of autonomy (Beauchamp & Childress 2001). Rather than being empowered, however, the patient is often at the center of a conflict between her understanding of what constitutes optimum health care and what she perceives as the multiple perspectives clinicians must use (Willems 2001). The patient must balance her own clinical judgment with the limitations of the patient's health plan and the economic oversight of the medical group (Weinberg, Schulz & Crawley 1999).

2. *Is Managed Care the Villain?*

Although studies suggest that few physicians feel that managed care has seriously compromised their judgment, that perspective has resulted in an undermining of trust in the health care system, and a sense there is an absence of a consistent pattern in how health plans interact with patient/consumers (Goold & Klipp 2002). The failure of Congress to construct a comprehensive regulatory umbrella for health care contributes to the erosion

of trust (Mechanic 1996). This view is echoed by calls for an organized system of consumer perspectives (Rodwin 1996).

B. DEFINITIONAL ISSUES

1. *The Language of Error*

The shift in the locus of decision making is further complicated by a lack of consensus as to the appropriate language about medical care and medical error. There is little agreement on the part of clinicians, administrators, regulators, or consumers about the appropriate terminology or the meaning of specific terms. The federal government, through the Agency for Health Care Research and Policy (AHRQ) has adopted the term patient safety following the passive characterization of the 2000 IOM report (Kohn, Corrigan & Donaldson 2000). The term *patient safety* has the added advantage of focusing attention on the subject, the patient. Most commentators in the U.S. have adopted the patient safety terminology; and have expanded the category to include accidental falls and injuries. *Medical error* remains in the public vernacular, focusing on the actor (and contributing to the culture of blame) (Handler et al. 2000); *adverse events* (Brennen et al. 1991) or the more elaborate *unanticipated adverse medical events* attempts to characterize the event rather than the cause as do the terms *mishap* (Gambino 1991), *near miss* (Barach & Small 2000) and *adverse incidents* (Stanhope et al. 1989). Some terms have specific meaning in health care culture, but the terms are often used interchangeably by the patient/consumer. The confusion is not only semantic. Individuals dissatisfied by their care have a range of options for action; they may undertake litigation, file a complaint, appeal a decision by a provider, or make an informal expression of dissatisfaction (Stanhope et al. 1999). Health administrators and courts use terminology and procedures that patients and clinicians may not fully comprehend. The culture of managed care and the trend toward cost cutting may unintentionally have increased the likelihood of error by using a *patient-directed* health care model, and replacing professionals and professional practice structures with quasi-professional care providers and a system dependent on patient initiative (Chassin & Galvin 1998).

2. *The Definition of Error*

Defining medical error would be difficult even if there were a standard terminology because there is still little agreement as to what actions or events constitute adverse events. At one extreme, some adverse events are unanticipated, cause serious patient harm, and could have been prevented through better training or back-up systems. These types of events are usually considered errors. Similarly, adverse outcomes that occur because of a patient's precarious condition, and not due to inadequate training, performance, or back-up, are probably not errors. However, a broad

spectrum exists between these extremes. Errors may be mistakes or lapses of commission or omission (Reason 2002). For example, medication errors are often errors of translation, like a child's game of "telephone," where a written or oral order that passes through several people changes in transit (Baldwin 2000). In the widely publicized Libby Zion case, the exhaustion of an inadequately supervised resident doctor was the problem; but it is not clear whether the cause was the fault of the resident, the supervising attending doctor, or the system that keeps residents on-call for thirty-six hours at a time (Asch & Parker 1998).

Is an error defined as error when it is reported? The 2000 IOM report noted that only a fraction of medical events are ever reported via voluntary reporting systems, and subsequent research has documented this (Pietro et al. 2000). In addition, near misses (adverse events that are averted) and adverse events resulting in no or minimal harm, which are potentially rich sources of information, are rarely reported. Should these be considered errors? In both of these instances, the *invisible college* of what various professionals know and do not report may be at least as important as what gets reported or, at least, raised at Mortality and Morbidity (M&M) conferences (Barach & Small 2000). Thus, the culture of patient safety exists in an environment of uncertainty.

C. LIMITATIONS OF THE BIOMEDICAL FRAMEWORK

The definitional issues also extend to whether medical error is always biomedical in scope. Most inquiries into whether a medical error has occurred or whether a complaint is valid, are designed to determine biomedical facts, rather than to address issues directly related to the quality of health care. For example, issues such as health plan denials or alterations of prescription medications, chronic symptom management, or duration of rehabilitative services or home care make up the majority of questions regarding medical error. This includes whether it is an error for a health plan or public health authority to deny coverage of a specific treatment protocol, as evidenced by cases in both the U.S. and the U.K. (Ham 1999; *Rush Prudential HMO, Inc. v Moran et al.* 2002). The inquiries include whether the definition of error should incorporate administrative or clinical miscommunication, and confusion that might arise because the managed care setting creates additional layers of decision making and a possible dilution of authority (Neale, Woloshynowych & Vincent 2001).

The result of this shift in culture is that patients have been empowered by their increased access to information and their heightened role in decision making while simultaneously they are faced with conflicting allegiance of clinical providers (Bressler 2000) and their ongoing vulnerability to the shifting winds of health insurance (Emanuel & Dubler 1995). It is understandable that patients feel as though they are subjects in a mega-clinical trial that is taking place without their informed consent (Mechanic 1998).

IV. THE CULTURE OF QUALITY MEASUREMENT: WALKING ON QUICKSAND

A. A SYSTEMS APPROACH TO ERROR

1. *The Shifting From an Adversarial Culture*

A call for improved health care quality and for mechanisms to improve the measurement of quality has evolved parallel to the adversarial culture of name and blame, but has not yet replaced it. Thus, the primary response of the medical culture to the patient safety/medical error concern has been to request a systems-based response to error that would focus on improving the mechanisms that make up quality. The concept makes sense, but it is problematic. Just as the definition of what constitutes a medical error is unclear, it is also not clear how a systems-based approach would affect the overall quality of care.

2. *Multiple Systems and Multiple Cultures*

(a) *Medical cultures*

In the medical culture, it is also not clear what *systems* means, since medicine is now comprised of multiple systems, and in fact, multiple subcultures; it might be more accurate to say that all of these separate groups make up a heterogeneous and rapidly changing health care culture. Unfortunately, the various groups do not always operate in concert. Even if the system of how errors are identified, investigated, and addressed, this change affects only one aspect of health care quality. Not only are the science and art of medicine part of a larger system, so is the business of medicine even as it exists separately. The differing perspectives of a diverse cross-section of stakeholders create additional systems. This is true in the United Kingdom as well as in the United States; not only because the U.K. has moved significantly away from its single health care payer roots (Ham & Alberti 2002), but also because advances in the science, most notably in technology and pharmaceuticals, have exploded the systems involved in health care quality bringing their own cultures into the mix (Weingert et al. 2000).

(b) *Legal Cultures*

Legal culture, with its adversarial stance, remains embedded in health care culture; at one time it had achieved an uneasy balance with clinical medical culture, standing as a sometimes overly active sentinel (Hastings 2000). Now, however, the role of legal culture is more uncertain. Litigation responds to limited aspects of medical error: the patient's need for compensation and, sometimes, sanction for the responsible clinician. But the current health care cultures have upset this balance, by exploding the myth of the physician as the "guilty party," and by creating new measures of quality in which error is only one element (Corrigan 2001).

In the U.S. and, increasingly throughout the industrialized world, malpractice litigation has been the default strategy for patients and families who feel that they have been injured by poor medical care. Accounts of malpractice litigation are a potential source of data on quality, especially if the analysis extends beyond court opinions. This quality data comprises only a minute percentage of malpractice complaints initiated, compared to qualitative analysis of other documents such as depositions (Brennan et al. 1991). However, tort law, while patient-initiated and patient-driven, is limited by the rules of legal process and does not necessarily perceive error in the same way as a patient, because the legal system requires a concrete, identifiable harm – a proximate, provable cause – and imposes strict limitations on the kinds of evidence that are admissible.

B. THE IMPACT OF PATIENT SAFETY ON SHIFTING CULTURES OF HEALTH CARE

1. *The Physician as Gatekeeper*

The impact on patient safety of the changes in the health care cultures are unclear. The new environment presents the potential for structuring and coordinating an individual's health care through a practitioner who is a gatekeeper as well as a clinician. But managed care, and the overall escalation in the costs of health care and pharmaceuticals, has intensified concerns about costs. Patients worry that restrictions or pressure to curb costs and avoid hospitalization may adversely affect the quality of their care (Morreim 1996). There is some data suggesting that certain patients in managed care settings receive a lower quality of care for certain health problems, notably for strokes and cataracts (Rothschild, Bates & Leape 2000).

2. *The Erosion of Trust*

Physicians may try to counteract an anticipated denial of care by a health plan by altering a diagnosis (Hellinger 1998). The result is an environment of conflicting messages and greater potential for error. The entry of third parties into a health care relationship may also increase opportunities for disagreement and dispute. These additional layers of administration may create problems not present in the fee for service system, for example, by overruling a physician recommendation or limiting access to specialists.

C. THE CULTURE OF CHANGE

1. *The Changing Roles of Health System Work*

Finally, the changes in health system structure during the nineties profoundly affected the practice of nursing: creating staffing shortages in many institutions, vastly increasing the patient load for nurses, and, not surprisingly,

creating a new category of nursing errors (Meurier 2000). As a result, the discipline of error prevention in health care has emerged based on the *safety sciences* – human factors engineering, industrial design, and cognitive and behavioral sciences – applied to the health care setting. Analyzing medical error through the lens of safety science has produced a number of important insights, most notably that the causes of most adverse medical events are systemic factors over which individual clinicians often have little control, such as: organizational structure, faulty communication, or poorly designed medical device interfaces (Andrews et al. 1997).

2. *Shifting Stakeholders*

The conflicting roles and responsibilities of different stakeholders in causation and investigation of medical errors were demonstrated at the same time as the Institute of Medicine issued its 2000 report. In 1994, two patients died as a result of a serious medication error at the Dana Farber Cancer Institute (Grant 1999). The facility investigated the incident and made extensive changes in its medication delivery system. Three separate professional boards investigated their particular members who had been involved: the pharmacy board, which reprimanded three pharmacists; the medical board, which suspended the license of the physician who wrote the initial incorrect order; and the nursing board, which punished eighteen nurses who had varying roles in the event. There was also, of course, a lawsuit brought by the families of the harmed patients. All of the disciplinary hearings focused on assigning individual responsibility; only the institution itself addressed the underlying systemic problem that allowed a miswritten medication order to be administered uncorrected. None of the supervising physicians were sanctioned by the medical board while the nurses who were sanctioned ranged from the administering nurse to the supervisors.

3. *Shifting the Culture of Blame*

The Dana Farber incident is the most publicized instance of the name and blame culture. Clearly there were serious errors committed resulting in unnecessary injury and death to patients. But, what also emerges from the description of the multiple investigations and sanction proceedings is that the perspectives of the nursing staff appears to have been submerged in the rush to assess blame and take action. Instead of highlighting the need for a comprehensive structure to alleviate the problem of adverse events, disclosures of specific events such as this one often result in discipline of individuals with little systemic change. In this case, the institution, to all accounts, implemented an admirable refinement of its system, but this did not prevent the professional associations from undertaking parallel and possibly conflicting investigations that focused on fault rather than systemic failure (Grant 1999).

D. ETHICAL RAMIFICATIONS OF NAMING AND BLAMING

1. *The Fallacy of Perfection*

Much has been written about the culture of blame that is reinforced throughout medical education and training (Wu et al. 1991). Clinicians are led to believe that humans are perfectible and that errors are caused by carelessness for which the responsible individual should be punished. The medical profession, the media, and the public remain quick to blame individuals when they make errors, resulting in clinicians' fear of both making a mistake and being caught. Because recognizing error is a necessary first step towards prevention, the public also suffers when clinicians hide their mistakes. To a large degree, the portrayals above represent the two poles of responses to the (apparent) inevitability of error in the provision of medical care, and to the attendant necessity for allocating responsibility or fixing (*righting*) the wrong: either by building an edifice called the system, which acts as a giant sponge to absorb all allegations of error; or searching for a fall guy, whose omission or commission is to be blamed, and without whom – if there is no finding of fault or negligence – the error goes unrecognized (and obviously unredressed). The problem with these exaggerated characterizations is that neither is correct. The system is not a monolithic entity, and it may even have multiple entities in today's current system of managed care. The error committer is not usually wholly bad, not alone in his or her act(s), and not always deserving of blame (Vincent 1997).

2. *The Disclosure Conundrum*

The conflicting systems within the health care culture raise ethical concerns, as well. A recent article discussed the dilemma of a physician who misdiagnosed a patient's heart attack, resulting in the patient's death (Wu 2000). The supervising physician, commenting that nothing would erase the death, falsified the records to show that the heart attack was the direct cause of death. No disclosure was made to the patient's family or to any institutional review committee. In terms of direct responsibility, these facts suggest an ordinary error, which could be handled by malpractice litigation. But, looking at the events surrounding the incident, it is clear that the health care culture may have caused the error, and certainly prevented disclosure: the junior physician was overworked and probably tired, a technician could have reviewed the damaging test and alerted the physician, and the senior physician was reluctant to make a report that potentially could damage both of their careers. In this case, there was no clear context for disclosure and the competing realms of risk management and institutional oversight would have separately addressed only their own specific concerns. Finally, the effect of the apparent error on the overall quality of care remained unaddressed.

V. THE NEED FOR SYSTEMATIC (AND SYSTEMIC) REGULATION

A. THE CULTURE OF REGULATION

1. *Squeaky Wheels and Defensive Politics*

The regulatory culture of health care is also in flux, both in the U.S. and the U.K. In the U.S., there has traditionally been an eclectic view of regulation which can be characterized either as *letting one thousand flowers bloom*, or regulating by whichever squeaky wheel is currently in favor. The federal government plays an increasingly important role in regulation, but it is far from comprehensive. The Medicare system is largely regulated at a national level and finally has agreed to disclose physician errors that resulted in beneficiary complaints (Pear 2001). Medicaid, with joint state and federal regulation, has been slower to adopt specific error-related regulation. Managed care has brought about a certain amount of privatization in the way that both of these programs are regulated (Charatan 2000). In addition, federal regulation is beginning to cover larger areas of health care, largely through the Employee Retirement Income Security Act (ERISA) and Emergency Medical Treatment and Active Labor Act (EMTALA) provisions, but also through civil rights laws and, potentially, a patient bill of rights – congressional lawmakers have agreed that there is a need for federal legislation providing legal protections to reports of medical errors (Reece 2000-01). So far, however, patient protections at the federal level have been subject to the shifting winds of political expediency and, in fact, a "patient bill of rights" has been discussed in the literature since at least 1974 (Mills 1974).

2. *The Frontiers of Regulation*

States parallel the federal government in many of these regulatory efforts, and have been somewhat more successful(Blum 2001). A number of states have adopted versions of a patient bill of rights and have established regulatory agencies to provide oversight of managed care and the provision of health care in general. Some states, such as California, are moving toward required Computerized Physician Order Entry Systems (CPOE) to avoid one of the most frequent causes of error – medication error (Doolan & Bates 2002). National and local health quality watchdogs and accrediting bodies have also stepped in to report breakdowns and to require specific kinds of reports (Joint Commission on Accreditation of Healthcare Organizations [JCAHO] 2001; O'Leary 2000). Health plans – whether or not formally under the managed care umbrella – also provide internal regulatory oversight, especially for purposes of assessing economic and scientific efficiency, however, this information is frequently considered proprietary. Other industries have provided some templates for assessing and reporting error and some of these mechanisms have been adapted to the medical arena

(Leape et al. 2000). And, of course, the media continues to play a major role (Jackson 2001; Millenson 2002).

B. QUALITY MONITORING

1. *Sources of Data*

The segmented regulatory culture in the U.S. also affects the data that can be collected to monitor quality. The federal government and the states have their own mechanisms for collecting and analyzing data, as do health plans; the data is frequently not shared and is often in incompatible formats (Saltman 2002). States have also struggled with the difficulty of managing large databases while preserving patient privacy (Kelly 2002). There is an increased call for some standardized quality data; but, at the same time that efforts are underway to bring this about, there is also pressure to protect the privacy of individual patients, especially with the imminence of strict privacy regulations (Goldman 2001). In the U.K., the regulatory culture has been relatively monolithic which gives policymaking a more focused approach, and provides a systematic context for collecting data about quality, although it is not always utilized. The disadvantage, however, is that the U.K. National Health System (NHS) is perceived as a fixed bureaucracy, and slow to change. But, in fact, there have been major changes in British health care culture in recent years, with increased privatization emerging under the last two governments, and what appear to be major national initiatives on quality and error (Wilkin 2002).

2. *Practitioner Data*

The National Practitioner Databank (NPD), with its extensive records of physicians who have been sued or disciplined by medical societies, potentially could be another source of data, although its existence symbolizes in many ways the name and blame culture. Release of NPD data is opposed by medical groups, however, because of the potential litigation risk, and the risk to physicians' reputation (Lovitky 2000). Moreover, while there is some data that suggests communication between physician and patient plays a critical role in patients' decisions about whether to sue for malpractice, the issue of physician/patient communication has more far-reaching implications for health care quality (Schattner & Tal 2002).

3. *Consumer Data*

Use of data from patient complaints and satisfaction surveys might fill in some of the gaps in the definition of adverse events. More importantly, the data can be a resource for addressing deficiencies in how quality is defined and measured. There is well-documented evidence that patients who have a

good ongoing relationship with their health care professionals are less likely to resort to formal complaints or to the courts (Moore, Adler & Robertson 2000). There is also evidence that physicians who have poor communication skills with patients are more likely to be sued (Lester 1993). Finally, the few studies that have looked at available complaint data through Medicare or other databases indicate that communication and administrative problems make up the largest proportion of patient complaints against health care providers as well as health plans (Schauffler & Mordavsky 2001; Harrington et al. 2001).

C. ERROR REPORTING

1. *Mandatory reporting*

One of the culture shifts is an effort to promote reporting of adverse medical events, whether or not they result in injury. The Veteran's Administration has instituted mandatory reporting (Weeks & Bajian 2000), as has the National Health Service in the U.K. (Dimond 2002). Medical groups and health care organizations have advocated for voluntary reporting, at least as an initial step towards mandatory reporting, to jump start the culture shift (Hobgood, Ma & Swart 2000), and to question whether reporting should be mandatory or voluntary (Sucov et al. 2001).

2. *Non-mandatory Systems*

However, it is still not clear whether either whether mandatory, voluntary, or no formalized system of reporting actually makes a difference in adverse event reduction (Stanhope et al. 1999), and there are convincing reasons for not having a formal reporting system at all (Vincent 1999). A large proportion of adverse events are due to medication errors and the pharmacy discipline mechanism has been active in promoting medication error reporting systems (Bates 1999). The field of anaesthesiology has also been a leader in developing reporting systems (Cheney 1999), as has emergency medicine (Handler 2000).

3. *The Need for Error Reporting*

Whether and how adverse medical events need to be reported has been the subject of ongoing debate within the health care culture. One area of concern is "Who should do the reporting?" – the person who committed the error; or anyone who observes that an error has been committed. Does the error belong to someone, if so, in light of the fact that most health care today is provided by multidisciplinary teams, who? Another concern is that reporting mandates could create a conflict between the error reporter's professional ethical behavior and the institution's administrative objectives.

However, reporting adverse events without conjunctive actions such as data collection, systemic causation analysis, and disclosure to the patient would be meaningless.

Additionally, most examinations of adverse medical events are just that – inquiries into medical events which are biomedical in focus. These inquiries tend to be directly related to whether a medical-therapeutic error occurred or whether a required treatment procedure was violated. In other words, even something as patient specific as complaint mechanisms, while clearly patient-driven, are not designed to address the full range of individual or system breakdowns (Liang 2001). Along with tort law and reporting system approaches, the focus of adverse medical events inquiries is to determine biomedical facts and not to address issues less directly related to the quality of health care. For example, issues such as health plan denials of care or mandated substitutions of prescription medications, chronic symptom management, or how extensive rehabilitative services or home care should be are all valid topics for examination. This is true both in the U.S. and in the U.K., where the lawsuit has assumed greater importance in the public eye in recent years (although not necessarily in practice) (Neale, Woloshynowych & Vincent 2001).

V. CONCLUSION

Within this general framework of inquiry, the core concerns are threefold. First, there must be research that qualitatively will catalog and assess the effectiveness of the existing health care cultures in relation to payers, providers, and patients and their families. Second, special attention needs to be given to the ethical presumptions underlying the interests of each stakeholder group, or each separate culture, and on how to most effectively incorporate ethical analysis in addressing the overarching issues of access, quality, and accountability. Finally, it is important to identify the best practices for addressing the specific problem of patient safety, from the biomedical perspective as well as from the patient-centered perspective. This more inclusive examination can further be stratified by the appropriateness of the procedures used with respect to characteristics of the patient population (e.g., race, ethnicity, socioeconomic status, and physical condition), and by the efficacy of the underlying mechanisms within the culture for meeting the needs of the various stakeholder groups: beneficiaries, practitioners (physicians, nurses, and other health professionals), providers or plans, and regulators.

In order to address the conflicts in the health care cultures, however, these concerns must be addressed through analyses that incorporate traditional health care methods for assessing quality – qualitative and quantitative – and through analyses of the medical-legal structure of regulation and adjudication. Addressing the conflicts will go a long way to restructure

health care cultures along a path that is more accessible to all of the stakeholders involved. Without such an examination, the cultures may well implode on one another.

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