

Beyond Negligence: Avoidability and Medical Injury Compensation

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Abstract

Disenchantment with the tort system and negligence standard in the United States is fueling interest in alternate compensation systems for medical injury. One possibility is experimentation with administrative “health courts,” through which specialized adjudicators would utilize neutral experts to render compensability determinations. Compensation would be based not on negligence, but rather on a broader avoidable medical injury (avoidability) standard. Although considerable interest in health courts exists, stakeholders frequently express uncertainty about the meaning and operation of an avoidability standard.

Three nations—Sweden, Denmark, and New Zealand—have long operated administrative schemes. We conducted interviews with administrators and stakeholders in these systems. Our goal was to garner lessons on how to operate a health court, and specifically, how to develop and apply alternate compensation criteria such as avoidability. This article reports our findings on the origins and operations of the systems, the evolution of their compensation criteria, and how these criteria are actually applied.

We found that all three systems had their primary genesis in ensuring compensation for the injured, as opposed to sanctioning providers. All have abandoned the negligence standard. The Nordic systems use an avoidability standard, principally defined as injury that would not occur in the hands of the best practitioner. Their experience demonstrates that this definition is feasible to apply. New Zealand’s recent move to a no-fault system sheds light on the benefits and drawbacks of a variety of compensation standards.

Key lessons for successfully applying an alternate standard, such as avoidability, include a strict adherence to national precedent, the use of neutral and experienced experts, and a block on routine transfer of information from compensation investigations to disciplinary authorities.

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Importantly, all three nations are harnessing their systems' power to improve patient safety, and the avoidability standard appears to be well suited for this task.

Introduction

The recent “crisis” in the United States medical malpractice insurance market in the spotlighted the problem of high and rising medical liability costs, and deepened policy concerns about the malpractice system’s ultimate effect on the quality of care.(Annas, 2006; Sage, 2003) Policy discussions about how to resolve these perennial problems are being influenced by a growing awareness that traditional tort reform measures, such as caps on noneconomic damages, will not solve them.(Mello, 2006; Thorpe, 2004) There is also increasing recognition that such measures do little or nothing to make care safer.(Clinton & Obama, 2006) Scholars and policymakers, much as they did in the wake of tort crises in the mid-1970s and mid-1980s, are again turning their attention to options for more fundamental reform.(Mello, Studdert, Kachalia, & Brennan, 2006)

Among those options is the prospect of an administrative approach to medical injury compensation. Proposals for administrative compensation systems are not new, but have been reshaped over the last thirty years. The latest incarnation is the “health court” model, which is currently garnering interest in state and federal policy circles.(Medical Errors Subcommittee of the Wyoming Health Care Commission, 2005) Health courts are state-run administrative tribunals that use specialized judges and neutral expert witnesses to adjudicate medical injury compensation claims. We and other proponents of this approach believe that health courts promise more prompt, fair, efficient, accurate, and predictable compensation.(Mello et al., 2006)

We have described the proposed structure of health courts in detail elsewhere.(Mello et al., 2006) Here we elaborate on a cornerstone of their design: the use of an “avoidability” standard instead of negligence to determine which injuries are eligible for compensation. The concept of avoidability offers an alternative that resides between negligence and strict liability.

A system based on an avoidability standard would award compensation to claimants who could show that their injury would not have occurred in the hands of the best practitioner or system.

Policymakers considering proposals for an avoidability-based compensation system have raised many questions about the concept: How, in practical terms, does avoidability differ from negligence? Is it reasonable to expect that an administrative model can operationalize the concept of avoidability in a way that advances the objectives of speed, fairness, efficiency, accuracy, and predictability? What evidence suggests that it is a workable standard?

Fortunately, real-world experience to help answer these critical questions is at hand. New Zealand and the Scandinavian countries have compensated medical injury through non-negligence-based administrative compensation schemes for decades.(Dute, Faure, & Koziol, 2004) In 2005, we conducted site visits to New Zealand, Sweden, and Denmark to interview administrators and stakeholders of these schemes. In this article, we report findings from our interviews with 44 administrators, medical experts who help decide coverage eligibility questions, and stakeholder group representatives, and consider key lessons learned for the operation of an avoidability-based compensation system in the United States.

International Schemes: Origins and Operation

Scandinavia

Origins and Objectives

Each of the Nordic countries—Sweden, Denmark, Norway, Finland, and Iceland—have abandoned their negligence-based compensation systems at different times over the last thirty years.("Patientförsäkringsföreningen: The Patient Injury Act," 2006; "Patientforsikringen: The Danish Patient Insurance Act," 2006; "Norsk Pasientskadeerstatning: About the Norwegian

System of Compensation to Patients," 2006; "Potilasvakuutuskeskus, The Finnish Patient Insurance Centre: Patient Injuries Act," 2006; "Iceland Ministry of Health and Social Security: Laws and Regulations," 2006) The shifts were motivated largely by perceptions that the tort system's adversarialism, combined with the highly specialized knowledge and fact-finding needed in medical injury claims, made the resolution process too long and expensive.(Danzon, 1994; Espersson, 2006; Brahams, 1988) A related impetus was concern that the tort system's cumbersome nature impaired patients' access to due compensation.

To address these shortcomings, replacement schemes were designed with the objective of channeling compensation more efficiently to eligible patients. Designers did not attempt to make provider discipline or deterrence of unsafe behaviors a formal part of the schemes' mission. On the contrary, they eschewed these functions because pursuit of them was regarded as corrosive to the compensation objective. Consequently, the Scandinavian schemes have erected a "Chinese wall" between compensation and disciplinary activities, cordoning off all information collected and used during compensation process from fault-finding activities. Patients and regulators may still bring disciplinary actions, but these must be brought separately along an entirely different path.(Erichsen, 2001)

The prioritization of injury compensation objectives also shifted preferences away from negligence as the compensation standard. The Nordic countries have supplanted negligence with the concept of avoidability. Their schemes seek to compensate to patients who have experienced injuries that could have been avoided under optimal circumstances.

Sweden pioneered the approach.(Espersson, 2006) In 1975, it established a voluntary scheme in which public and private providers assumed responsibility for compensating patient injury through a consortium of insurers. The system was restructured and made mandatory in

1997, partly to capture the 5% of providers who were not participating and partly to respond to new antitrust requirements following Sweden's entry into the European Union.(Espersson, 2006) Finland adopted its compensation system in 1987 ("Potilasvakuutuskeskus, The Finnish Patient Insurance Centre: Patient Injuries Act," 2006; Brahams, 1988) and Norway in 1988;(Jorstad, 2002; "Norsk Pasientskadeerstatning: About the Norwegian System of Compensation to Patients," 2006) both are modeled closely on Sweden's. Denmark's scheme, introduced in 1992, incorporated a number of distinctive elements which reflected national preferences and a close evaluation of Sweden's experience.("Patientforsikringen: The Danish Patient Insurance Act," 2006) Iceland's scheme, introduced in 2001,("Iceland Ministry of Health and Social Security: Laws and Regulations," 2006) resembles Denmark's.

Sweden and Denmark operate two of the largest schemes in Norway. They also exhibit some interesting variation in their approach to defining avoidable injury. Hence, we selected these countries for site visits, and the discussion of Nordic systems hereafter focuses on them.

Claiming Process

In both Sweden and Denmark, patients who believe they have experienced a medical injury may file a claim free of charge; in cases of incapacitation or death, family members may initiate the claim (Figure 1). Patients often seek the advice of physicians in deciding whether to make a claim, but are not required to obtain a physician's support. In Sweden, however, an estimated 60 to 80 percent of all claims are facilitated by health care providers.(Espersson, 2006)

Public companies—the Swedish Patient Insurance Association (Patientförsäkringsföreningen or PFF) and the Danish Patient Insurance Association (Patientforsikringen or PIA)—were formed to process, adjudicate, and determine compensation

amounts for medical injury claims. These companies have a broad compensation mandate which includes patient injuries from non-medical accidents, such as slips and falls, that occur in a health care facilities. One notable carve-out relates to medication-related injuries: injuries due to drug administration or prescribing errors are covered by the main schemes, but injuries due to defects in pharmaceutical products themselves are handled through separate compensation schemes.

The PFF and PIA employ claims handlers to manage the claims. The handlers typically have clinical or legal backgrounds, and they tend to specialize by handling claims related to a particular injury type or medical field. To investigate a claim, a handler may interview patients or request medical information directly from involved clinicians and facilities.

Once sufficient factual information is gathered, the handler decides whether the injury meets the statutorily-defined compensation criteria. For claims that are not clear cut, decision-makers may examine past decisions in similar cases; previous case determinations are recorded in a searchable database. In addition, claims handlers frequently consult with relevant medical experts. These experts, who generally are senior specialist physicians from nearby teaching hospitals, are retained by the company through standing agreements and selected for consultation in particular cases according of their expertise. They tend to be highly experienced reviewers, having worked with the compensation system for years.

Once the decision is made, the claims handler informs the patient. Rejections include a written explanation of why the claim was not compensable. In Sweden, the PFF pays claims. In Denmark, the PIA adjudicates, and the self-insured public county in which the injury occurred then compensates successful claimants. In 2004, approximately 45 percent of claims received compensation in both Sweden and Denmark (Table 1).

As in tort litigation, compensation payments consist of two general components—economic and noneconomic damages. Economic damages cover lost wages and medical expenses not covered by other insurance. Noneconomic damages compensate for pain and suffering, with levels set according to schedules based on injury type, severity, and duration. In the case of a patient's death, families may be entitled to funeral costs and loss of financial support.

Both countries have limitations on compensation awards.(Espersson, 2006; "Patientforsikringen: Claims," 2006) Total awards are capped at approximately US\$1.2 million (7.9 million Swedish Crowns and 7 million Danish Crowns). There is also a floor; claims must be valued at more than approximately US\$275 (1985 Swedish Crowns) in Sweden and approximately US\$1700 (10,000 Danish Crowns) in Denmark to be eligible for compensation. In 2004, the average compensation per paid claim was approximately US\$22,000 (160,000 Swedish Crowns) in Sweden and US\$30,000 (180,000 Danish Crowns) in Denmark, substantially lower than averages seen in Anglo-American tort systems. In part, the difference is explained by the existence of other forms of social insurance, including wage loss insurance and universal health insurance, present in these countries. The medical injury compensation schemes are able to minimize their costs by offsetting awards to these other payment sources.

Patients who are unhappy with either compensation decisions or award amounts may appeal; about 20 percent of claimants in Sweden and Denmark who are initially denied compensation do so. The first appeal is heard by a board that includes a broad range of panel members. The appeals boards in both Sweden and Denmark generally have seven members, including several government-appointed patient advocates. Patients in Sweden are permitted to attend appeal board meetings, but rarely do so.

Patients who are dissatisfied with the appeals board determination may appeal to the courts. In both countries, appeals accepted for judicial review are heard by courts of general jurisdiction. The available remedies are limited by law: appellants may not recover any more compensation than would have been available under the scheme.

New Zealand

Origins and Objectives of the Scheme

New Zealand's medical injury compensation scheme grew out of a movement to ensure that disability insurance was available to all residents who lost their employment ability because of an accident at work.(Miller, 1989) In 1967, a government inquiry set forth a system blueprint recommending coverage be extended to all types of accidental injury.(Woodhouse, 1967) In 1972, the recommendation was legislated and almost all personal injury litigation was foreclosed. In addition to the standard array of workplace injuries, the scheme was designed to compensate a broad range of accidental harms such as domestic cooking accidents and injuries sustained in sporting activities. The Accident Compensation Corporation (ACC) came into operation in 1974 to administer the scheme.

The initial legislation paid little attention to medical injuries.(Corkill, 2002) Although they were quickly recognized as being covered by the scheme, the bases for compensating them were left to the ACC and courts to determine. Successive rulings clarified that medical injuries did not enjoy the same no-fault status as other injuries. Only injuries due to "medical misadventure" were compensable. Courts labored over what this term meant until legislation in 1992 specified it.("ACC: Accident Rehabilitation and Compensation Insurance Act 1992 - Repealed," 2006) Political considerations of the day and concerns over the ACC's ballooning

budget persuaded legislators that only a subset of medical injuries should qualify for compensation as a medical misadventure—"medical errors" and "medical mishaps." We explain the terms in the next section.

Unlike the Scandinavian schemes, the New Zealand system did not establish a Chinese wall between compensation and disciplinary activities.(Corkill, 2002) Under the medical misadventure standard, the ACC could share information obtained from claims with profession oversight authorities. In addition, if the ACC made a finding of medical error, the matter was automatically referred to an appropriate disciplinary agency for possible investigation of the involved clinicians.

Claiming Process

Like Scandinavia, physicians are integral to the filing of claims; unlike Scandinavia, their participation is required as a prerequisite to claiming (Figure 1). Patients must initiate claims through a physician (or other statutorily-qualified provider).("Making a Claim: Treatment Injury Claim," 2006) The claims form is completed jointly, but filed by the physician. The filing physician need not be the physician involved in the injury; in practice, it is typically the patient's general practitioner.

The early steps in the review process in New Zealand are similar to those in Scandinavia. Claims handlers, who tend to specialize in particular types of claims and have clinical experience, investigate the event. They gather medical records and other relevant information from involved facilities and parties. The claim handlers then render an initial decision about compensability, frequently relying heavily on precedent and consultation with physician experts. Patients receive written notification of the reasons for the decision.

Under medical misadventure, almost 40 percent of claims were initially accepted for compensation (Table 1). Compensation payments cover economic damages, including costs associated with treatment and rehabilitation as well as lost earnings. Non-economic damages are paid in lump sums determined by the resultant degree of impairment. For injuries of indefinite duration, payments may be conditioned on periodic review of patient's condition. Unlike their Scandinavian counterparts, ACC awards do not have any minimum threshold requirements or caps on total damages. Under the medical misadventure standard, the average award was approximately US\$12,500 (NZ\$18,300) in 2002.(Davis, Lay-Yee, Briant, & Scott, 2006)

The appeals process in New Zealand also operates somewhat differently from Scandinavia. Patients may appeal a coverage or compensation determination; providers may do the same when a finding of medical error is handed down. Appeals are handled by a separate but wholly-owned subsidiary of the ACC. The adjudicator is generally an experienced staff attorney. Both parties, as well as the ACC, file documentation prior to the hearing. Patients may bring advocates to the hearing, but rarely do. Occasionally, the parties agree to dispense with the hearing and submit to an appellate determination based on the documentation. Parties dissatisfied with the outcome of this appeal may then lodge further appeals with the district courts; however, few claims per year proceed to this second level of review.

On July 1, 2005, soon after our visit, the medical injury scheme underwent several substantive changes, most notably to relax the scheme's compensation criteria and jettison the medical error standard.("Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2) 2005," 2005) (Bismark & Paterson, 2006) The basic claims and appeal processes described above remain intact. The move appears to have been prompted by two main concerns. First, it was felt that the fault standard had detrimental effects on the physician-patient

relationship and physicians' willingness to participate in the claims process. Clinicians found the error standard punitive and stigmatizing, and consequently tended to be reluctant provide information about injuries to the ACC. This reaction slowed claim investigations and reduced the information available for learning about quality improvement. Second, the government sought to standardize compensation criteria across different parts of the ACC. Individuals injured in non-medical settings were not required to prove that an error had occurred, and this double standard was seen as unfair to patients.(Bismark & Paterson, 2006) We describe both the old and new criteria in the next section.

Compensating Avoidable Injury

The criteria used to determine whether a claim is compensable are a central feature of the schemes in Scandinavia and New Zealand. These criteria help determine the schemes' viability by influencing the pool of eligible claims, the volume of claims received, the costs of resolving claims, and, ultimately, the aggregate costs of a compensation system. What technical definition of "avoidability" and how it is defined and operationalized as a decision rule are largely unknown outside Scandinavia and New Zealand.

Use of the Avoidability Standard in Sweden

The Swedish scheme divides claims into five categories of injury for purposes of determining compensability: (1) treatment injury; (2) diagnostic injury; (3) material-related injury; (4) infection-related injury; and (5) accident-related injury. Table 2 summarizes the criteria applied to each category.

The compensability of treatment and diagnostic injuries turns on whether they are avoidable, as determined by the “experienced specialist” rule. Because treatment and diagnostic injury claims capture approximately 85% of all paid claims, this rule is the linchpin of the decision-making in Sweden’s scheme (Table 3). Application of the experienced specialist rule is similar to negligence in that compensability is determined by assessing the quality of care rendered. Where it differs, however, is in the standard of care applied. Rather than asking whether the treatment in question fell below the standard customarily expected of a clinician in a particular specialty, as is done in negligence law, the experienced specialist rule asks whether the injury would have occurred at the hands of the experienced or “best” specialist in the relevant specialty.

This is a demonstrably higher standard. Excellent care, as opposed to acceptable care, is the benchmark, rendering some injuries compensable in Sweden that would fall short against a negligence standard. Table 4 presents a series of specific injury scenarios. In approximately half of the cases presented, the negligence and experienced specialist standards would be expected to reach the same conclusion about compensability; in the rest, the experienced specialist rule would dictate compensation while a negligence standard would not.

The Swedes have confronted two important practical questions in applying the experienced specialist rule to treatment related injury. First, should the inquiry focus exclusively on the quality of the care actually delivered, or should it also consider alternative courses of action (besides the one taken) that may have been equally or more effective? Second, to what extent should decision makers use the wisdom of hindsight (retrospectivity) in evaluating whether the injury was avoidable?

With respect to the first question, Swedish adjudicators do consider the risks and benefits of the treatment options other than the one pursued. The “alternate treatment” rule guides such considerations. The rule states that if at the time of treatment another course of treatment that is at least as safe and efficacious existed, could have been chosen, and would have averted the injury, then the claim is compensable.

Consider, for example, a physician who orders studies of the patient’s biliary tree as part of a treatment plan (Table 4, Scenario 9). By today’s standards, a physician may choose to order either a magnetic resonance cholangiopancreatography (MRCP, a non-invasive radiological study) or endoscopic retrograde cholangiopancreatography (ERCP, an invasive procedure requiring endoscopy of the upper gastrointestinal tract) and be within the bounds of best practice. The ability of the procedures to visualize the biliary tree is considered to be equivalent, but the risk of complication is greater with ERCP. Therefore, a patient who sustains an injury from an ERCP, even from one performed flawlessly, would probably be eligible for compensation under the alternate treatment rule.

At first glance, this rule would seem to dramatically widen the possibilities for compensation. The Swedes’ experience suggests otherwise. In practice, the situations in which it applies are uncommon because best practice rarely countenances competing approaches that have different levels of risk when efficacy is equivalent. The availability of clinical evidence is another constraint. If medical science has not amassed data on the nature and degree of one treatment’s superiority over an alternative, the rule’s criteria cannot be met. The management of disc herniation helps illustrate this point (Table 4, Scenario 5). In the absence of special clinical circumstances, orthopedic experts regard either surgical or conservative medical management as reasonable; best practice and epidemiologic studies do not militate strongly against one or the

other. Therefore, the patient who sustains a post-operative wound infection after a discectomy would be ineligible for compensation under the alternate treatment rule, even though conservative management would have avoided this complication.

With respect to the retrospectivity question, the Swedes permit some hindsight wisdom in the evaluation of treatment injuries. The “retrospective rule” asks whether the injury could have been avoided if previously unknown clinical information was potentially discoverable at the time of the treatment. If the answer is yes, it will be compensable. On the other hand, retrospectivity is not permitted in determinations about the compensability of injuries resulting from a missed or delayed diagnosis, as that would axiomatically lead to compensation of all such injuries.

The latex reaction described in Scenario 3 (Table 4) illustrates application of the retrospective rule to treatment injuries. Notwithstanding the fact that best practice does not call for routine testing of patients for unknown latex allergies, the injury qualifies for compensation because it was technically possible to have learned of the allergy prior to the operation. Similarly, neonatal or maternal injury caused by attempted vaginal delivery of a large baby may qualify under the retrospective rule if foreknowledge of the baby’s size could have been obtained and would likely have prompted a cesarean section. Contrast this with an example in which a patient undergoes surgery and, and in the face of optimal care, develops a hemorrhage (for unknown reasons) requiring a blood transfusion. Even though, in hindsight, not performing the surgery would have avoided the bleeding, the retrospective rule would not apply, because there is no further information that could have been obtained prior to the operation that would have portended the bleeding.

Sweden’s other compensation categories are less nuanced and, with the exception of infections, account for relatively few claims. These categories are for special circumstances in

which injury may not be avoidable, but because of social considerations, the Swedes have determined that patients should be entitled to compensation. Infection-related injuries are compensable if the following conditions are met: the infectious agent must have been transmitted from an external source during the delivery of care, and the infection's severity and rarity must have outweighed the seriousness of the patient's underlying disease and the need for the treatment that caused the infection. The Swedish system compensates injuries caused by medical equipment and prostheses where there is evidence of a defect in or defective use of the product (Table 4, Scenario 12). Injuries not directly related to medical care, such as falls and burns from fires, are compensated without regard to fault if they result from accidents for which patients are at increased risk while obtaining care (Table 4, Scenario 11).

The Avoidability and Endurability Standard in Denmark

The Danish scheme hews closely to Sweden's in many respects (Table 2). The main area of overlap is in use of the experienced or best specialist standard for defining avoidable injury. The Danish scheme also applies the alternate treatment rule and compensates equipment-related injuries in the same way as its Swedish counterpart.

There are, however, some notable departures that make comparatively fewer injuries eligible for compensation under the avoidability standard. For example, Denmark did not embrace the retrospectivity within its experienced specialist rule. Also, there are no special rules related to infection-related injuries in Denmark, and accident-related injuries are compensable only if they are due to negligence. Table 4 displays the areas of overlap between the schemes; it also presents examples of injury types that would meet the avoidability standard in Sweden but not Denmark.

To soften the impact of adopting stricter avoidability criteria than Sweden, the Danes added a large new class of compensable events under its “endurability rule” (Tables 2 and 3). This rule permits compensation for unavoidable medical injuries when those injuries result in a level of disability that exceeds what a patient should reasonably be expected to endure. In making judgments under the endurability rule, decision makers consider a range of factors, including the severity of underlying disease, the need for treatment, and the severity and likelihood of the injury sustained. Thus, the weighing exercise resembles the one used in Sweden to evaluate infections, but is applied to a much broader range of injuries.

The endurability rule can be somewhat difficult to grasp. It is perhaps best understood as a type of catastrophic compensation safety net, with catastrophe defined according to patients’ and providers’ baseline expectations rather than the objective severity of the harm involved. Although quantitative clinical information about risk may enter the calculus, the determination is ultimately based on a qualitative assessment of the case. Injury scenarios 3, 5, and 10 in Table 4 provide examples of the types of harm that are likely to satisfy the endurability rule, but not make the grade under conventional avoidability standards.

Compensation Criteria in New Zealand

The 1992 reforms in New Zealand clarified that to be eligible for compensation under the medical misadventure standard, a patient must have experienced a “medical error” or a “medical mishap” (Table 2). A medical error was defined as a failure to observe a standard of care and skill reasonably expected in the circumstances; it closely resembles a negligence standard. A medical mishap was defined as consequence of properly given treatment that is rare (occurring in no more than 1 percent of cases) and severe (leading to more than 14 days hospitalization,

significant disability lasting more than 28 days, or death). Examples of mishaps include rare and idiosyncratic reactions to medications and unusual surgical complications following treatment.

Medical mishap determinations do not involve an assessment of provider fault, and thus clearly signaled the expansion of New Zealand's compensation criteria beyond negligence (Tables 2 and 3). However, the expansion was limited by a requirement that the injury be caused by "active" treatment. This meant that injuries due to omissions of treatment or diagnosis, no matter how egregious, did not qualify as mishaps. Consider, for instance, a patient who died from a failure to diagnose pneumonia despite a cough, fevers, and a chest x-ray showing opacification. Evidence showing that such misses occur in less than 1 percent of similar situations would be irrelevant because the care at issue takes the form of an omission, not actual treatment gone awry (Compensation in some such cases, however, could still be available under the medical error standard.).

Despite the relatively clear mishap definition, New Zealand found that application of the criteria could be challenging. Determining whether complications fell beneath the 1 percent threshold proved difficult in practice, often because of gaps in epidemiologic data. Moreover, decision makers soon realized that the threshold may be a moving target in medicine. A new type of prosthesis, for example, may initially be regarded as very safe, but with time and broader use, data may reveal a complication rate of greater than 1 percent. The peculiar result would be that an early cohort of claims would be compensable under the mishap rule whereas later claims would miss out.

Practical difficulties also emerged in applying the severity criteria. While death and hospitalization periods were relatively easy to measure, "severe disability," which can be a highly subjective notion, left considerable room for interpretation. To take an extreme example,

consider a patient who undergoes knee surgery, develops a deep venous thrombosis despite proper prophylaxis, and then requires anticoagulation for several months. Such an outcome may not qualify as severe for a white collar worker or retiree, but would pose major limitations for a professional rugby player.

On July 1, 2005, the medical mishap and medical error standards were replaced with a new concept of “treatment injury.” (“Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2) 2005,” 2005) This change is expected to expand dramatically the pool of eligible injuries, moving the scheme very close to a true “no-fault” model. In general, any injury that is causally related to medical management is now eligible for compensation, unless it is a “necessary part of treatment” or among the “ordinary consequences of treatment.” For example, no compensation is available for abdominal pain and scars resulting from an appendectomy or hair loss secondary to chemotherapy from leukemia (Table 4, Scenario 14).

Though the new criteria will almost certainly simplify most compensation decisions, some residual challenges are inevitable. Whether a complication was necessary and ordinary, for example, is not always evident (Table 4, Scenarios 7 and 13). Difficult questions will continue to arise in disentangling eligible injuries from ordinary complications of the underlying disease. In addition, decision making around diagnostic-related claims will call for counterfactual questions about what else could have been done and whether it would have made a difference.

Lessons for Testing a New Compensation Standard in the United States

Our review of medical injury compensation systems and standards in the Sweden, Denmark, and New Zealand gives rise to several observations that may help inform consideration of health courts--and other approaches to compensation that do not turn on the

concept of negligence--in countries like the United States where such approaches would entail fairly dramatic changes to the *status quo*.

“No fault” Is Too Broad

Although it may be tempting to choose as broad a standard as possible to maximize the simplicity of the compensation decision and facilitate patient access to compensation, cost implications cannot be ignored, even in relatively wealthy countries. New Zealand’s recent move to what is more-or-less a pure no-fault standard will soon provide more insight in this regard (Table 1). Financial and political considerations in the United States, today suggest that there would be little appetite for a pure no-fault system along these lines.

Faster decision-making

Interviewees in all three countries cited quicker adjudication as one of the most important perceived advantages of the move away from negligence. Determinations under the avoidability standard in Sweden and Denmark, for example, averaged 8 months—far shorter than the average 4 to 5 years needed to resolved negligence disputes in the United States. Procedural innovations, such as the use of neutral experts and a streamlined, administrative fact-finding process, explain part of the difference. However, many interviewees, including some with experience working with the negligence standard, suggested that non-fault based standards such as avoidability, despite involving some consideration of the quality of care delivered, were generally more efficient to apply than negligence. In other words, deciding what could have been done in the best hands was generally regarded simpler than judging whether a provider’s actions fell below the customary standard of care.

Use of Neutral Experts and Precedent

Each of the systems we studied relied on a set of technical inputs to make their compensation standards a workable basis for decision-making. Chief among those inputs was a panel of neutral expert reviewers, who gained experience over time in applying the criteria. Adjudications also relied on precedent and institutional memory within the compensation agency to ensure consistency in decision-making. The judicious use of precedent proved particularly effective in achieving administrative efficiencies. A claim of first impression may be quite labor- and time-intensive, but subsequent determinations of the same or similar type will benefit from this initial investment, provided that initial decisions are carefully cataloged.

Patient Safety Improvement

With the advent of the patient safety movement and public attention to the problem of medical error, compensation schemes in all three countries were moving aggressively to harness the potential contributions that claims databases could make to the study and prevention of medical injury. In-house and external analysts were involved in epidemiologic analyses of clusters of events reported in claims. The power of a claims database to support such analyses depends to a considerable extent on the choice of compensation criteria. Of all the compensation criteria we encountered, the Danish formulation of the experienced specialist rules comes closest to the kind of events that patient safety experts would regard as gold nuggets.

Stakeholder Support

No matter how consistent, technically precise, and efficient compensation decisions are, the operational success of the standards would not have been possible without buy-in from the two key stakeholders in the process—physicians and patients.

Physician Support

Though organized medicine in all three countries was generally supportive of the move to administrative non-negligence based compensation, it cares a great deal about the extent to which information generated in the compensation process is transferred to disciplinary bodies. In particular, New Zealand's porous boundary under the medical misadventure standard engendered substantial resentment among physicians in that country. The new scheme with the treatment injury standard has in part allayed these concerns because the ACC must now report only in instances in which there is a "risk of harm to the public."

Patient Support

Successive interviewees echoed the view that patients are ultimately the critical constituency. Any compensation system must be trustworthy and deliver what patients want. What patients in these countries appear to want most from their compensation schemes, according to the people who run them, is to know that if they are injured by medical care, a consistent and fair system of adjudication, one that is not biased toward provider interests, will deal with their claim promptly. This assurance takes time to build. The Swedish and Danish schemes appear to have accomplished this and, remarkably, so does the New Zealand scheme, despite the flux in its decision rules over time.

Causation Will Remain Vexing

Whatever criteria are chosen, thorny causation issues will remain. Claimants still must establish a causal relationship between their injury and the care rendered (or not rendered). The question of whether medical care, as opposed to underlying illness or some other factor, caused the patient's adverse outcome can be a vexing one. Moving to an avoidability standard, or even of "no-fault," does not change this.

Conclusion

As United States policymakers consider proposals for health court pilots, they will continue to ask hard questions about the feasibility and wisdom of an alternative system. Some of those questions—about the legality and costs of a health-court scheme, for instance—have yet to be definitively answered. But the experience of foreign medical injury compensation systems provides useful information about one key question: whether it is feasible to operate a system that bases compensation decisions on a standard other than negligence.

Untethering American medical malpractice law from the negligence standard is a radical step, and experience from foreign countries probably is not sufficient evidence on which to base wholesale reform of the legal system. However, it should boost confidence that small-scale pilots of health courts are worthy of experimentation and likely to produce good results. In this way, disenchantment with the negligence standard in the United States may be turned toward constructive, evidence-based policy reform.

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Figure 1. Overview of Compensation Process in Four Countries

	United States	Sweden	Denmark	New Zealand
Patient suspects/ identifies injury				
Statute of limitations for filing	Generally 3 years from discovery of injury, but varies by state	3 years from discovery / 10 years from treatment date	5 years from discovery of injury / 10 years from treatment date	None
How patient files claim	Patient, usually with attorney	Patient	Patient	Physician must file for patient
Option to go directly to court?	N/A	No	No	No
Who reviews claim?	Lay jury	Claims handler	Claims handler	Claims handler
Average time to initial decision	5 years	70% within 8 months	7 months	Medical misadventure: 7 months Treatment injury: 16 days
Patient appeal right?	Yes	Yes	Yes	Yes
Venue for first appeal	Appellate court	Appeals panel	Appeals panel	Administrative hearing
Venue for further appeal	Next level of appellate court	District court	District court	District court

Table 1. Approximate Filing, Appeal, and Acceptance Rates of Medical Injury Claims in Four Countries

	United States	Sweden	Denmark	New Zealand (1992-2005)	New Zealand (current)
Annual Claims Rate (per million population)^a	200	1000	1000	750	<i>New system.</i> Early estimates indicate an overall claim success rate of 60% (including early appeal success rate of 14%)
Initial Claim Success Rate	30%	45%	40%	38%	
Claimant Appeal Rate	N/A ^b	18%	20%	20%	
Appeal Success Rate	N/A ^b	10%	15%	10%	
Overall Claim Success Rate	30%	47%	43%	40%	

^aApproximate populations: United States, 290 million ; Denmark, 5 million; Sweden, 9 million; New Zealand, 4 million.

^bAppeals rates in the US are difficult to estimate and thought be negligible. Moreover, favorable patient appeals would need to be offset by successful provider appeals.

Table 2. Criteria for Compensability of Medical Injury in Four Countries

Country	General Principle(s)	Type(s) of Injury	Compensability Rule	Definition	Fault Showing Required?
United States	Negligent injury	All	Negligence	Injury due to the failure of a provider to act with the care and skill that a reasonably prudent practitioner would exercise under the same circumstances.	Y
Sweden	“Avoidable” injury	Treatment Related	Experienced Specialist (with retrospective and alternate treatment elements)	Injury that is due to treatment (including diagnostic studies) and would not have occurred in the hands of the “best specialist” in the same circumstances. In some cases, the determination may be retrospective, incorporating limited types of information not available at the time of the treatment. Also included is injury that would have been avoided if another equally efficacious and safe method of treatment had been chosen instead.	N
		Diagnosis Related	Experienced Specialist (no retrospective element)	Injury due to a missed diagnosis that would not have occurred in the hands of the “best specialist” in the same circumstances. This determination is not retrospective; only information available at the time of care is considered.	N
	“Unavoidable” injury arising in special circumstances	Material Related	Strict Liability	Injury due to defects in or the improper use of medical products or hospital equipment.	N
		Infection Related	Infection	Injury due to the transmission of an infectious agent to the patient during care. The infection must be beyond what should be reasonably tolerated. The severity of underlying disease and the need for treatment must be outweighed by the severity and rate of occurrence of the infection.	N
		Accident Related	Strict Liability	Injury from an accident (such as a fall from a stretcher) or fire that occurs on a health care facility’s premises where a patient is receiving treatment	N

Denmark	“Avoidable” injury	Treatment Related	Experienced Specialist (no retrospective element)	Injury due to treatment (including diagnostic studies) that would not have occurred in the hands of the “best specialist” in the same circumstances. This determination is not retrospective; only information available at the time of care is considered.	N
			Alternate Treatment	Injury that is due to treatment and might have been avoided if another equally efficacious and safe method of treatment had been chosen instead.	N
		Diagnosis Related	Experienced Specialist (no retrospective element)	Injury due to a missed diagnosis that would not have occurred in the hands of the “best specialist” in the same circumstances. This determination is not retrospective; only information available at the time of care is considered.	N
		Equipment Related	Strict Liability	Injury due to the malfunction or failure of technical apparatus, instrument or other equipment used in connection with treatment.	N
	“Unavoidable” injury that is rare and severe beyond reasonable expectations	Treatment Related	“Endurability”	Injury due to treatment that is beyond what a patient should be reasonably expected to endure, even if it is a known complication. The severity of underlying disease and the need for treatment must be outweighed by the severity and rate of occurrence of the complication.	N
	Negligent injury	Accident Related	Negligence	Injury from an accident that occurs on the hospital premises where a patient is receiving treatment (and is not covered by the rules above) when the accident is the result of the hospital’s negligence.	Y

New Zealand (1992-2005)	Negligent injury	Treatment Related and Diagnosis Related	Medical Error / Negligence	Injury that results from the failure of a health professional to observe the standard of care and skill reasonably expected in the circumstances.	Y
	Rare and severe injury	Treatment Related	Medical Mishap	Injury due to a treatment complication that is rare (occurring less than 1% of the time) and severe (death, hospitalization for greater than 14 days, or significant injury lasting longer than 28 days).	N
New Zealand (current)	Unexpected “treatment-related” injury	All	Treatment Injury	Injury that is not a “necessary and ordinary” consequence of treatment. The circumstances of the treatment, including the patient’s underlying health condition at the time of the treatment and the available clinical knowledge at the time of treatment, are considered in making this determination. Treatment is defined broadly in this rule and includes all aspects of diagnostic evaluation.	N

Table 3. Bases for Compensation Decisions in Four Countries

	Compensation Rule	Approximate Proportion of Accepted Claims
United States	Negligence	100%
Sweden	Treatment Injury (Experienced Specialist)	75%
	Diagnostic Injury (Experienced Specialist)	10%
	Material	1%
	Infection	10%
	Accident	4%
Denmark	Experienced Specialist	54%
	Endurability	43%
	Alternate Treatment	1%
	Equipment	1%
	Accident	1%
New Zealand (1992-2005)	Medical Mishap	85%
	Medical Error	15%
New Zealand (current)	Treatment Injury	100%

Table 4. Clinical Scenarios Illustrating Injury Compensability in Four Countries

Scenario	Compensability and Basis for Compensation				
	likely uncompensable		close call ^a		likely compensable
	United States	Sweden	Denmark	New Zealand (1992-2005)	New Zealand (current)
1. Anaphylaxis from use of latex gloves during routine surgery on patient with known latex allergy.	Negligent	Avoidable (experienced specialist)	Avoidable (experienced specialist)	Medical error	Treatment injury
2. Anaphylaxis from use of latex gloves during emergent surgery on unconscious patient with known latex allergy (information listed in medical record, but not readily available). Recovery in 2 days.	Negligent	Avoidable (experienced specialist or retrospectivity)	Avoidable (experienced specialist)	Medical error	Treatment injury
3. Anaphylaxis, requiring a ventilator for 7 days, from use of latex gloves during routine surgery on patient with no history of latex reaction (assume rate of latex allergy <1%)	Non-negligent	Avoidable (retrospectivity)	Unavoidable but endurability criteria met	No medical error, no mishap	Treatment injury
4. Ureteral ligation during uncomplicated hysterectomy. No evidence of error in medical record.	Non-negligent	Avoidable (experienced specialist)	Avoidable (experienced specialist)	Mishap	Treatment injury

Scenario	Compensability and Basis for Compensation				
	likely uncompensable		close call ^a		likely compensable
	United States	Sweden	Denmark	New Zealand (1992-2005)	New Zealand (current)
5. Epidural abscess causing paraplegia after discectomy for disk herniation. No evidence of error in medical record.	Non-negligent	Unavoidable, but infection-related	Unavoidable but endurability criteria met	Mishap	Treatment injury
6. Retained foreign body (regardless of clinical circumstances).	Negligent	Avoidable (experienced specialist)	Avoidable (experienced specialist)	Medical error	Treatment injury
7. During hip replacement, patient suffers nerve palsy due to anomalous nerve path not previously known (nor should have been known). Recovery takes 2 weeks in hospital.	Non-negligent	Avoidable (retrospectivity)	Endurability criteria not met	Mishap	Treatment injury
8. During partial laparoscopic colectomy, bladder perforation. 1 week of hospitalization for recovery. No evidence of error in medical record. Procedure is new, growing in adoption, and complication rates are decreasing (but still higher than open procedure).	Non-negligent	Avoidable (alternate treatment)	Avoidable (alternate treatment)	No mishap	Treatment injury

Scenario	Compensability and Basis for Compensation				
	likely uncompensable		close call ^a		likely compensable
	United States	Sweden	Denmark	New Zealand (1992-2005)	New Zealand (current)
9. Mild pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP) performed for purely diagnostic purposes. A non-invasive, equally effective and safer imaging modality, magnetic resonance cholangiopancreatography (MRCP), was available.	Non-negligent	Avoidable (alternate treatment)	Endurability criteria not met but avoidable (alternate treatment)	No mishap	Treatment injury
10. Contrast nephropathy requiring hemodialysis for 3 weeks (proper indication and no contraindications to administration).	Non-negligent	Unavoidable	Unavoidable but endurability criteria met	Mishap	Treatment injury
11. Injuries from fire in hospital that occurred without fault of hospital.	Non-negligent	Accident-related	Non-negligent	No medical error, no mishap ^b	No treatment injury ^b
12. Death resulting from malfunction of implanted pacemaker that has good track record (occurring in far less than 1% of implantations)	Non-negligent ^b	Material-related	Avoidable (equipment rule)	Mishap	Treatment injury

Scenario	Compensability and Basis for Compensation				
	likely uncompensable		close call ^a	likely compensable	
	United States	Sweden	Denmark	New Zealand (1992-2005)	New Zealand (current)
13. Deep venous thrombosis after surgery for hip fracture (despite proper prophylaxis) requiring only outpatient treatment.	Non-negligent	Unavoidable	Unavoidable and durability criteria not met	No mishap	No treatment injury
14. Neutropenic sepsis after appropriate prescribed, administered, and monitored chemotherapy for acute leukemia.	Non-negligent	Unavoidable and infection injury criteria not met	Unavoidable and durability criteria not met	No medical error, no mishap	No treatment injury
15. Induction of early delivery of twins at 32 weeks because of preeclampsia. One newborn subsequently has an intraventricular hemorrhage.	Non-negligent	Unavoidable	Unavoidable and durability criteria not met	No medical error, no mishap	No treatment injury

^aIn the close call scenarios, the probable determination is provided.

^bAlternate sources of compensation may be available (such as a manufacturer or other injury compensation system).