MALPRACTICE INSURERS' MEDICAL ERROR SURVEILLANCE AND PREVENTION STUDY (MIMESPS)

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1. STRUCTURED ABSTRACT

Purpose: We aimed to (1) develop a framework for investigating errors through reviews of medical malpractice claim files; (2) advance understanding of the etiology of diagnostic, medication, obstetric, and surgical errors; and (3) identify opportunities for error prevention.

Scope: A total of 1452 closed malpractice claims from five liability insurers.

Methods: Trained physicians reviewed the claim files and accompanying medical records to determine whether a medical injury had occurred and, if so, whether it was due to medical error. We analyzed the characteristics of errors.

Results: Eighty-three percent of the reviewed claims closed between 1995 and 2004; 62% closed in 1998 or later. The average time between occurrence of the injury and closure of the claim was 5 years. Ninety-seven percent (n=1415) of claims involved medical injury, and 63% (n=889) of those injuries were judged to be due to errors. The injuries were typically severe, with 80% causing significant (39%) or major (15%) disability or death (26%). We have conducted, or are in the process of conducting, 21 separate analyses of the dataset. The analyses are grouped as follows: (1) general descriptive studies within each of the four clinical areas; (2) subanalyses focused on recognized patient safety problems (e.g., retained foreign instruments after surgery, wrong site surgery, missed diagnoses of breast cancer); (3) case-control studies of errors in emergency surgery and management of fetal distress, respectively; and (4) medico-legal analyses of frivolous litigation, informed consent litigation, and the concept of clinical negligence.

Key words: patient safety, medical error, medical malpractice, litigation, human factors

2. PURPOSE

MIMESPS had 5 broad aims:

i. To harness the potential of professional liability insurance programs to operate as a nationwide error reporting system through structured human factors analysis of a large number of incidents leading to malpractice claims.

ii. To use this approach to identify the most frequent factors contributing to error in four major categories of care (obstetrics, surgery, diagnosis, medication administration) as well as in specific problems areas (e.g., retained foreign bodies after surgery, fetal injury during prolonged second stage of labor).

iii. To test case-control analysis as a method of quantifying the role of various contributing factors (alone and in combination) to the occurrence of specific errors.

iv. To assess how the errors and contributing factors identified in claims file analysis compare to those identified through other types of reporting systems.

v. To design, disseminate, and implement a series of targeted patient safety interventions based on results from the contributing factor analyses.

3. SCOPE

Background

The medical malpractice system has operated for more than 150 years in the United States.[1] With a few exceptions,[2,3] however, it has been largely ignored as a source of data about medical errors and the factors that cause them. It consists of the approximately 55,000 claims, and at least as many reports of harmful incidents, received each year by the 150 medical malpractice insurers writing policies throughout the country.[4]

Why have medical malpractice data been bypassed as a source of information about error? One obvious reason is that, until recently, relatively little attention was paid to collection and analysis of data on errors from any domain. However, reasons for the omission in the case of malpractice run deeper; they stem from a fundamental divide between risk management and quality improvement activities in American healthcare,[5,6] for which there are several explanations.

First, organized medicine has not traditionally regarded the malpractice system as a useful means of advancing or understanding quality of care. On the contrary, most physicians perceive litigation as a barrier to excellence in healthcare.[7,8] There is some empirical support for this viewpoint insofar as the intersection between quality of care and malpractice law is defined in terms of "deterrence"—that is, the power of the latter to promote the former by steering clinicians away from substandard care.[9,10,11,12] However, new perspectives on patient safety expose this conception of the intersection as unduly narrow. It ignores the possibilities for synergies between the risk management/malpractice systems and quality improvement activities that are unrelated to the deterrence function, such as use of claims data as a "portal" for observing and understanding preventable adverse events.[13]

Second, disinterest to date in pursuing such activities has generally been mutual: the principal players in the malpractice system—insurers, risk managers, plaintiff and defense attorneys, and courts—tend to look at each case individually, attending more to legal and insurance information than clinical data. Negligence or the processes that lead to errors, not error *per se*, is the focus of litigation. Moreover, the impulse of those involved in litigation is to cloak claims information in confidentiality, protecting it from aggregation and analysis out of concern for defendants' reputations.

Third, to the extent that a common interest in advancing patient safety goals coexists across healthcare delivery and malpractice camps, a couple of logistical hurdles bar progress. One problem is that single insurers lack the critical mass necessary to support a focused claims analysis. Even the largest insurers in the country, such as CNA HealthPro™ and the St. Paul Companies, probably see too few claims to support reasonable statistical analysis of specific types of errors.[14,15] Another problem is that many large insurers, including CNA and St. Paul, cover diffuse populations of healthcare professionals. Coverage is occasionally encompassing at a given institution, but physicians within the institution will often be covered by multiple insurers. This heterogeneity undercuts the potential for the sort of coordinated, systemwide action that is pivotal to the success of error prevention strategies.

Context

It is an opportune moment to be investigating strategies for deploying of risk management data toward patient safety ends. The Institute of Medicine's report on medical error[16] galvanized interest in studying the etiology of medical errors and injuries. However, a vital step toward progress in this area is the marshalling of detailed information on such events. The structures used to report malpractice data are firmly established in healthcare markets throughout the country, and the remarkable success of closed claims analysis in anesthesia[2,17,18] highlights the potential for these data to be used to improve quality of care.

There have also been signs in recent years that the malpractice insurance industry is interested in findings ways to make substantive contributions to error-reduction efforts. After "crises" in the mid-1970s and mid-1980s, the 1990s was a period of relative calm, but medical malpractice premiums spiked again in the early 2000s.[19,20] The industry desires stability, and addressing the underlying causes of most lawsuits—adverse outcomes—is increasingly seen as a logical and productive step toward achieving this. The IOM report, moreover, linked the principal underlying causes of medical error—most notably, failures to measure and learn from errors and a continuing focus on individual rather than systematic causes—to medical malpractice regimes, a connection that was not lost on the media or policymakers in the aftermath of the report.[21,22,23] Leaders in the insurance industry responded positively to release of the report and signaled the willingness of their organizations to explore ways of contributing to efforts to address the problem of medical error.[24,25,26] Consequently, for the first time in more than a decade, there is serious discussion about how the medical malpractice system can be used to enhance, rather than simply police, patient safety.[27,28,29,30]

Settings/Participants

Five malpractice insurance companies based in four regions (Northeast, Mid-Atlantic, Southwest, and West) participated in the study, granting us access to their claim files for purposes of clinical review. Collectively, they covered approximately 33,000 physicians, 61 acute care hospitals (35 academic and 26 nonacademic), and 428 outpatient facilities. The study was approved by ethics review boards at the investigators' institutions and each review site.

4. METHODS

Study Design

The study consisted of a review of claim files at participating insurers by physicians trained to use a sequence of instruments. The instruments were designed to (1) detect injuries due to medical care (as opposed to the underlying disease process); (2) guide implicit judgments as to whether those injuries were due to treatment or diagnostic error; and (3) disentangle the etiology of errors identified.

Data Sources: The Claim File Sample

Data were extracted from random samples of closed claim files at each insurer. The claim file is the repository of information accumulated by the insurer during the life of a claim. It captures a wide variety of data, including the statement of claim, depositions, interrogatories, and other litigation documents; reports of internal investigations; expert opinions from both sides; medical reports and records detailing the plaintiff's pre- and post-event condition; and, while the claim is open, medical records pertaining to the episode of care at issue. We reacquired the relevant medical records from insured institutions for sampled claims.

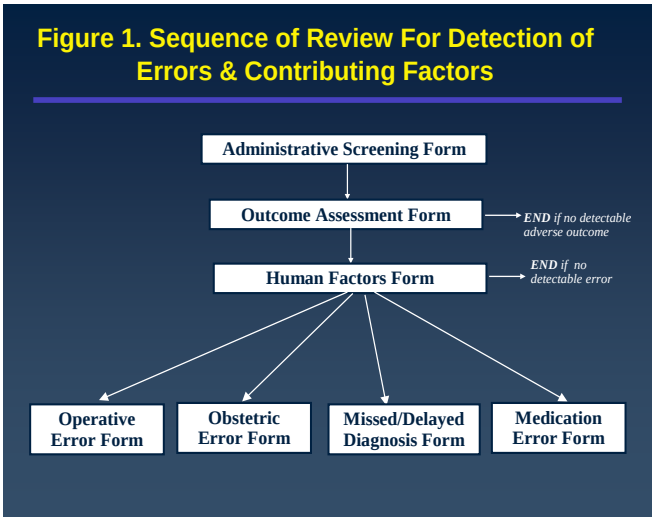
Following previous studies, we defined a claim as a written demand for compensation for medical injury.[31,32] Anticipated claims or queries that fell short of actual demands did not qualify. We focused on four clinical categories and applied a uniform definition of each across insurers: (1) obstetric; (2) surgical; (3) missed and delayed diagnoses; and (4) medication. Alleged injuries in these categories dominate the caseload of malpractice insurers in the United States, accounting for approximately 80% of all claims and an even larger proportion of total indemnity costs.[33,34, 35]

Insurers contributed to the study sample in proportion to their annual claims volume. The number of claims by site varied from 84 to 662 (median=294). One site contributed obstetric claims only; another site had claims in all clinical categories except obstetrics; and the remaining three sites contributed claims from all four clinical categories.

Data Collection: The Claim File Review

The reviews were conducted at the insurers' offices or insured facilities by physicians who were board-certified attendings, fellows, or final-year residents in surgery (surgical claims), obstetrics (obstetric claims), and internal medicine (diagnosis and medication claims). Physician investigators from the relevant specialties trained the reviewers in the content of claims files, use of the study instruments, and confidentiality procedures in 1-day sessions at each site. The reviewers were also assisted by a detailed manual. Reviews took 1.6 hours per file on average and were conducted by one reviewer. To test the reliability of the review process, 10% of the files were re-reviewed by a second reviewer who was unaware of the first review.

Reviews followed a sequence of four instruments (Figure 1). For all claims, insurance staff recorded administrative details of the case and clinical reviewers recorded details of the adverse outcome the patient experienced, if any. Physician reviewers then scored adverse outcomes on a 9-point severity scale ranging from emotional injury only to death.[36] Reviews were terminated for claims without identifiable adverse outcomes (i.e., no score on the scale). For the rest, reviewers considered the potential contributory role of 17 "human factors" in causing the adverse outcome. These factors were selected based on a review of the patient safety literature and covered system-, clinician-, and patient-related causes.



Next, reviewers judged, in light of all available information and their decisions about contributing factors, whether the adverse outcome was due to medical error. We used the Institute of Medicine's definition of error: "the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."[37] Reviewers recorded their judgment on a 6-point confidence scale ranging from "1. Little or no evidence that adverse outcome resulted from error/errors" to "6. Virtually certain evidence that adverse outcome resulted from error/errors." Claims that scored 4 ("More likely than not that adverse outcome resulted from error/errors; more than 50-50 but a close call") or higher were classified as having an error. For these claims, reviewers completed a final form that gathered additional clinical information about the nature and circumstances of the error.

Reviewers were not blinded to the litigation outcome but were instructed to ignore it and exercise independent clinical judgment in rendering determinations about injury and error. Training sessions stressed both that the study definition of error is not necessarily synonymous with the legal definition of negligence and that a mix of factors extrinsic to merit influence whether claims are paid during litigation.

Analysis

The hand-filled data forms were electronically entered and verified by a professional data entry vendor and sent to the Harvard School of Public Health for analysis.

Additional validity checks and data cleaning were performed by study programmers. Analyses were conducted using the SAS 8.2 and Stata/SE 8.0 statistical software packages. We used kappa scores to measure inter-rater reliability of the injury and error determinations.[38]

Limitations

Our study has a number of limitations, with different analyses presenting different issues. For purposes of this summary report, we describe six limitations that have wide applicability to the analyses undertaken.

1. *Generalizability.* The sample was drawn from insurers and clinical categories that are not representative of malpractice claims nationwide. Academic institutions and the physicians who staff them are overrepresented, as are claims that fall within our clinical categories of interest, as reflected in the relatively high number of primary care physicians (medication and diagnostic) and childbirth injuries (obstetrics).

2. *Representativeness of malpractice claims.* Malpractice claims data generally also have several other biases when used to investigate medical injuries. Severe injuries and younger patients are over-represented in the subset of medical injuries that triggers litigation.[39,40] It is possible that the factors that lead to error in litigated cases may differ systematically from the factors that lead to error in nonlitigated cases, although we know of no reason why they would.

3. *Reliability*. The reliability of error judgments was moderate and approached poor for claims involving missed and delayed diagnoses (Table 1). To address this, we used a variety of approaches to test the robustness of our findings. Sensitivity analyses were tailored to the specific analyses.

Table 1. Inter-Reviewer Reliability of Adverse Outcome and Error Determinations

Clinical Category	Kappa: Adverse Outcome	Kappa: Error
Operative (n=40 pairs)	1.00	0.80
Obstetric (n 32 pairs)	0.70	0.56
Missed/delayed diagnosis (n=42 pairs)	0.63	0.41
Medication (n=28 pairs)	0.91	0.76

- *Kappa for adverse events: 0.38 - 0.42 (intermediate)*
- *Kappa for negligent adverse event: 0.24 - 0.28 (poor)*

4. *Negligence vs error.* Merit was determined by reference to error, which is not identical to the legal concept of negligence, though the two cleave so closely

that medico-legal experts have trouble explaining the difference. This limitation was applied to our medico-legal analyses, which used the error-payment relationship as a measure of the system's accuracy.

5. *Hindsight bias.* Reviewers' awareness of the litigation outcome may have biased them toward finding errors in paid claims, and *vice versa*.[41,42] Several factors militate against this bias: reviewers were instructed to ignore the litigation outcome; one quarter of error judgments *did* diverge from the litigation outcomes; and physicians, who as a group tend to be skeptics of the malpractice system, may have been disinclined to credit the system's findings (or even pleased to conclude that it was wrong). To the extent that hindsight bias operated, its likely impact would be to pull the non-error rate (37%) toward the payment rate (56%), resulting in an overestimate of the prevalence and costs of non-error claims. The impact on differences between non-error and error claims is unknown; it would depend on the profile of the misclassified claims.

6. *Limits of documented evidence.* Unlike prospective observational studies or root cause analyses, retrospective review of records, even the detailed records found in malpractice claim files, will miss certain breakdowns (e.g., patient noncompliance) and contributing factors (e.g., fatigue, workload) unless they emerged as issues in the litigation. This measurement problem means that prevalence findings for such estimates will be lower bounds, and the multifactorial causality we observed probably understates the true complexity of the MIMEPS group of errors.

5. RESULTS

Overview of Principal Findings

We reviewed 1452 claims. The breakdown of these claims by clinical category is shown in Table 2.

Table 2. Reviewed claims by clinical category

Clinical category	n	%
Operative	444	31
Obstetric	335	23
Missed/delayed diagnosis	429	30
Medication	244	17
Total	***1452***	***100***

The dates of closure for the claims spanned 20 years, but most were relatively recent (Table 3). Eighty-three percent of the claims closed between 1995 and 2004; 62% closed in 1998 or later. The average time between occurrence of the injury and closure of the claim was 5 years.

Table 3. Time periods within which reviewed claims were closed

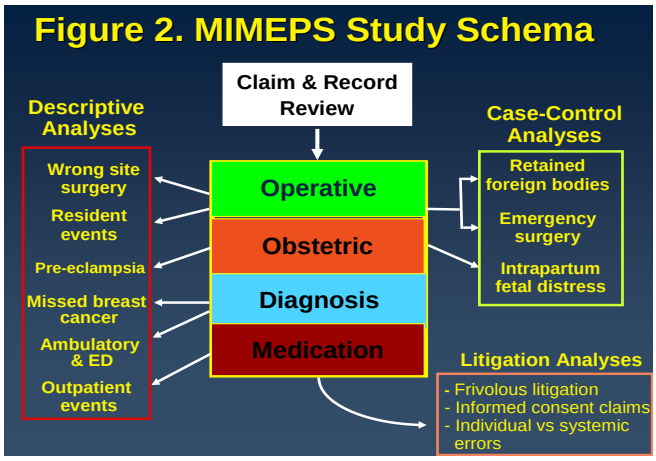
Closure period	n	%
1984 – 1989	57	4%
1990 – 1994	190	13%
1995 – 1999	542	37%
2000 - 2004	663	46%

In 3% of claims, no adverse outcome from medical care was evident (Table 4). An additional 4% of claims involved emotional injury or failure to obtain the patient's informed consent to treatment but no physical injury. The remaining 93% of claims involved physical injury, and typically these injuries were severe. Eighty percent of claims involved injuries that caused significant (39%) or major (15%) disability or death (26%).

Table 4. Injury types

No injury	3%
Breach of informed consent (only)	1%
Psychological/emotional	4%
Minor physical	13%
Significant physical	39%
Major/grave physical	15%
Death	26%

Beyond these basic descriptive statistics of the study dataset, results for the project are difficult to bring together in summary form, because the MIMEPS analyses are wide-ranging in nature. They are depicted in Figure 2.



The analyses can be divided into four groups. Group 1 consists of general descriptive papers with report results from each of the four clinical categories. Group 2 involves subanalyses directed at recognized patient safety problems. In some cases (e.g., missed breast cancer, wrong site surgery) these subanalyses involve use of data drawn from within one of the four clinical categories; in other cases (e.g., analysis of residents' involvement in errors) the subanalysis is cross-cutting and does not observe the boundaries of clinical categories.

Group 3 consists of case-control studies in which the MIMEPS data furnishes the cases and the controls come from other sources. Group 4 involves three legal analyses that address (i) the prevalence and cost of claims that did not involve error; (ii) claims alleging a breach of informed consent; and (iii) an etiologic analysis of the legal concept of negligence in which the litigation outcomes are compared with human factors data.

Discussion & Conclusions

As with the results from this study, a brief overarching summary of conclusions is difficult; they tended to be quite specific to the analyses in question. However, several broad themes are evident.

- *Value of malpractice claims in patient safety research.* From a methodological perspective, we found that closed malpractice claims yielded a rich source of data about errors and the factors that caused them. The most valuable validation of this conclusion was our ability to analyze the MIMEPS data in key areas of concern in patient safety (*see* Figure 2, above), with results that will inform ongoing and future error-reduction initiatives. Another validation came in the form of a question posed to reviewers toward the end of the Human Factors Form. Reviewers were asked to rate on a 5-point Likert scale the value the medical record and other information in the claims file, respectively. Table 5 summarizes the results. Although medical record review remains the gold standard in large-scale retrospective review of medical injuries, we believe that claim file review represents an improvement on this methodology in some key respects.

Table 5. Physician reviewers' assessments of the comparative value of medical records & malpractice claims files in making judgments about contributing factors

Clinical Category	Value of Medical Record *	Value of Other Documents * *(e.g., testimony, expert reports, hospital committee reviews, etc.)*	*P* value
Overall	3.7	4.3	<0.001
Operative	3.7	4.4	<0.001
Obstetrics	4.2	4.2	1.0
Missed/delayed diagnoses	3.6	4.2	<0.001
Medication	3.2	4.3	<0.001

** Mean scores from a 5-point Likert scale ranging from "No value" (1) to "Somewhat valuable" (3) to "Indispensable" (5)*

- *Cognitive and system errors.* We found that systems factors played a critical role in the occurrence of errors. Individual errors in judgment, vigilance, or memory were certainly not irrelevant. On the contrary, approximately nine out of 10 errors involved at least one of these cognitive factors. More than three quarters of the time, however, they acted in concert with other more system-oriented factors (e.g., communication breakdowns, supervision problems) in producing harm. This was true even among those surgical errors that, at a superficial level, appeared to be purely technical in nature.

- *Patients' role in errors.* Patient-related factors, both behavioral (e.g., compliance, follow-up) and clinical (e.g., difficult anatomy, atypical presentation), were also critical contributors to errors. They were present in approximately one third of all errors detected in MIMEPS.

- *Multifactorial nature of errors*. Our findings highlight the complexity of errors, especially diagnostic errors that occur in the ambulatory care setting. Just as Reason's "Swiss cheese" model of accident causation suggests,[43] diagnostic errors that reach patients appear to result from the alignment of multiple breakdowns, which in turn stem from a confluence of contributing factors. For example, the median number of contributing factors involved in diagnostic errors in the outpatient setting was 3; 59% had $\geq$3 contributing factors, 27% had $\geq$4, and 13% had $\geq$5.

- *Trainee involvement in errors.* Trainees were involved in approximately one third of errors detected in our study. To some extent, this reflects MIMEPS' focus on teaching hospital settings. Nevertheless, supervision breakdowns and lack of experience emerged as important human factors, and these breakdowns were driven largely by the involvement of residents, fellows, and interns.

- *Frivolous litigation.* Findings from our litigation analyses suggested that frivolous litigation may not be as large a problem as some in the recent debates over medical malpractice reform have suggested. Although a nontrivial proportion of claims lack evidence of error, their fiscal impact tends to be limited, because the system performs quite well in denying them compensation. The vast majority of resources go toward resolving and paying claims with errors.

Implications

In many respects, the findings to date from the MIMEPS project are humbling. They shed light on the tremendous causal complexity that underlie many errors. The task of effecting meaningful improvements to the medical care process—with its numerous clinical steps, stretched across multiple providers and months or years, and the heavy reliance on patient initiative—looms as a formidable challenge. The prospects for "silver bullets" in this area appear remote. Our results underscore the need for continuing efforts to develop the "basic science" of error prevention in medicine,[44] which remains in its infancy.

However, the public demands action today. Are meaningful gains achievable in the short to medium term? The answer will likely turn on whether relatively simple interventions that target two or three critical breakdown points are sufficient to disrupt the causal chain or whether interventions at a wider range of points is necessary to avert harm. An important goal of the MIMEPS research was identify key points of breakdown and link them with interventions that have the potential to attenuate them. Each of the clinical analyses (groups 1, 2, and 3) are geared toward this goal. Using the overall analysis of missed/delayed diagnoses in the ambulatory setting as an example, Table 6 illustrates the strategy and exemplifies the type of intervention lists developed for each of the MIMEPS clinical categories.

Table 6. Potential interventions to address selected breakdowns in the diagnostic process

Process Breakdown	Potential Patient Safety Intervention	Contributing Factors Addressed
Failure to order appropriate test	• Improving decision making via decision support systems that recommend certain tests based on available information • Audits of certain diagnoses to ensure adherence to guidelines • Improved access to guidelines	• Lack of knowledge • Judgment • Vigilance/Memory • Patient-related factors
Failure to create a proper follow-up plan	• Improved scheduling systems for patients undergoing active treatment or evaluation • Ticker systems if patients do not return for follow-up • Guidelines for appropriate follow-up for certain diagnoses	• Lack of knowledge • Judgment • Vigilance/Memory • Patient-related factors
Failure to perform adequate history/physical	• Standardized histories for certain complaints or diagnoses	• Lack of knowledge • Judgment • Vigilance/Memory
Incorrect interpretation of a diagnostic test	• Process for rapid review of certain studies by an expert physician (e.g., x-ray read by internist in clinic should have radiology review in a timely way) • Process for internal second review of certain high risk test results (e.g., breast biopsies)	• Lack of knowledge • Supervision • Judgment
Diagnostic/laboratory test results not transmitted to patient	• Results management and tracking systems to ensure that results are seen for every test ordered • Implementation of best practices around communication of critical test results per Joint Commission	• Vigilance/Memory • Patient-related factors • Handoffs

6. LIST OF PUBLICATIONS AND PRODUCTS

As at the date of writing this report, the status of manuscripts from the MIMEPS project is as follows:

Published:

Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. A case-control study of the retention of instruments and sponges after surgery. *New England Journal of Medicine* 2003;348:229-235

Accepted for publication:

Kwaan M, Studdert DM, Zinner M, Gawande AA. Incidence, patterns, and prevention of wrong-site surgery (accepted for publication: *Surgery*, 2005).

Under revision:

Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Accuracy of the medical malpractice system: relationship between claims, errors, and outcomes of litigation (under revision: *New England Journal of Medicine*, 2005).

Rogers SO, Gawande AA, Kwaan M, Puopolo AL, Yoon C, Brennan TA, Studdert DM. Analysis of surgical errors in closed malpractice claims at four insurers (under revision: *Surgery,* 2005).

Kachalia A, Gandhi TK, Gawande AA, Puopolo AL, Yoon C, Poon E, Thomas EJ, Brennan TA, Studdert DM. Missed and delayed diagnoses in the emergency department (under revision: *Annals of Emergency Medicine*, 2005).

Under review:

Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, Studdert DM. Missed and delayed diagnoses in the ambulatory setting (under review: *Annals of Internal Medicine*, 2005).

Table 7 provides a broader overview of the MIMEPS manuscripts, both completed and underway. The table organizes them according to the four analytical groups outlined above.

Table 7. Overview of MIMEPS manuscripts as at December 15, 2005

	MIMEPS papers	Analysis complete	Manuscript drafted	Submission to peer-reviewed journal	Published
Group 1 analyses					
1	Surgery – overall	X	X	X	
2	Diagnosis – ambulatory	X	X	X	
3	Diagnosis – ED	X	X	X	
4	Obstetrics I - infant injuries	X			
5	Obstetrics II - maternal injuries				
6	Medication				
Group 2 analyses					
1	Missed cancers				
2	Pediatrics	X			
3	Nursing events				
4	Surgery – communication	X	X	X	
5	Surgery - technical competence				
6	Patient factors				
7	Trainees				
8	Wrong site surgeries	X	X	X	X
9	Interventions	X			
Group 3 analyses					
1	Case-control I (fetal distress)				
2	Case-control II (emergency surgery)				
Group 4					
1	Litigation I - prevalence and cost of frivolous litigation	X	X	X	
2	Litigation II - predictors of frivolous litigation	X			
3	Informed consent				
4	Nature of error/negligence				

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