Part One

Setting the Stage

Although physicians have been worrying about and studying *adverse events* for as long as the profession of medicine has existed, systematic, large-scale studies are recent phenomena. The single most comprehensive such effort is the Harvard Medical Practice Study of adverse events in a random sample of State of New York hospitals, released in 1990.

Ten years later, a special committee of the Institute of Medicine published *To Err Is Human,* an important exploration of medical error. This report relied heavily on the findings of the Harvard Medical Practice Study. It also included important work from other disciplines such as human factors engineering and high reliability organization theory, which explore the influence of organizational conditions and systems elements on human error.

Part One of this book provides a comprehensive review of the original Harvard Medical Practice Study in Chapter One, and looks at ways that study may have been misinterpreted. This chapter also summarizes findings from more recent research conducted by some of the original HMPS investigators. It highlights the scale and importance of the problem. It also points out the weaknesses inherent in conducting studies of this sort. It explores the complications and contortions produced by our country's reliance on the tort system for settling malpractice disputes. Perhaps the most serious impact

of that reliance is the chilling effect malpractice threats have on medical error reporting.

By discussing how the HMPS started the current national discussion of medical error and where we have come since its publication, Part One offers a fitting beginning for this book's exploration of what we know and what we do.

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What Have We Learned Since the Harvard Medical Practice Study?

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Interest in the study of medical injury gained momentum through the 1990s, culminating in the Institute of Medicine's report *To Err Is Human* (Kohn, Corrigan, & Donaldson, 2000). The report brought unprecedented attention to the field among researchers and the general public—publicity that will no doubt provide the impetus for numerous studies of error and injury in the years ahead. New research in this area is welcome, both because of the gravity of the problem and our currently limited knowledge.

A significant contribution to what we do currently know about medical mistakes and malpractice litigation comes from a series of studies of iatrogenic injury, its economic consequences, and the resolution of associated claims. Pioneering work was undertaken in California in the late 1970s and early 1980s. Responding to a perceived crisis in malpractice litigation in the mid-1970s, the California Medical Association and the California Hospital Association

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jointly commissioned the Medical Insurance Feasibility Study (MIFS)—an investigation of medical records designed to measure rates of injury in hospitalized patients (California Medical Association & California Hospital Association, 1977; see also Mills, 1978). A team of medico-legal experts, led by Don Harper Mills, reviewed nearly 21,000 records in twenty-three hospitals across the state and found 970 incidents of disability caused by health care management. Because the hospitals were carefully selected to be representative of hospitals statewide in terms of size, ownership, teaching status, and region, the findings implied that approximately 4.6 percent of Californians hospitalized in the mid-1970s (roughly one in twenty) suffered some sort of iatrogenic injury. One in every one hundred inpatients suffered an injury that gave rise to permanent or grave disability.

In the midst of a second surge in malpractice claims in the mid 1980s, a group of Harvard investigators undertook a similar evaluation of malpractice litigation in New York State (Harvard Medical Practice Study, 1990). The objective of the Harvard Medical Practice Study (HMPS) was to answer three questions: (1) How frequently do medical injuries occur in hospitals, particularly the subset of injuries attributable to negligent care? (2) What portion of those injuries gives rise to litigation, and conversely, how much litigation proceeds in the absence of such injuries? and (3) What are the economic consequences of medical injuries?

This chapter revisits the results of the HMPS in light of new information about medical injury and malpractice litigation. In particular we report findings from a recently completed set of investigations in Utah and Colorado, which replicated many of the HMPS methods. The chapter begins by reviewing the HMPS and describing several important changes to the health care system that made repetition of this kind of large-scale study of iatrogenic injury worthwhile. Next we outline results from each of the four main areas of analysis comprised by the Utah-Colorado Medical Practice Study (UCMPS): incidence of medical injury, malpractice claim-

ing behavior, the economic consequences of medical injury, and the feasibility of alternative approaches to compensation. In conclusion we summarize our findings and discuss their implications for health care policy.

The Harvard Medical Practice Study and Its Findings

Led by Howard Hiatt, M.D., the former dean of the Harvard School of Public Health, the HMPS investigators quickly recognized that the dual tasks of charting the epidemiology of medical injury and malpractice claims would require a medico-legal data collection effort on an unprecedented scale. Hiatt secured a significant funding commitment from the New York Department of Health and from the Robert Wood Johnson Foundation. After three years of design work, the investigators commenced data collection in New York.

HMPS investigators assembled a representative sample of fifty-two hospitals from among the more than three hundred acute care facilities in New York, and randomly sampled medical records for the year 1984 from those hospitals (for a full description of the HMPS sampling methodology, see Harvard Medical Practice Study, 1990, chap. 4.). The study sample was weighted to allow statistical transformation of results from this selection of institutions and records into statewide estimates. Teams of physicians and nurses then reviewed each record, looking for evidence of *adverse events*—defined as injuries caused by medical practice, as opposed to a disease process, that either prolonged the patient's hospital stay or resulted in disability at the time of discharge. When an adverse event was detected, the chart review protocol directed the physician reviewers to judge whether it had been caused by negligence. Negligence was defined, in accordance with standard tort criteria, as actual injuries proximately resulting from a treating physician's failure to meet the standard of care expected in his or her practice community (Prosser, Keeton, & Dobbs, 1984, § 30, pp. 164–165).

While record review proceeded, the investigators contacted more than twenty insurance companies underwriting malpractice risk in New York for injury year 1984. Unfortunately, by the time this process began in 1990, the effects of a second tort crisis in the mid-1980s had been felt. Many insurers had gone into state receivership, having failed as a result of unanticipated increases in expenditures on litigation and settlements. This made the task of identifying claims quite arduous. Nonetheless, investigators successfully created a database of nearly 68,000 malpractice claims filed between 1984 and 1989. Patients were then linked to claimants using software programs designed to maximize the identification of name matches. In this way, investigators were able to identify which patients whose medical records were examined in the chart review were subsequently involved in litigation.

Finally, a survey of individuals who had suffered adverse events gathered information on the economic consequences of the injuries. This survey occurred more than four years after the injury itself to allow investigators to make a reasonable assessment of the repercussions of the injury. Unfortunately, respondents' ability to recall actual costs appeared to be significantly impaired by the time elapsed. The site team applied unit cost estimates to information obtained in the surveys to assess overall costs of injury (Johnson et al., 1992).

The results of the HMPS have been widely reported (for a summary of articles published through 1993, see Weiler et al., 1993, pp. 155–175). The investigators detected a slightly lower rate of adverse events than had been found in MIFS. Approximately 3.7 percent of patients hospitalized in New York in 1984 were estimated to have suffered a medical injury associated with their stay (Brennan et al., 1991). Just over one-quarter of those injuries were due to negligence. When these figures were *up-weighted* to account for all hospital discharges in the state, they indicated that 100,000 New Yorkers suffered medical injuries in 1984, 13,000 of which resulted in death. Negligence gave rise to approximately 20,000 disabling injuries and 7,000 deaths.

These alarming statistics have become the chief legacy of the HMPS. For the first time, the burden of morbidity and mortality from medical injuries was widely publicized. This attention, in turn, helped to spawn interest in error measurement and prevention—one of the most vibrant fields of inquiry in health services research today (Leape, 1994, 1998). Efforts to understand medical error, however, remain largely contained within a frame of analysis concerned with quality of clinical care. Commentators and researchers involved in the study of error—many of them clinicians—typically view the law's role with disdain and pay it little attention. Few have explored legal means for deterring accidents (Liang, 1999).

The patient safety movement's orientation away from scrutiny of the legal system is problematic, given the solid evidence from the HMPS that the tort system has been failing in both its compensation and deterrence functions. In total, approximately 3,600 malpractice claims relating to injury year 1984 were made in New York (Localio et al., 1991). A comparison to the 27,000 negligent adverse events arising in that year produces a negligence-to-claims ratio of 7.5 to 1—not much smaller than the ratio identified by Danzon (1985) using data from the MIFS a decade earlier. Even when the injury sample is narrowed to a subset of more monetarily valuable tort claims—those involving serious injury to patients less than seventy years old—a negligence-to-claims ratio of 5 to 2 persists (Weiler et al., 1993, p. 71).

But the HMPS analysis of litigation went a step further than the MIFS analysis had by matching specific claims to specific injuries. This exercise shed new light on the dimensions of the disconnection between claims and injuries: not only did few documented instances of negligent injury give rise to claims, the majority of claims that were initiated did not appear to be grounded in identifiable instances of negligence. Investigators estimated that, among the 3,600 claims in New York relating to injury suffered in 1984, more than one-half arose from instances in which there was neither negligence nor any identifiable injury, and one-third arose from instances of

injury but no negligence; only one-sixth corresponded to "true" negligent incidents (Localio et al., 1991).

We have previously described this paradoxical relationship as both lopsided and mismatched (Studdert et al., 2000). Paul Weiler draws an analogy to a traffic officer ticketing random drivers, a process that penalizes some violaters, but also some nonviolaters, and allows many violaters to pass (Weiler et al., 1993, p. 75).[1] This dysfunctional situation clearly implies that compensation and deterrence objectives are not fully realized by malpractice law. In fact the only clear evidence of a relationship between malpractice claiming and actual behavioral responses found in the HMPS was at the level of the hospital, and here the important signal was the overall number of medical injuries, not the number of medical injuries actually due to negligence (Brennan, 1998). This finding intimated that institutions may be best positioned to channel the liability threat and experience toward injury-reduction strategies, an argument made persuasively by several legal commentators (see Abraham & Weiler, 1994; Sage, Hastings, & Berenson, 1994) and one that resonates with contemporary organizational theories of safety. Overall, HMPS investigators did not interpret their findings about the dynamics of litigation as supporting ongoing reliance on individually targeted tort litigation to ensure patient safety (Weiler et al., 1993, pp. 139–149).

The Need for Validation

Given such clear-cut findings about the incidence of medical injury and the dynamics of malpractice litigation, why should the HMPS require validation? The most obvious reasons stem from a couple of significant market transitions in the United States. Perhaps most important, managed care has emerged as a major force in U.S. medicine. The penetration of managed care in New York in 1984 was minimal. Managed care's rapid rise began in the late 1980s, not only in New York but also in many other regions of the country, and within

several years managed care had taken root as a new way of life in the practice of medicine. The other market shift concerns proprietary medicine. New York had no for-profit sector of hospital care in 1984. By the early 1990s, for-profit institutions were well established in many markets around the United States, including those in New York. Managed care, for-profit medicine, and the points of intersection between these two phenomena have largely transformed the health care industry that existed before 1990. It is unclear what effect these changes are likely to have on the rate and types of medical injuries, although the industry's greater emphasis on financial considerations has undoubtedly elevated concerns about errors of omission (as opposed to commission).

Issues of generalizability aside, a series of recurring questions has arisen about aspects of the HMPS itself. First, with regard to identification of medical injuries, a number of critics have pointed out that the reliability of judgments about injury and negligence is less than stellar (see, for example, Anderson, 1996; Brennan, Localio, & Laird, 1989; Localio et al., 1996). Second, questions have persisted about the extent of the gap identified between numbers of malpractice claims and of medical injuries in the HMPS; most other studies of malpractice claims suggest a smaller mismatch between claims and negligence (see Taragin, Willet, Wilczek, Trout, & Carson, 1992; White, 1994). Third, the task of collecting data on malpractice claims in New York proved particularly challenging due to the volatile malpractice environment that existed in 1984. Fourth, HMPS investigators did not have the tools to estimate the costs of different compensation models or to compare these costs to those of the tort system; consequently, assessments of the economic feasibility of alternative schemes, such as *no-fault* compensation, were crude.

En masse, this set of defects and unanswered questions is very serious. Before policymakers could reasonably be expected to rely on the HMPS findings, we believed it was necessary to validate that study. In preparing to bring the medical injury statistics up to date,

we sought states that differed markedly from New York, both regionally and in their demographic mix. Another important criterion was the existence of a mature health care industry, including a managed care and for-profit hospital presence. To simplify and improve the study of malpractice litigation, we also hoped to find states with relatively stable, monopolistic indemnity insurance markets.

The Utah-Colorado Medical Practice Study

In 1995, the Robert Wood Johnson Foundation provided us with a grant to undertake a study similar to the HMPS in Utah and Colorado. We worked closely with the legislatures and the dominant physician malpractice insurers in these two states. Collaborators provided us with an unprecedented level of access to hospital data systems and malpractice claims. In collecting and analyzing these data, we redeployed the basic methods of the HMPS, making several design changes and running repairs in places where we thought significant deficiencies existed. The lead results of the UCMPS were recently reported in the medical literature (see Thomas et al., 1999, 2000a; Studdert et al., 2000).

The Health Burden of Medical Injury

Our validation goals demanded that the pool of injuries detected in the mountain states be directly comparable with that from New York. As we have noted, however, the reliability of record reviewers' judgments—both adverse event and negligence determinations—was a major focus of the methodological critiques that followed release of the New York findings. Drawing on knowledge gained from work done in the interim on *inter-rater reliability* and from ongoing analyses of the New York experience, we made several modifications to the review process. Most notably, we revamped reviewer-training practices and instituted a series of quality checks on physician reviewers' judgments.

From thirteen representative hospitals in Utah and fifteen in Colorado, we completed reviews of 4,943 (98.9 percent) of 5,000 sampled records in Utah and 9,757 (97.6 percent) of 10,000 records in Colorado. Physician reviewers identified a total of 169 adverse events in Utah and 418 adverse events in Colorado. When these totals are up-weighted to the state populations, they yield estimates of 5,614 adverse events among hospitalized patients in Utah in 1992, and 11,578 in Colorado. We estimated an adverse event rate of 2.9 percent in both states, a remarkable similarity considering that medical records were reviewed by completely different teams of physicians in each state. In Utah 32.6 percent of the adverse events were judged due to negligence; in Colorado the proportion was 27.5 percent.

To analyze types of adverse events, we pooled the results. As Table 1.1 illustrates, the most prevalent injury type was adverse events connected to surgery, accounting for approximately half (44.9 percent) of adverse events across both states (for a detailed analysis of the surgical adverse events identified in the UCMPS, see Gawande, Thomas, Zinner, & Brennan, 1999). Nearly one-third of these were the result of technical complications in the operation. Only 16.9 percent of surgical adverse events involved negligence. Approximately the same proportion resulted in permanent disability.

Drug-related adverse events were the next most prevalent group. They accounted for more than one-third of the balance of the injuries. The four most common classes of drugs involved were antibiotics (24.9 percent), cardiovascular agents (17.4 percent), analgesics (8.9 percent), and anticoagulants (8.6 percent). Strikingly, more than one-third of all drug-related adverse events detected were due to negligence. The mistakes included prescription of the wrong drug (20.9 percent), prescription of the wrong dose (7.9 percent), and prescription of a drug to a patient with a known allergy to that drug (5.7 percent).[2]

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).

Compared to the findings from New York, iatrogenic death was a relatively rare occurrence in the mountain states. Only 6.6 percent of adverse events resulted in death, although the death rate was slightly higher (8.8 percent) among negligent adverse events. In total, 439 patients hospitalized in Utah and Colorado in 1992 died due to negligent care; another 160 victims of negligence suffered grave or major disability.

These mortality statistics confirm the existence of an epidemic of potentially preventable iatrogenic death in the United States. However, they present a considerably less bleak picture than emerged from New York eight years earlier. When extrapolated to the U.S. population, iatrogenic deaths detected in the HMPS suggested nearly 200,000 deaths a year were due to adverse events, whereas the UCMPS suggests approximately 65,000 deaths. The difference widens for negligent adverse events: 120,000 negligent deaths nationwide versus somewhat fewer than 25,000, extrapolating from the HMPS and the UCMPS rates respectively. This fivefold difference in deaths due to negligent care is particularly striking.

There are several explanations for it. First, by the time we initiated the UCMPS, we had become aware of a growing literature suggesting that severity of injury tended to inappropriately color judgments about quality of care (see, for example, Hayward, Bernard, Rosevear, Anderson, & McMahon, 1993). Therefore, during reviewer training, we dealt specifically with the need to differentiate injury severity from the judgment of causation or negligence. Second, the standard of medical care may simply have been better in Colorado and Utah in 1992 than in New York in 1984. Third, we cannot, of course, rule out the possibility that limitations in the methods we used, principally chart review, at least partly explain disparities between the two studies (for a recent critique of the questionable role of reviewer consensus, see Hofer, Berstein, De Monner, & Hayward, 2000).

But despite the differences noted, the story that emerges from comparison of the HMPS and UCMPS results is chiefly one of tremendous similarity. Beginning with the overall adverse event rate itself, there is no statistically significant difference between the proportions of hospital discharges involving patients who have experienced adverse events. Cross-study analyses of a variety of other measures show that the UCMPS findings essentially reinforce those from the HMPS. For example, the proportion of operative adverse events is stable between studies. Slightly more than one-half of all

negligent adverse events in both studies occurred in the emergency department, and a very high proportion of all adverse events attributed to emergency physicians were judged to be due to negligence (70.4 percent in New York and 52.6 percent in Utah and Colorado). Together, the studies provide overwhelming evidence that the burden of iatrogenic injury is large, enduring, and an innate feature of hospital care in the United States.

Two other studies since the HMPS have yielded contrasting results and warrant mention. In August 1995, to much public clamor, the Australian government announced results from the Quality in Australian Health Care Study (QAHCS). Ross Wilson and colleagues (1995) estimated that 16.6 percent of admissions to Australian hospitals were associated with adverse events, 51 percent of which were considered preventable.[3] Having consulted with QAHCS investigators throughout their study, we were surprised by these results because the Australians also drew a sample from 1992, identical in size to the UCMPS sample, and then modeled their methods, as we had, on those developed during the HMPS. Yet they detected nearly six times more adverse events than the UCMPS did. A closer analysis of the respective study methods and samples showed that several relatively straightforward adjustments were necessary to allow direct comparability (Thomas et al., 2000b). However, such adjustments still reduced the disparity only to a fourfold difference.

The UCMPS results are also quite different from those obtained in a 1997 study by Lori Andrews and colleagues (1997) in Illinois. Using ethnographic measurement techniques to track adverse events occurring in "real time," they found a rate of 17.7 percent in one university teaching hospital. However, fairly major differences between the Andrews study and the UCMPS in sampling and other aspects of the methodologies limit the studies' comparability.[4]

The Relationship Between Malpractice Claims and Medical Injuries

An important component of the UCMPS, like the HMPS before it, was to link the medical injuries identified in record review to malpractice claims. The task was less onerous than had been the case in New York, thanks to a more stable claims environment in the mountain states, more detailed and readily accessible claims files, and the existence of several dominant indemnity insurers. All the leading insurers contributed claims data. We then used computer-matching techniques to identify patients from the medical record review who filed malpractice claims during or after 1992.

We identified eighteen claims arising from records we had reviewed, eight in Utah and ten in Colorado. The low number of matches was expected, given the relatively small sample size of both medical records and claims in the UCMPS. Nonetheless, we were still able to link the claims information with chart review findings and sketch an empirical picture of the relationship between medical injuries and malpractice litigation. Table 1.2 summarizes this relationship and compares the UCMPS findings to those from New York and California. The data tell quite a consistent story about the claims-negligence dynamic.

Markedly different litigation environments prevailed in the four states at the time of each study (see row 1). California and New York were experiencing frenetic claims activity, whereas the situation in Utah and Colorado was relatively calm at the time of our medico-legal measurements. The high litigation rates on the East and West coasts are no doubt partly attributable to the medical malpractice "crises" that unfolded in the mid-1970s and mid-1980s. However, California and New York are distinctive in other ways that could affect claims, incidence of negligence, and claims-negligence dynamics: both are heavily populated, are among the states with the highest lawyer-to-population ratios, and are renowned for having consistently high rates of malpractice litigation.

Table 1.2. Relationship Between Negligent Adverse Events and Claims.

Relationship	Utah 1992	Colorado 1992	New York 1984	California 1976
Claims per 100 physicians per year	7.1	7.3	14.0	17.4
Negligent adverse event rate (per 100 discharges)	0.90	0.80	1.00	0.79
Ratio of negligent adverse events to claims	5.1	6.7	7.6	10.0
Probability claim follows negligent adverse event	2.5%		1.5%	—

Row 2 of Table 1.2 restates findings from the chart reviews: it illustrates that volume of litigation has no significant bearing on the incidence of malpractice. Nor do litigation rates appear to affect accuracy of claiming, as shown in row 4. However, fewer claims combined with steady negligence rates must mean that the "malpractice gap" narrows. Row 3 shows that the degree to which instances of substandard care outstrip claims that allege such care was less in Utah (ratio of 5.1. to 1) and Colorado (ratio of 6.7 to 1) than it was in the high litigation states of New York (ratio of 7.6 to 1) and California (ratio of 10.0 to 1). Taken together, the data in Table 1.2 suggest that the dysfunctional characteristics of the medical malpractice system—most notably, its *adequacy* and its *accuracy*—when viewed through an epidemiological lens, have a resilience over time and across jurisdictions.

An important caveat is in order at this point. Regardless of the similarity between the methods that generated these comparative data, any conclusions about intertemporal and cross-regional trends must be tempered by an acknowledgment that the data are not longitudinal. Because we have no evidence that the disconnection observed between negligent injury and claiming behavior existed in the mountain states in earlier periods, we are unable to infer that

it is insensitive to overall rates of claims and stable across time and regions of the country. However, our findings certainly lend plausibility to the argument that the findings from Utah, Colorado, New York, and California are a reasonable reflection of the situation in other states.

The final analysis in the malpractice component of the UCMPS was focused on the significant population of patients—more than 97 percent of those who suffered negligent adverse events in our study—who experience malpractice but never file claims seeking compensation. To profile this group, we compared UCMPS information on 157 patients from Colorado who were found to have suffered negligence but had not sued with information on individuals who had sued for injuries allegedly suffered in 1992. (Information on the latter group was obtained directly from insurers.)

Our results are shown in Table 1.3. Predictably, people who did not claim despite having suffered negligence were more likely to have suffered minor injury. Nonclaimants were also much more likely to be Medicare recipients, Medicaid recipients, seventy-five years old or older, and low-income earners. These findings support and elaborate those of Burstin, Johnson, Lipsitz, and Brennan (1993) from the HMPS.

How can the strong association between the sociodemographic factors we identified and underclaiming be explained? Financial incentives provide one explanation. Economic theories of tort law suggest that individuals who are poor or who do not earn income, whether or not they are poor, will be less likely to sue. Malpractice litigation is rarely initiated without attorney involvement, hence a prospective litigant's ability to claim typically hinges on an attorney's willingness to take on the case. Because the financial return accruing to plaintiffs' attorneys in tort cases is generally linked to the size of the award through contingency fees, and lost income typically forms a significant component of malpractice awards, these lawyers would tend to maximize their own income by choosing to act for clients with ongoing sources of income. (Indeed, the

Table 1.3. Multivariate Odds of Failure to Claim Despite Negligence, by Sociodemographic Characteristics (Colorado, incident year 1992).

	Nonclaimants compared to all claimants (n = 109 and 256, respectively)	
Characteristics	Odds Ratio	95% Confidence Interval
Female	1.4	0.8–2.6
Patient age[a]		
< 18	1.0	0.3–3.3
45 to 64	1.7	0.8–3.6
65 to 74	2.2	0.6–7.3
≥ 75	7.0	1.7–29.6*
Payer[b]		
Medicare	3.5	1.3–9.6*
Medicaid	3.6	1.4–9.0*
Uninsured	2.0	0.7–5.8
Income[c]		
Poor	2.0	0.8–5.3
Low income	2.0	0.9–4.2**
High income	0.8	0.3–1.8
Disability[d]		
Minor	6.3	2.7–14.9*
Significant	1.7	0.8–3.9

[a] Reference group was patients aged 18 to 44 years. [b] Reference group was privately insured. [c] Reference group was middle income. [d] Reference group was major disability.

* $P < 0.05$. ** $P < 0.1$.

costs of bringing a claim may simply exceed the damages recoverable.) The elderly and the poor are particularly unlikely to generate income. Moreover, any income they do generate is less likely to be "lost" owing to a decline in physical capacity occasioned by negligent injury. In addition, the size of any award to elderly patients will usually be constrained by their shorter life expectancy.

Other factors that we did not account for in our statistical analysis, such as regulatory barriers (see Legal Services Corporation Act,

1999; McNulty, 1989) and level of education, may also play a role in defining the nonclaimant group. But whatever the true underlying cause of patients' failure to claim despite having suffered negligence, the critique leveled at the efficacy of the current malpractice system is the same: factors other than individual merit appear to play a strong role in determining who uses the malpractice system and who receives compensation from it. These concerns should be understood in the context of our more general findings that claims lag well behind the incidence of negligent injury, and the two are seldom connected in the current system.

Economic Burden of Medical Injury

Using information obtained in surveys of injured patients, HMPS investigators estimated that adverse events among patients hospitalized in New York in 1984 led to $3.8 billion in total health care costs (Johnson et al., 1992). This figure implied total national costs of slightly more than $50 billion in 1984. After carefully weighing a mix of considerations, including residual reservations about potential recall biases among HMPS patients, resource constraints, and the ethical complexities associated with recontacting patients with knowledge in hand about both injuries they had suffered and causes of those injuries, we chose to use experts' judgments of costs instead of patient surveys in the UCMPS. The specific methods used to estimate each of the key expenditure items—lost wages, lost household production, and health care costs—are described in detail elsewhere (Thomas et al., 1999).

We estimated that the economic consequences of the adverse events in Utah and Colorado in 1992 totaled $661.9 million. The subset of adverse events judged to have been preventable accounted for nearly one-half of this total, or $308.3 million. Postoperative complications and adverse drug events were the most expensive type of adverse events, with the former giving rise to $232.0 million in costs and the latter, $213.7 million.

Table 1.4 shows that the largest share of the total was accounted for by health care costs. More than $348 million was spent on treat-

ment in response to adverse events suffered in hospitals in the two states in 1992. Surprisingly, one-half of these health care costs were attributable to nursing home care expenditures. Inpatient hospital costs absorbed the next largest portion (41 percent), followed by non-intensive care bed days (31 percent) and intensive care (10 percent). In total, the health care costs of adverse events in Utah and Colorado that accrued in outpatient settings, inclusive of nursing home costs, were nearly twice as large as the inpatient costs. This finding is all the more remarkable when one considers that the UCMPS focused on adverse events suffered in the inpatient setting.

When extrapolated to the thirty-three million discharges from U.S. hospitals in 1992, our estimates put the annual costs of adverse events nationwide at approximately $38 billion. This is smaller than, although not greatly dissimilar from, the $50 billion figure derived from patient interviews in the HMPS. Some of this difference is driven by the slightly higher adverse event rate detected in New York. When adjusted to 1996 dollars and recalculated with UCMPS adverse event rates, the New York data suggest annual costs of $147 per capita; the UCMPS estimates are $132 per capita. The proximity of the two estimates is noteworthy given the quite different methodological approaches used to derive them.

One lesson from our cost analyses concerns the importance of looking expansively at health care costs in estimating the effects of iatrogenic injury. Despite the fact that the UCMPS gathered data on inpatient injuries, we nonetheless found more than 60 percent of total health care costs arising outside the hospital. This suggests that other studies of adverse events that have focused exclusively on inpatient costs—for example, those undertaken in the field of drug-related adverse events (Bates et al., 1997; Classen, Pestotnik, Evans, Lloyd, & Burke, 1997)—are likely to have missed the full economic implications of the medical injuries they examined. Efforts to understand the implications of injuries in a broader range

Table 1.4. Adverse Event Costs in Utah and Colorado (in thousands, discounted to 1996 dollars).

	All Adverse Events (%)	Preventable Adverse Events (%)
Health care costs	348,081 (53)	59,245 (52)
Lost wages	160,946 (24)	63,309 (20)
Lost household production	152,862 (23)	85,828 (28)
Total	661,889 (100)	308,382 (100)

of health care settings have begun (Gandhi et al., 2000) and will add vital information to the knowledge base.

Our findings also provide some targets for improvement. The most costly areas appear to be adverse surgical events, adverse drug events, and adverse events due to incorrect diagnoses. Front-end expenditures devoted to preventing medical error in these areas could yield savings overall, although precise estimates of the cost trade-offs involved are desperately needed. Thus the next phase of research into the economic consequences of medical injury may well belong to cost-effectiveness analysts. But even without the benefit of such analyses, the economic research to date suggests that as a whole, U.S. hospitals are almost certainly underspending in their efforts to prevent adverse events. More than one-half of the adverse events we detected were judged preventable. If such prevention occurred, it could relieve the U.S. health care system of nearly $20 billion in health care costs, or 2 percent of present health care expenditures.

The Persistent Question: How to Improve Compensation for Medical Injuries?

Many commentators have suggested that alternative strategies for compensating medical injuries should be considered in the United States (see, for example, Havighurst & Tancredi, 1973; O'Connell, 1975; Saks, 1992; Sugarman, 1985). An administrative system, somewhat similar to current workers' compensation regimes, that

does not make compensation contingent on proof that fault or negligence caused the injury in question, has long been heralded by some as the best candidate (Weiler, 1993). But concerns have been raised about a pure no-fault system, the principal one being that such a system would be inordinately expensive to operate in this country (Abramson, 1989–1990; Bovbjerg, 1993; Mashaw & Marmor, 1994; Saks, 1994; Sugarman, 1991).

Given the policy imperatives that motivated the UCMPS, a key study goal from the outset was to evaluate the economic feasibility of a practical, workable no-fault scheme. Building on work done by Marilynn Rosenthal, Randall Bovbjerg, and Lawrence Tancredi, we investigated design options. We were attracted to the Swedish Patient Injury Compensation Fund (see Rosenthal, 1987; Oldertz, 1998). Sweden has successfully operated this fund, an administrative compensation program, for the past two decades. The criteria used do not contemplate all adverse events as compensable injuries. Rather, they incorporate consideration of the *avoidability* of the injury—a notion we have previously described in detail (see Studdert et al., 1997). We hypothesized that a no-fault program designed around Swedish compensation criteria would demarcate a generous, yet manageable body of medical injuries as eligible for compensation. In terms of volume, the pool of injuries contemplated lies between all adverse events (that is, pure no-fault) and negligent adverse events (that is, the malpractice system).

We applied Swedish compensation criteria to the pool of injuries detected in the UCMPS. Table 1.5 shows that this exercise resulted in estimates of a total compensation budget, including projected administrative costs, that are significantly lower than the total injury costs obtained in our earlier analysis of the economic consequences of medical injury. Costs are further decreased if an eight-week disability (or *deductible*) period is added as a prerequisite to accessing compensation.[5] In Utah, the total for compensating the Swedish compensable events with an eight-week disability

period was $76.8 million. In Colorado, the cost was almost exactly $100 million.

Table 1.6 examines the affordability of candidate no-fault schemes, comparing their estimated cost to the estimated cost of the current medical malpractice system in each state. According to our best estimates and those of our collaborators in Utah and Colorado, malpractice premiums paid in those states in 1996 totaled approximately $60 million and $100 million respectively. In Utah, one approach to compensation under consideration during the UCMPS proposed use of Swedish compensable events, a $100,000 cap on pain and suffering, a four-week disability period, exclusion of household production, and 66 percent wage replacement. The estimated cost of such a program, after addition of administrative and birth injury costs, would be $54.9 million (in 1992 dollars). In Colorado, the preferred model also involved use of Swedish compensable events, an eight-week disability period, full wage replacement, and exclusion of household production. Our calculations suggested total system costs of $102.4 million for Colorado.

Thus our cost estimates for the Swedish-style systems in Utah and Colorado compare favorably to the tort system: at $54.9 million, the Utah model would cost approximately the same as the tort system, whereas at $82 million, the Colorado model would be expected actually to reduce the costs of compensating medical injury by $18 million to $28 million annually. To keep these estimates in perspective, it is worth noting that in 1992, our study year, total personal health care expenditures were $3.8 billion in Utah and $9.4 billion in Colorado (see Levit et al., 1995, table 11).

Table 1.7 shows the *ratcheting* effects of removing household production and pain and suffering, items that some policymakers may believe are dispensable in a system of compensation. The table also shows how the number of beneficiaries shifts with the selection of different deductible periods. For example, the number of patients eligible for compensation in Colorado decreases from 5,919 to 1,604 with use of a four-week deductible period and to 973 with an eight-

Table 1.5. Cost Components of Swedish Compensable Events, with Eight-Week Deductible Period (in millions of dollars).

	Loss Total		*1992 Value of Loss (%)*			
Type of Loss	Utah	Colorado	Utah		Colorado	
Income and household production						
Gross wage loss	21.35	31.49				
Fringe benefits	5.47	7.92				
Less:						
Taxes	− 4.16	−6.90				
Consumption deduction	− 2.36	−3.64				
Household production	−11.63	−7.14				
SSDI benefit	− 1.65	−3.39				
Household production loss	44.02	52.03	45.78	(59.6)	57.51	(57.5)
Net income and household production loss	51.05	70.37				

Health care costs						
Gross costs	21.58	49.99	19.63		45.12	
Less:						
Compensation from health insurance	−17.26	−40.00	−15.70		−36.10	
Net health care costs	4.32	9.99	3.93	(5.1)	9.02	(9.0)
Other compensable costs						
Burial expenses	2.08	1.25	2.08	(2.7)	1.25	(1.3)
Pain and suffering	25.00	32.21	25.00	(32.6)	32.21	(32.2)
Total compensable costs	82.44	113.82	**76.79**	**(100.0)**	**99.99**	**(100.0)**

Table 1.6. Affordability of Preferred No-Fault Models in Utah and Colorado (in millions, discounted to 1992 dollars).

State	Estimates of Preferred No-Fault Models	Current Malpractice System Costs
Utah	54.9[a]	55–60
Colorado	82.0[b]	100–110

[a] Based on use of Swedish compensable events; health care costs; $100,000 cap on pain and suffering; four-week disability period; no household production; 66% wage replacement. [b] Based on use of Swedish compensable events; health care costs; eight-week disability period; no household production; full wage replacement.

week period. Proportionally similar decreases occur in Utah when the same time thresholds are used.

More generally, Table 1.7 illustrates how the various components of the compensation package can be treated as modules. Policymakers could use precisely such methods to cost out alternative compensation schemes. Decisions about the trade-offs involved in design issues, such as numbers of patients eligible for compensation and the importance of household production to awards, could play out in public and legislative debates about appropriate uses of scarce resources. Of course these decisions go to the central problem of distributive justice in compensation. An administrative compensation scheme cannot circumvent the need to make difficult decisions about who and what types of injuries should receive compensation. However, it would (and does in the workers' compensation setting) allow stakeholders to agree on eligible injuries and obtainable remedies in advance, which we believe would promote equity, predictability, and efficiency in the distribution process.

Two other advantages of a no-fault approach warrant mention. First, if it were carefully designed, a no-fault scheme could eliminate much of the adversarial approach to medical malpractice litigation. We were astonished to find that physicians in Sweden actively participate in 60 to 80 percent of the claims that are made, helping their patients complete and file the relevant forms. Com-

Table 1.7. Economic Consequences of Swedish Compensable Events (in millions, discounted to 1992 dollars).

	Utah	Colorado
Any disability	(*N* = 2,940)	(*N* = 5,919)
Total	$90.90	$128.88
Less household production	60.38	90.55
Less household production and pain and suffering	27.16	38.51
>4 weeks disability	(*N* = 1,465)	(*N* = 1,604)
Total	$82.55	$84.23
Less household production	52.42	52.99
Less household production and pain and suffering	25.22	21.21
>8 weeks disability	(*N* = 889)	(*N* = 973)
Total	$76.78	$87.44
Less household production	45.96	52.18
Less household production and pain and suffering	20.96	19.97

pensation there appears to be culturally ingrained as a matter of social justice, not necessarily as an admission of provider guilt or negligence. Hence it tends to support rather than conflict with the health care professional's commitment to the patient and to excellence in medical practice. This milieu appears to be ascribable, at least in part, to the structural separation of insurance and disciplinary mechanisms.

Second, we believe that an avoidability-based compensation scheme could provide an enormous boost to error reduction efforts. As the Institute of Medicine's report has recently made clear, many errors fall into the avoidable category and could be reduced if proper error prevention strategies were put into place. There is also increasing recognition that the implementation and success of such strategies hinges on the free flow of information. The specter of litigation currently stands as a major barrier to the free flow of infor-

mation about medical errors. Thus, removing it would align the foci of the compensation and quality improvement systems and center them on precisely those injuries that are eradicable.

Conclusion

The main objectives of the UCPMS were to test the results of the HMPS in another health care environment and to explore the feasibility of a no-fault system for compensating medical injury. With support from the Robert Wood Johnson Foundation; cooperation from hospitals, physicians, and malpractice insurers in Utah and Colorado; and the efforts of numerous collaborators, these objectives were achieved. Overall the UCMPS lent strong support to the iatrogenic injury rates, economic calculations, and malpractice patterns estimated in New York nearly a decade earlier. The UCMPS findings were no carbon copy, however. For instance, we found significantly lower iatrogenic death rates in Utah and Colorado. We also gained fresh insights into the burden of iatrogenic injury by investigating several previously understudied areas, such as the resources devoted to outpatient services to treat the morbidity caused by adverse events.

The results of our efforts to conceptualize and cost out an administrative compensation scheme based on avoidability criteria provide considerable cause for optimism about the feasibility of a no-fault system. Even before our work was complete, however, it was apparent in both states that the enthusiasm of our collaborators would not be sufficient to transform the no-fault initiative into political action. The 1990s malpractice crisis that many pundits envisioned, owing to the experience of the two previous decades, did not eventuate, and relative stability in malpractice insurance markets appeared to sap legislative interest in large-scale tort reform.

Thus skeptics would have some foundation for concluding that the true mission of the UCMPS failed; a key part of its empirical findings has not generated policy reform. We prefer to take a longer-

term view of the value of the study. It is our hope that when the political winds shift, a probable occurrence given a history of cyclical interest in alternative compensation approaches in the United States, the UCMPS methods and findings will stand ready to be used by those policymakers who become newly interested in a no-fault approach.

Hints of just such a shift have surfaced at the federal level over the past six months. Ironically, rather than being born of dissatisfaction with the malpractice system as a mechanism for compensating injured patients, interest in malpractice alternatives has been invigorated by a spate of media and political attention directed at error in medicine. As optimal strategies for reducing medical error continue to emphasize the need for open communication about mistakes and attention to systemic, not individual, fault, new light is being cast on the merits of a different approach to medical injury compensation.

Notes

1. Note, however, that this phenomenon does not necessarily lend support to views about greedy personal injury lawyers and vexatious plaintiffs. "[I]t is more likely due to the fact," Weiler (1995) argues, "that (previously ill) patients and their lawyers have a difficult time identifying in advance valid claims that demonstrate that something went wrong in treatment" (p. 1162).
2. These percentages relate to the proportion of drug-related events due to negligence, not drug-related adverse events in general.
3. QAHCS investigators did not make determinations about negligence. Instead, physician reviewers were asked to determine whether each adverse event detected was "preventable," defined as "an error in management due to failure to follow accepted practice at an individual or system level" (Wilson et al., 1995, p. 458).
4. Chief among these differences is the fact that Andrews and colleagues focused on surgery—precisely the area where we had detected the highest rates of adverse events in the general hospital population we examined.

5. A deductible, or threshold, period of this kind is a device for eliminating relatively nonserious injuries from the pool of injuries eligible for compensation. It also has the benefit of channeling available funds to victims whose losses are least likely to be covered by other sources of coverage, such as sick pay for time lost from work (see Haas, 1987).

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