Appendix B-3

Medical Errors and Patient Safety (Rosenthal)

MEDICAL ERRORS AND PATIENT SAFETY

By

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INTRODUCTION

The current "Patient Safety" movement should be seen as a recent development rooted in an old history. The traditional medical professional struggle to reduce errors has been carried out within closed professional circles for almost one hundred years. In 1999, this struggle has become a national public concern to an extent hitherto unknown to the profession. Pressures from outside continue to mount, insisting on demonstrable progress in error reduction. The major response has been technological, with all its promise and problems.

The Patient Safety movement was "officially" launched by the Institute of Medicine report TO ERR IS HUMAN (Kohn et al, 1999). Basing its recommendations primarily on the Harvard Medical Practice Study (Brennan, T, Leape, LL et al, 1999), and including other research, the IoM report tries to discuss why errors happen and provide recommendations for a comprehensive approach to improving patient safety. It urges the use of safety systems developed for industrial sectors of the society.

This ambitious and seminal document made headlines everywhere: newspapers, TV, radio and professional journals and newsletters across the country. It has produced profound external pressure on the profession of medicine, health care organizations, and the health care system. Media, the White House, Congress, government agencies, those who pay the medical care bills, and consumers were and are aroused. In this, the IoM report is a success. Its very success has brought new challenges and dilemmas. It is natural that questions have arisen when its recommendations have been evaluated and attempts made to put them into action. But its impact cannot be underestimated.

It urges the corporations who are the biggest payers of health are benefits to require particular activities of their providers, in order to be contractually acceptable. These include mandatory error reporting systems, physician

computerized order entry systems (PCOES) and fifty per cent error reduction in five years. Each of these, and other recommendations, while clearly important has serious implementation problems.

It generated a flurry of reaction from the White House where the President called for a national mandatory reporting system, ordered HICFA to set new error-reduction standards for Medicare payments and demanded that the 300 provider groups competing for Federal Employees Health Insurance meet such standards. Congressional committees called hearings in preparation for legislative action. Big corporate payers of health benefits formed the "Leapfrog Group" to make its own demands for error reduction. The message to the public has been one of concern and concerted action. There has also been a considerable amount of "backing off" as the realities of implementation are understood.

Choice of the term "Patient Safety" was a judicious one. "Patient Safety" is meant to include medical errors as well as non-clinical concerns like infant abduction, patient falls and patient suicide. Further, this term has created an acceptable umbrella under which we can bring together a number of efforts to improve quality of clinical care for patients and combine them with some 'new' ideas.

Before proceeding with this brief, we must bear in mind that the patient safety movement emerges at a time of tremendous pressures for cost containment.

To better understand the background and thrust of the Patient Safety movement, this paper will present a brief analysis of the cumulative efforts of traditional medical errors research, the relevant ethnography of medical professional culture, and the impact of systems theories, about safety and risk. It will suggest where we are today in efforts to understand and reduce medical mistakes. It will point to some cautions in these efforts, and the dilemma of demands for immediate action.

((Note: Continuous quality improvement efforts, hospital risk management as well as claims, malpractice court and settlement data, evidence-based medicine and outcomes research also provide important insights into patterns and problems of medical mistakes. It is my understanding these will be addressed in other analytical briefs.)

RESEARCH STREAMS

Empirical Research on Medical Error

Doctors have been doing empirical research on errors for many decades, crowned by several very large quantitative studies. These latter include the Medical Insurance Feasibility study (MIFS) led by (Don Harper Mills, 1979) to measure rates of injury in hospitalized patients in California (Mills, 1978), its 1990 counterpart in the Harvard Medical Practice Study (HMPS) and the replication of the latter in The Quality in Australian Hospitals study, 1995). The Harvard study was also replicated in Utah and Colorado (UCMPS, 1999). One noteworthy qualitative study was carried out at the University of Chicago. (Andrews, 1997) in a joint effort of the medical and legal associations.

Each of the studies was not only complex in methodology, but utilized 1) different definitions of Adverse Event (a standard medical term meaning "an injury resulting from a medical intervention" and 2) somewhat different methodological processes. Below find a comparison of a single major finding-the Adverse Event rates. All these studies focus on in-hospital services.

Study	AE Rate	Terminology
MIFS (1979)	4.6% AE rate	(causing disability)
HMPS (1990)	3.7% AE rate	(negligent)
Australian (1995)	16% AE rate	(preventable)
U of C (1997)	17.7% rate	("eyebrow raising" events)
UCMPS (1999)	2.9% AE rate	(negligent)

It can be noted that three basic categories of AEs appeared in all the studies: 1) operating room events are a major cause of AEs; 2) close to half of AEs take

place in emergency rooms; 3) mediation errors in prescribing, filling and administering. The following table is taken from the Utah and Colorado study and provides an example of additional detail. (from Studdert, Brennan and Thomas in *Medical Errors*, 2002).

Table 1.1. Types of Adverse Events.

Type	Adverse Events	%[a]	% of Adverse Events with Negligence
Operative	7,715	44.9	16.9
Technical	2,309	29.9	23.6
Bleeding	1,319	17.1	9.8
Wound infection	877	11.4	20.8
Nonwound infection	775	10.0	7.5
Drug-related	3,325	19.3	35.1
Antibiotic	828	24.9	6.8
Cardiovascular agent	579	17.4	38.9
Analgesic	297	8.9	33.3
Anticoagulant	286	8.6	25.1
Medical procedure	2,315	13.5	15.3
Incorrect or delayed diagnosis	1,181	6.9	93.8
Incorrect or delayed therapy	736	4.3	56.8
Postpartum	620	3.6	25.5
Neonatal	532	3.1	25.3
Anesthesia-related	226	1.3	32.7
Falls	220	1.3	65.8
Fracture-related	66	0.4	0
Other	256	1.5	59.9
Total	17,192		

[a] Percentages shown for the subtypes of operative and drug-related adverse events represent proportions of the total number of adverse events in the relevant category (that is, 7,715 and 3,325, respectively).

There are methodological issues in all these studies. The American and Australian studies depend on record review despite the fact that medical records are incomplete (Craddock, 2001; Thomas, 2002). Teams of reviewers often disagree on the definition of an Adverse Event. (Hayward and Hofer, 2001). The

conditions of health care delivery changed between the decades during which data were gathered for each of the studies. Managed care and other market and regulatory dynamics as well as new technologies intervened which limits the comparability and durability of findings.

The key insights to be gained here are that data collection is done within a dynamic and changing field; that there isn't a uniform definition of an Adverse Event, error or mistake, negligent or not, preventable or not; that state-of-the-art studies are finding different results. Researchers, policy makers and administrators should be judicious in using the data and in drawing conclusions.

Although these large studies garner great attention, they are not the only source of data on errors and adverse events. Many small studies have been conducted over the last six decades, most by physicians (Rosenthal, 1995 Ch.6). These range from autopsy studies, studies of residents and fatigue, medication error studies, studies of maternal and infant deaths and inquiries into post-operative morbidity and mortality. Methodologies vary; definitions vary as do interpretations and remedies. Below are summaries of findings from selected small studies.

Autopsy Studies

An autopsy study conducted by Harvard University Professor Lee Goldman claims that one out of five cases has a missed diagnosis. In half the cases the "correct diagnosis would have saved the patients life or prolonged it". (Landefeld and Goldman, 1989).

A review of forty-seven years of published autopsy studies (Anderson, R. et al, 1989) assesses the accuracy of clinical diagnoses through 5,000 autopsies of patients dying from 1 to 11 specific diseases. Authored by pathologists from two American medical schools, the findings are used to discuss four issues: 1) the accuracy of diagnoses; 2) the change in accuracy over time; 3) the impact of

improved diagnostic equipment; 4) the probable existence of some degree of "irreducible necessary fallibility" in the practice of medicine. As for overall accuracy of diagnosis, "….there can be little question that a significant proportion…were misdiagnosed. Further it is physician factors rather than patient factors that account for the vast majority of missed diagnoses….with the misdiagnoses approximately evenly divided among errors of omission and errors of judgment…."

The authors go on to note that the autopsy studies reviewed indicate that recent diagnostic technology improvements "have not had an apparent impact on the accuracy of clinical diagnosis among persons coming to autopsy". In fact, several studies indicate that over-reliance on diagnostic testing can adversely affect diagnostic accuracy.

Finally, the authors suggest two realities: The uncovering of systematic faults that can be corrected, and the 'presence of an irreducible necessary fallibility emanating from the uncertainty inherent in medical predictions based on human observations and the laws of natural science".

Residents and Medical Mistakes

A 1991 study (Wu, 1991) of 114 residents reports on a small, anonymous survey on house officer mistakes and responses to those mistakes. There were serious adverse outcomes in 90 percent of reported cases, thirty-one percent of which were death. Categorically, 31 percent of errors were diagnostic, 29 percent prescribing, 21 percent evaluation, 11 percent procedural complications, 5 percent communications,

A literature review of 68 studies (published between 1981 and 1996) on resident and medical error in a variety of specialties found that 76% of errors were Omission and 24% Commission. They further broke down into:

Diagnostic	67%
Treatment	38%
Patient Management	16%
Equipment	7%
System	18%

Many of these studies, 69% of which are based on record review, describe multiple categories of errors and often a cascade of factors. (Rosenthal and Wallag 1998)

Medication Errors

Medication error studies are particularly plentiful. Our knowledge in this category is more extensive then any other. The IoM report lists some 30 studies published between 1974 and 1999. These cover the medication process from writing the prescription to administering the medication. For example (Bates, 1995) in a quantitative study, found that 56% of preventable adverse drug events (ADE) occurred at the ordering stage, 34% at administration, 5% during transcription and 4% during dispending. This study found that there were 6.5 ADE and 5.5 potential ADE per 1000non-obstetrical admissions per year. One per cent of all ADE was fatal, 12% life threatening, 30% serious and 57% significant. Twenty-eight per cent of all ADE were preventable.

Lesar (1997) found 3.99 errors per 1000 medication orders. Classen (1997) found that ADE complicated 2.43 per 100 admissions and that almost 50% of all ADE are preventable.

A meta-analysis of all the medication studies published in peer-reviewed journals would help standardize methodology and definitions and provide a useful overview.

Ethnography of the Medical Profession: Medical Uncertainty

In order to understand the work of the medical profession better, it is essential to look at the culture of the medical profession, particular medical uncertainty. While this was ignored in the IoM report, it provides seminal insights into the context for understanding medical mistakes. This work has been done by social scientists.

Fox (1959), in her study of medical education, points out that students are being "trained for uncertainty" and suggests that clinicians often cannot distinguish between the limitations of medical knowledge and their own limitations in clinical knowledge and skills. When there is an adverse event, is it because of the limitations of medical knowledge or the practitioner's limitations?

Friedson's (1970) extensive work on the medical profession focuses on a distinct collegial culture that demands autonomy and makes it difficult for doctors to accept outside regulation Bosk's study (1982) of resident training for surgeons demonstrates that the most rigorous training standards are for the *process* of performance and a high sense of responsibility because surgeons know there will be adverse events in the operating room. Rosenthal's study of problem doctors (1995) underscores that doctors know they work in a world of uncertainty and therefore accept their fallibility and shared vulnerability, tend to understand and forgive their colleagues and share strong feelings that only fellow professionals can judge their work.

The ethnographic studies of the medical profession provide important clues to how doctors regard their work, why they speak of adverse events rather than

medical mistakes and why they accept the concept of the “unpreventable adverse event” and the “known risk”.

Systems Theories

The IoM report promoted the idea of looking at safety systems from other sectors of society and applying them to hospital are. It offered a particular focus on Human Factors ideas pioneered by an English professor of psychology James Reason (1990). These ideas, adopted by the airline industry and the nuclear power plant industry, examine the interaction between fallible humans and the organizational systems within which they work, including technology. Human Factors concepts seek to emphasize organizational policies and work practices to provide fail-safe supports for human activity.

Human Factors Concepts

The basic principles of Human Factors concepts are 1) human error is inevitable, 2) adverse events are the result of a complex chain of events, a string of flaws throughout the system, 3) prevention requires recognition of human cognitive processes and organizational characteristics that save humans from errors 4) safety factors must be emphasized at four levels: task, team situation, organization.

The IoM report strongly promoted airline models, particularly reporting systems and crew resource management as appropriate for hospitals.

High Reliability Organizations

Another set of system concepts merit our attention: High Reliability Organizations. (Wieck,1987) This model, promoted through American business schools, emphasizes perpetual “mindfulness” in the processes of organizations to turn high-risk organizational activity into high reliability activity. This set of concepts claim that high risk and high effectiveness can coexist. And that high reliability organizations emphasize the ability to handle unforeseen situations in

ways that forestall unintended consequences. This suggests a new way to look at hospitals: as places where high-risk work is carried out and various forms of adaptability are needed.

Finally, one additional industrial model should be noted: the Six Sigma test (Chassin, 1998). This is a statistical concept from quality improvements in industrial production that seeks to reduce the number of defective products to the smallest possible number.

These are three concepts that have now entered the health care system domain in the hopes they will help reduce error. Because of the now widespread acceptance of systems factors as implicated in medical mistakes, there have been some efforts to develop analytic frameworks that direct attention to a variety of system, organizational, clinical, and patient factors that may contribute to errors.

At the University of Michigan, (2003) we have been working on an analytic framework for educational purposes and as a guide to analysis of individual cases of errors. Our framework includes an emphasis on medical uncertainty as well as drawing from Human Factors and High Reliability research. Charles Vincent (2003) from Imperial College in England, has recently published a similar schema, applying Human Factors concepts. (See appendices)

TERMINOLOGY and CLASSIFICATION OF ERRORS

Those engaged in recent medical errors research do not yet agree on terminology or categorization. Terminology varies along three continuums: 1) process; 2) outcome for the patient and; 3) degree of injury severity.

Some definitions suggest that errors in the p*rocess of care* should be the focus of the definition; others say the definition should emphasize the *outcome for the*

patient. Both of these positions raise questions like: “If something was wrong with the process, but did no harm to the patient, is that a medical error?” “If the process was carried out correctly but the result was not good for the patient, is that an error”? “Is it an error only if the process was ‘negligent’ (not to standard of care)? “Is it an error only if the outcome was preventable?” Is there an agreement in the profession of what is preventable?”

Until the terminology moves towards more agreement, it is important to identify what definition a particular piece of research is using. For example, the HMPS focused on ‘negligent’ errors that caused at least one additional day in the hospital. The Australian study looked for ‘preventable’ errors. Hayward and Hofer (2001) indicated that it can be difficult to get equal experts to agree on whether an error (they use the term ‘adverse event’) was correlated with a patient death.

Some terminology has entered hospital usage through voluntary regulation via the Joint Commission of Accreditation of HealthCare Organizations (JACHO), which mandates a “root cause analysis” of all “Sentinel Events” (unexpected deaths and blatant errors like removal of the wrong limb). Traditional medical terminology has recognized “Adverse Events” of two kinds: preventable and unpreventable (a “known risk”). There is also increased interest in the “Near Miss””, a possible adverse event that was stopped before it could harm the patient, or, didn’t harm the patient.

Sentinel Event, Adverse Event (preventable and unpreventable) and Near Miss are reasonable and useable taxonomies.

Other forms of classification include processes. Errors that are diagnostic, treatment, patient management, palliative errors, use of equipment and technology. Some forms of classification use specialty as the categorizing standard: surgical events, internal medicine, nursing care, pediatric, obstetric,

and psychiatric. A separate, important category is medication errors which cut across specialties.

Because “Patient Safety” is the umbrella term, this is interpreted as including patient protection. For example, infant discharge to wrong person, patient kidnapping, patient falls and suicide as well as criminal events. These should be seen as distinct from medical error.

Often process, specialty, severity and patient safety categories are mixed together. There is not yet agreement among scholars and administrators as to universal terminology and universal classification.

COMMUNICATIONS ISSUES

There is an extensive literature on problems in communications in organizations and organizational failures. Studies of accidents in various high-risk organizations suggest errors are often a combination of individual action and chain of hidden or latent flaws throughout the organization, including communications failures (Jablin, 1987).

Building on experience, research and prevention in other organizations, growing research examines communications failures as one of the factors contributing to medical mistakes (McCue, 1994; West, 1999). In the hospital setting, this research has focused primarily on communications problems *among* practitioners. Such research is increasingly important, as sicker patients demanding more complex treatments require the coordinated attention of more specialists. Clear and complete transfer of information is essential.

The four relationships during which communication problems can arise include: residents and nurses, residents and attendings, hospital staff and community physicians and among hospital specialists, particularly emergency room staff and

other departments. Communications problems can be shaped by inadequate information, hierarchical relationships and modes of communication used (Sutcliffe, 2003).

Communication Problems between Clinicians and Patients

There is extensive research literature on doctor-patient communications (see other expert brief). Medical mistakes and failures of communications between providers and minority patients has not been a subject of direct research until recently and in only a small number of studies. One 2003 study in particular, may be the beginning in a new wave of research on this topic (Flores et al, 2003). "Errors in medical Interpretation and their potential clinical consequences in pediatric encounters", demonstrates that errors in medical interpretation by translators are common (31 errors per medical encounter) and most frequently omit information which could have important clinical consequences.

We are still developing techniques for the systematic identification and study of medical errors and patterns of errors, in hospital settings. There is little direct empirical study of the relationship between communications, minority status and medical errors although there is ample evidence concerning general quality of care.

Well documented are racial and social class differences in clinical encounters and as barriers to care; minority differences and misdiagnosis, under utilization of health care resources, race, ethnicity and general quality of care, delay in seeking care, race and ethnic differences in description of symptoms, discrimination in referral patterns, experiences of discrimination, patient non-adherence to medical advise and failure to ensure patient understanding, minority differences in morbidity and mortality rates, have all been subjects of research, well before the advent of the patient safety movement.

We have yet to see the empirical link between these topics and medical mistakes per se.

Any such studies will have to consider variations in minority group's education, cultural attitudes toward health care providers and health behavior, access and utilization, as well as patient co-operation factors. Both inpatient and outpatient studies will be relevant.

STRATEGIES FOR REDUCING MEDICAL ERRORS

Approaches to understanding, preventing and reducing error are legion. The following list provides an overview (certainly not complete) of longstanding approaches, and newer ones put into place in the last several decades. The medical profession has relied on educational strategies and unique forms of peer review. The government and voluntary organizations rely on legislation and regulation, the corporate payers on market strategies. We might ask why so many mechanisms have failed to produce the desired results. We might find the answers in lack of evaluation, failure to revisit problems, enormous pressure for action without enough time for thorough understanding. The dominant (and most expensive) new approach is technological.

Traditional Approaches

Threat of Medical Malpractice claims
Licensing Requirements
Education:
    Medical students, residents and doctors; CME

Morbidity and Mortality Conferences
Rounds
Traditional Approaches - continued

Peer Review Feedback
Guided Decision Systems (e.g. Apache System)
Autopsy Reports

Public/ Regulatory/ Legislative/ Market Pressures

Calls for Reporting Systems
Institute of Medicine Reports
Agency for Healthcare Research and Quality
Corporate Initiatives: LeapFrog Business group:
    Contract Requirements
National Patient Safety Foundation
Congressional Hearings and legislation
JCAHO regulations for Accreditation

Technological Approaches

Computerized Reporting Systems: voluntary or mandatory; Near Miss reporting systems

Physician Computer Order Entry (PCOE)
    Medication orders
    Transmission of Lab and Radiology data
    Clinical practice data collection and analysis

New In-Hospital Initiatives

Hospital Patient Safety Committees (multidisciplinary)
Hospital "Patient Safety Plans (see Appendix for example)
Hospital culture change: Transparency and No-Blame
Openness with Patients and Families
Medical Mistakes Rounds
Near-Miss Rounds
Evidence-based medicine
Benchmarks and guidelines
Education of Patient as consumers
Education of Residents for Patient Safety

CAUTIONS

There is a powerful tug between immediate action and thoughtful action, the omnipresent conflict between the realistic need for action and the need for thoughtful, deliberate action. Often, the demand for action undercuts the time for understanding a problem as complex as medical errors and their reduction. There is still not enough understanding of organizational and cultural barriers to change. We have not yet mastered the art of organizational learning using

interdisciplinary teams. We do not have a full understanding of how integration of humans and systems can improve patient safety.

Some specific cautions include recognition that one size doesn't fit all and each specialty needs to devise its own studies, goals and interventions. Reporting systems have legal, privacy, accuracy, security and standardization problems. Although it is an added expense, systematic and objective *evaluation* of all initiatives is crucial.

We live with the political problem of over-promising as well as the need for better public understanding of medical uncertainty and the known risks of medical care, at the same time that the medical profession demonstrates continuing focus on error reduction. All this has to be accomplished in the larger context of cost containment.

NEW CHALLENGES FOR RESEARCH

Meta analysis of the myriad empirical studies for better grasp of patterns of errors.

Use of evidence-based medicine to evaluate "known risk". That is, challenge the medical profession to a more rigorous examination and reduction of the "unpreventable" adverse event.

Evaluating the effectiveness of reporting systems

Can safety models from other industries be adapted to the hospital?
Is medical care unique enough to develop unique models of safety?

Encourage research on the variety of errors: sentinel events, adverse events and the near-miss.

Encourage research using a variety of methodological approaches: qualitative and quantitative.

Research on the productive, informal ways teams approach medical error problems in their work environment.

Research on errors in outpatient settings.

Research on whether minority status of patients expands risk for medical error.

CONCLUDING STATEMENT

The Agency for Healthcare Research and Quality director (Meyer, 2003) has recently called for greater research emphasis on what works in practice to improve patient safety. That is, which applications show "the greatest promise in impacting safety?" There is an urgency in this strategic direction reflecting rising public concern. In addition, there has been a very recent declaration by a group of corporations that they will offer financial incentives, paying doctors bonuses for improved medical and health care outcomes. This may mean that leaders in health care systems will look for techniques and tools before there is a rich buildup of deep understanding of the complex factors that produce medical errors. The incentives are now increasing: regulatory, legislative and market, as the impatience for improvement grows. We will see increasing pressure for reduction of errors by whatever means seem to produce results.

There have been decades of concern and research about medical error by the profession, which has always recognized the intrinsic uncertainty in its knowledge and practice. It has learned to live with the uncertainty and its probabilistic nature by thinking in terms of preventable and unpreventable adverse events. Leape's seminal 1994 JAMA article brought to medicine ideas about uncertainty and risk from other sectors of society. He introduced Reason's work that links inevitable human error to systems factors. Leape's article was a bridge to an entirely new way of thinking about medical mistakes that links uncertainty, risk and systems together for error reduction.

The Institute of Medicine report brought some of the existing research and systems concepts to a national audience. It launched new resources and energy in research, new approaches to understanding and reducing medical error and

new, sustained public attention to the challenges of medical errors. Corporate payers took on this challenge by insisting on proof of error reduction as a term of contracts with providers. The pressure has become enormous on health care systems, hospitals and providers to adopt safety models from industry.

All this useful pressure has revealed problems of definition, research methodology; myriad problems with reporting systems; and the need to adapt rather than adopt models from industry. The complexities and ambiguities of medicine make all these efforts particularly challenging. Research dollars will now divide between identifying error and proof of reduction.

At this point in the "medical error movement", the health care system is turning to technology, particularly physician computer order entry to find solutions. This will be a powerful but not a perfect tool to reduce particular kinds of errors. Advances in medical knowledge will always bring new kinds of errors. There will be new educational efforts in medical schools to make future doctors more aware and knowledgeable bout error dynamics (AAMC, 2003). The education of patients will be improved.

The motivations and resources have never been greater to improve medical care outcomes for patients. What used to be a hidden burden of individual medial practice has now become the joint concern of a coalition of stakeholders. Medical error reduction requires eternal vigilance and innovative thinking. The challenges and barriers are great but the cause a worthy and necessary one.

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APPENDICES

Conceptual Frameworks: Rosenthal; Vincent

Academic Hospital Patient Safety Plan

Lessons from Richard Cook