Washington Healthcare Forum

A 21st Century System of Patient Safety and Medical Injury Compensation

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Submitted by the Washington Healthcare Forum

Patient Safety and Medical Liability Reform

Steering Committee

Washington Healthcare Forum

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Introduction

The current fault-based medical liability system is unreliable, expensive, inefficient, and unstable. Patients and their health care providers are treated unfairly. Patients who are injured by negligent care are compensated inconsistently and inequitably. Providers abhor the blame inherent in being sued for negligence, and they do not trust the results of the system. The administrative and legal costs of the system are high, and yet many injured persons are not able to access the system at all. Periodic liability insurance crises occur. Even worse, today's liability system impairs the systematic patient safety improvement that Washington state residents deserve.

Recent legislation enacted in the 2006 legislative session begins to address some of the problems plaguing the current system. We applaud both Governor Gregoire for her leadership, and the members of the legislature for their support of House Bill 2292.

Highlights of the bill include:

- Physicians would be able to apologize for a medical error within 30 days without it being used against them in court.
- Mediation would be mandatory before a lawsuit could proceed.
- Both sides have the option to use binding arbitration to avoid litigation.
- Juries would be allowed to hear if an injured patient had received payment from an insurer or other source.
- Plaintiffs' attorneys would have to have malpractice claims reviewed by a medical professional from the discipline involved in the case.

More fundamental restructuring of our flawed system needs to be done. The Washington Healthcare Forum believes the state can build on the forward momentum established by HB 2292 by creating a new, patient-oriented system to meet 21st century needs. This better system will accomplish the following:

- Support patient safety programs to prevent injuries.
- Compensate injured patients faster and more fairly, in ways that are more respectful and supportive to all involved.
- Reduce medical injuries and boost economic and social productivity.

It will take some time to further develop, refine and pilot the components of this new system, but it is high time to start.

This issue brief summarizes current problems and goals for reform. It describes the components of a patient-oriented system of safety and injury compensation. It outlines many of the steps needed to move closer to such improvement.

Problems with the Current "System"

The recent medical liability and insurance crisis has kept malpractice in the policy spotlight. Malpractice insurance premiums are unstable and at times unaffordable, but fundamental problems go deeper than periodic insurance crises. The medical liability system falls far short of the key goals of preventing medical injuries, compensating those injured, and doing so in a fair and humane manner.

Compensation is poor because only some injured patients with legitimate claims sue, and too many pursue claims found invalid after great monetary and emotional cost. Payouts are very slow—averaging more than three years in Washington state from incident to payout— according to the Office of the Insurance Commissioner. Awards and settlements are inconsistent across cases, and unpredictability prolongs disputes.

Our current system is inefficient:

- Administrative and legal costs are high.
- Successful claimants receive less than half of the money available to pay an award and associated expenses.[1]
- Most expenses consist of fees for legal counsel and expert witnesses, other claims-handling costs, other insurer expenses and profit, plus the lost time of claimants and defendants alike.
- The single biggest category of expense is the percentage of awards paid to plaintiffs' lawyers.

[1] Source: Physician Insurers Association of America, www.piaa.us/

A Piecemeal System

Deterrence of injuries is more piecemeal than systematic. Claims are brought haphazardly. The system resolves individual disputes better than many medical practitioners believe, disposing of many non-meritorious claims without payment, albeit at high administrative and legal cost. But its standards of fault and causality are vague and inconsistent.

Standards are set by whatever experts are selected for a given case, a process grounded more in advocacy than in medical science. Results are unpredictable and determinations can come years after the fact, by which time medical practice may have changed anyway.

Whatever prevention signals come from litigation are muted by liability insurance and the secrecy that cloaks many settlements, and also lack credibility with practitioners. There is little systematic feedback to inform providers or the public. Most negligent injuries are never litigated, but some awards are intimidating, especially for a solo practitioner. Deterrence would be better served by more comprehensive, measured, and credible results.

Capping off all these observations are 30 years of studies documenting that unacceptable rates of preventable error and injury persist despite generations of increasing legal interventions in medicine.

Dispute-Based System Impedes Patient Safety

Underlying these current problems is medical liability law's basic nature: It resolves disputes; it is not systematic about promoting safety or compensation. The liability "system"

addresses only those cases brought before it. Each set of litigants is guaranteed many procedural rights and allowed great scope to shape cases. Some surveys often have found plaintiffs are satisfied, even those who have lost their cases. Many had felt stonewalled before suing, and the suit gave them the chance to learn more and voice their concerns.

Legal theory asserts that medical liability law does much more, constituting a powerful system for injury prevention and compensation. But reality shows a different picture:

- Liability processes lack any systematic approach to injury or compensation.
- Lawyers, judges, and juries have no information about medical injuries or safety generally, no way of knowing about how well injuries are compensated (or not), and no way of generating consistent results.
- Studies find that legal process omits most injuries, resolves claims slowly and somewhat haphazardly, and pays out hugely variable amounts in similar cases—hardly attributes of a fair injury-resolution system, much less of a safety and compensation system.
- Few defendants believe the system treats them fairly, and even some successful plaintiffs have lately become crusaders for legal reform to better serve patients and patient safety.

The system also has harmful side effects on health care, patient safety, and patient-practitioner relationships. The current legal environment has led some physicians to curtail the services they offer, change locations, or even leave practice altogether. Because practitioners lack confidence in the clinical validity of legal results, they too often practice defensively to minimize the risk of losing a lawsuit.

The current effort to avoid being sued is a major impediment to creating a culture of safety within which people can talk openly about mistakes and mishaps, and learn how to fix problems systematically rather than blame individuals.

Goals for Reform

In short, the liability system is poorly serving the public, injured patients, and providers. This conclusion and our proposal for a patient-oriented system are consistent with proposals for fundamental reform from the Joint Commission on Accreditation of Healthcare Organizations and the American College of Physicians. We recommend five key goals for reform:

- Promote patient safety and reduce medical injuries
- Make compensation fairer, faster and more readily available for patients still suffering injury
- Make the system cost effective and efficient by reducing legal and administrative costs
- Improve accountability and trust between patients and caregivers
- Make the system more predictable and therefore more sustainable and less susceptible to periodic crises

Change must be affordable. Costs to health care providers will be designed to be similar in magnitude to today's liability premiums. Even with this constraint, injured patients will be much better off. The new system will compensate more injured patients than the current system, in the process surfacing more information about problems to help prevent future injuries. Legal and administrative costs per case, however, will be markedly lower for the patient-oriented system, so a greater share of the system's funds will go to meeting the needs of injured patients. Thus, the new system will offer better value than today's inadequate system.

Significant progress requires fundamental changes. What we really need is to move to a quite different and better system.

A New System: Overview

The Forum believes the goals of reforms can be fully met only by replacing today's fault- and judicial-based malpractice system with a new, patient-oriented system that links patient injury compensation and patient safety. Because safety efforts focus on prevention, the new system will compensate preventable injuries rather than negligent ones. A prevention-based standard will:

- Directly tie the injury compensation system to patient safety
- Focus economic incentives on avoiding injuries
- Generate and report data essential for:
  - Improving patient safety and accountability
  - Identifying best practices

A list of Avoidable Classes of Events (ACEs), prepared in advance, will help providers and patients identify and resolve cases promptly and efficiently, without need for legal process. Providers will have incentives to proactively identify and accept responsibility for preventable injuries.

Most cases should be resolved expeditiously by mutual agreement because standards will be so much clearer under the new patient-oriented system. When patients and providers do not agree on preventability or compensation, a form of alternative dispute resolution will resolve disagreements in a fairer, speedier, and more predictable fashion. The system will seek to compensate a high proportion of those cases meriting compensation, and more injuries will qualify for compensation than under the current negligence-based system. It will be kept affordable by compensation reforms, including full offset of funds received from collateral sources such as health insurance, and schedules for non-monetary damages.

A new kind of patient representative could do much to:

- Help patients investigate and assess potential claims
- Obtain compensation when warranted
- Work with providers to stimulate patient safety improvements
- Help patients engage good legal representation on reasonable terms when claims are disputed

The following sections describe the attributes of this new system in more detail. Considerable work has already been done on many of its components. As a pioneer in this area, however, Washington state will need to further develop and pilot test its new system, then evaluate and revise it as needed before adopting it statewide. We recommend that the state move expeditiously to begin this process.

Better Prevention of Medical Injuries

Preventing injuries is the top priority, because avoiding them to begin with is preferable to merely compensating them after they occur. Three key aspects of the new system will improve the prevention of medical injuries:

1. **Preventability standard**

The standard for compensation will be based on preventability. This is the key step in linking compensation to prevention. Preventability will be evaluated in a non-adversarial way for most significant injuries—because a comprehensive listing will be made in advance of classes of preventable injuries that are to be compensated automatically.

2. **Proactive case identification**

In the event of an unexpected bad outcome, providers will work proactively to identify all preventable injuries and to make reasonable restitution without adversarial process.

3. **Using the data to prevent injuries**

The data collected by this injury identification/compensation system will be used by providers, health care organizations, and others to craft systematic patient-safety efforts to prevent future injuries.

1. Preventability Standard

We recommend that preventability replace negligence as the standard for identifying and compensating medical injuries. This change is essential for the compensation system to improve patient safety and prevent injuries. It will properly focus economic incentives (having to pay compensation) on injuries that can be prevented, and improve accountability for those injuries. It will help generate comprehensive data about the full set of injuries best suited for patient safety efforts—preventable ones. Using preventability to determine which injuries are compensated will promote development and use of best practices.

Moreover, caregivers' temptation to defensively provide extra tests or procedures for courtroom protection should diminish. Such unnecessary effort will be unavailing under a fully reformed system unless the extra services are shown to be a best practice that actually prevents injuries.

Shifting to a preventability standard will also support the culture of safety needed to prevent injuries. Non-fault-based compensation will be less threatening to caregivers and more conducive to open communication. Under current law, it appears that payments made under a preventability standard will not be reported to the National Practitioner Data Bank. That threat is often cited as a large barrier to disclosing errors and settling claims under the current liability system.

Fostering a non-punitive culture will help nurture the transparency, trust, and reporting that patient safety programs need to succeed.

Another advantage is that preventability is a more reliable standard than negligence. Different reviewers applying the standard are likely to make the same determination about preventability. That is not the case with a negligence standard. As a result, judgments of preventability will be more consistent and predictable, so they will send a clearer signal to providers about

the injuries on which they need to focus preventive efforts. Preventability will be assessed in one of two ways. First, providers and patients will check to see if an apparent injury appears on a pre-established listing of avoidable events. Second, for unlisted events, an individualized assessment of the circumstances will be made to determine whether a particular injury was preventable.

a. Avoidable Classes of Events (ACEs)

The best way to implement preventability as the standard of compensation is to identify in advance entire categories of preventable medical injuries that will be deemed compensable whenever they occur. Advance listings also simplify and streamline the compensation process. Much work has already been done on this concept, called ***Avoidable Classes of Events or ACEs***.

ACEs are medically caused injuries that experts agree in advance are usually preventable. For example, one ACE might be the occurrence of a severe allergic reaction after a patient is given a medication to which she has a known allergy and for which there are reasonable alternatives. Any resulting injury is generally preventable, because under almost all circumstances, the patient's medical history should be available and readily checked, so that providers will know not to give the patient the problematic medication. It is not worth disputing every case just to avoid compensating a minority of cases that, because of unusual circumstances, might be argued to be unavoidable.

Any injury falling within an ACE class would thus be compensated automatically without need for an in-depth inquiry or contentious dispute. Another ACE might be a peripheral nerve injury remote from the operative site that occurs during general anesthesia. Such injuries are usually caused by inadvertent excess pressure on the nerve in an arm or leg that is being kept out of the way during the operation. When such an injury occurs, the claimant would not need to investigate or prove that in her particular case the limb was positioned or padded improperly or negligently; the patient would simply be compensated.

The requirement for an injury to be an ACE is statistical avoidability as a class, as in epidemiology; not every instance of the injury need be preventable. An infected peripheral IV site could be an ACE, for example, even though some such infections might not be avoidable even with best practices. Injury to the common bile duct during laparoscopic cholecystectomy might happen in some cases even in the best of hands, but if this injury is usually avoidable it could still be an ACE. Paying all cases within an ACE automatically is a trade-off made to avoid the expense, stigma, and all-around hassle of making case-by-case determinations. That ACEs will pay some claims that could be successfully defended in an expensive trial for negligence is actually an advantage, because it further removes the stigma of fault from the compensation process.

The simplicity of ACEs allows ACE claims to be rapidly compensated through a process more closely resembling insurance than adversarial litigation. Compensation decisions will be more credible because they are objective and expertly pre-determined. In a study applying a set of obstetrical ACEs to a major sample of hospital liability claims, the study's nurse reviewers found the ACEs easy to use, and they readily resolved by consensus the few borderline determinations they needed to make.

An important feature of ACEs is that they are known in advance, and both

patients and providers can readily recognize them when they occur. This will make compensation more comprehensive and consistent across patients.

ACEs can also help make clear when injuries are not compensable: For example, the ACE for a severe allergic reaction to a medication can specify that an allergic reaction is not compensable when the allergy was previously unknown. This feature of ACEs could help reduce the incidence of unwarranted claims or compensation.

The link between ACEs and prevention of injuries is clear: ACEs identify areas where injuries can and should be prevented. This will promote the development and consistent use of best practices. ACEs will help providers and health care organizations track avoidable injuries and target systemic improvements. Those that do so effectively will be rewarded with fewer claims and lower compensation costs. Hospitals that consistently use peripheral IVs only when indicated, insert them in a sterile manner, inspect the IV sites regularly, and rotate IV sites at safe intervals will pay fewer claims for infected IV sites than those that do not—and they will have the data to know how they are doing.

As discussed further below, an inclusive and authoritative process needs to be organized to develop the ACEs for the new system. To be most effective, the list of ACEs should be comprehensive. An early version of obstetrical ACEs was found to account for about half of a major sample of hospital liability claims—including two thirds of serious injuries and three quarters of dollar payouts. Today, these listings need to be updated and expanded to cover more care. Listings also need to be harmonized across specialties so that they may apply equally to all care given to any type of patient and condition; compensation and safety standards should not vary across disciplines.

As written information accumulates on the settlements and decisions on preventable non-ACE injuries (discussed in the next section), these data can inform the revision of ACEs and the development of new ones. Over time, the clarity and inclusiveness of the list of ACEs should increase.

We recommend against implementing ACEs as a "carve-out" from the existing medical liability system; that is, litigating in the usual manner every injury not covered by an ACE. The experience with the birth injury carve-out in Florida suggests the maintenance of two systems provokes confusion and litigation over which system applies. Courts naturally are more comfortable with their own process and over time tend to undercut the boundaries and independence of the alternative system. The uncertainty that this would cause for the ACE carve-out would impede prompt resolution of claims. Even worse, the potential to end up back in medical liability would cripple the transparency and reporting of medical injuries that are essential to consistent compensation for patients, preventing injuries, and fostering a culture of safety. The principal advances of the new system would be lost.

Examples of Potential Avoidable Classes of Events, or ACEs[2]

- Surgery on the wrong body part
- Surgery on the wrong patient
- Wrong surgical procedure performed on a patient
- Object left in patient after surgery
- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics
- Patient death or serious disability associated with the misuse or malfunction of a device
- Infant discharged to the wrong person
- Patient death or serious disability associated with a medication error
- Patient death or serious disability associated with transfusion of blood or blood products of the wrong type
- Death or serious disability associated with failure to identify and treat hyperbilirubinemia, a blood abnormality, in newborns
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred in the hospital
- Patient death or serious disability associated with the use of restraints or bedrails

[2] Referenced in Washington State House Bill 2292 and included in "*Serious Reportable Events in Healthcare*," 2005-2006 Update, National Quality Forum

A Process for Identifying ACEs

An expert panel made up of individuals with national credentials and medical/clinical expertise, ethicists, consumer representatives, and economists would oversee the development of an initial ACE list. Such a panel could be appointed by the Governor, selecting from highly credible experts.

The panel might contract with a neutral, well-respected research organization to help develop the initial list. Possible organizations include:

- RAND
- Institute for Healthcare Improvement
- National Quality Forum

The panel would hold public hearings on proposed ACEs and approve an initial list. The panel also would be responsible for:

- Determining a schedule for non-economic compensation
- Setting parameters or formulas for economic compensation

The panel would review ACEs and other preventable events on a regular (perhaps quarterly) basis with the goal of incorporating additional classes of events over time.

b. Non-ACE Injuries

Some injuries will not fall into an ACE category. For these, a general standard of preventability must be used, case by case, to determine whether each injury is to be compensated.

This standard is new for the United States, but it is consistent with the best thinking about patient safety and is used elsewhere. A preventability standard for medical injury compensation has been used successfully for decades in

Sweden. Swedish patients are compensated if their injury is caused by health care and the injury is avoidable. A similar preventability standard can readily be drafted for Washington state.

U.S. researchers tested the Swedish standard by applying it to a set of medical injuries they detected in a representative sample of 15,000 non-psychiatric 1992 hospital discharges in two states. They achieved excellent reliability with the standard: two independent reviewers classified each injury the same way 91 percent of the time. This level of agreement is far better than for the less reliable negligence standard.

In the new patient-oriented system, the reliability of judgments of preventability—and therefore their consistency and predictability—will be further improved in two ways. For cases that cannot be settled between the parties, a method of alternative dispute resolution will be used that will afford more expert and reliable decisions than those made by random juries convened to decide a single case. Second, each claim that is decided or settled will be memorialized with a written, de-identified summary of the facts, result, and reasoning of the case. These records will provide guidance on similar cases in the future, much as published appellate court decisions now serve as precedent for future legal questions.

2. Proactive Case Identification

To improve compensation and safety, it is important to "surface" and study all preventable injuries that occur. ACE lists will facilitate the prompt identification and disclosure of listed injuries, and providers should disclose ACEs immediately. ACEs are highly likely to be discovered later if they do not, and disclosure will no longer provoke expensive, lengthy, and highly unpleasant lawsuits.

Preventable non-ACE injuries also should be promptly disclosed when they are discovered, though it may understandably take longer to recognize them than ACEs. (Some disputes about preventability will occur; dispute resolution is considered later in this paper.) As patients, caregivers, and health care organizations come to trust the new system to work well, they will more likely embrace transparency and other components of a culture of safety.

The new system's basic incentives to disclose preventable injuries and cooperate in subsequent safety processes are good, but they should be augmented. Professional associations should re-emphasize that proactively identifying preventable injuries and disclosing them to patients is a professional duty of care and an essential element of assuring quality and safety.

Further encouragement could come from some form of public oversight—perhaps a combination of regulatory monitoring and public disclosure of performance. Care must be taken not to penalize caregivers and organizations for finding and disclosing preventable injuries. Especially in the early stages of implementation, observed rates of ACEs and disclosed preventable injuries may be highest among the best caregivers—because they are best at detection and disclosure as well. Early disclosers should be praised for advancing safety, not scolded for initially higher rates of observed injury. Indeed, low rates of disclosed injury may merit some attention from public or private overseers.

3. Using the Data to Prevent Injuries

The new system will generate comprehensive data on the occurrence of preventable medical injuries. Each provider and health care organization will possess this information on the injuries they compensate. They can use the data to target areas for patient safety attention, devise systemic interventions, and measure the effectiveness of their efforts. De-identified versions of these data could also be reported to outside patient safety or other organizations for aggregation, analysis, and benchmarking.

A hospital that experiences few peripheral IV site infections might think it is doing well until it learns of similar hospitals that experience no such infections. Data on uncommon injuries need to be aggregated across providers for analysis and trending. The effectiveness of patient safety interventions could be assessed by comparing the results of organizations that adopt different approaches.

In short, the data need to flow to organizations that are capable of responding to it with systems-oriented analysis and prevention. Consideration should be given to how this kind of data reporting, analysis, and benchmarking can best be accomplished. How insurance is organized and rated to cover providers for their risk of ACEs and other preventable injuries has a role to play here.

Right now, most people who are harmed by preventable errors are not compensated. Health care providers are not organized in a way that enables a focus on prevention of future errors. This new system would help ensure that many more people who are harmed by a preventable error would be compensated and that fewer errors would occur over time. The medical liability system may pay less per individual, but more as a system over the short term. Over time, both costs and preventable errors should decrease because health care providers would receive information to help them improve patient safety.

Here's how the new system would work with preventable events:

- A preventable injury occurs.
- The provider apologizes and offers economic and non economic compensation as appropriate.
- A patient advocate is available for the injured party.
- There is an opportunity for the patient and provider to discuss the offer.
- If no agreement is reached, the dispute moves to mediation.
- If mediation does not produce an agreement, the case would move to a binding alternate dispute resolution, such as a medical court, binding arbitration or an administrative agency.
- If an incident were determined by the provider not to fall under the preventability standard, and if the patient disputes that finding, the patient would have a choice. The patient either could stay with the alternate dispute resolution process or use the current tort system under the negligence standard.

Fair and Faster Compensation of Medical Injuries

Under a patient-oriented system, compensable injuries should be easily and reliably identified. They also should be adequately and promptly compensated, with low administrative and legal costs. Adopting an objective system based on preventability of injury will also facilitate taking an objective approach to compensation.

Today's medical liability system is so unpredictable that parties even make confidential "high-low" agreements before going to trial, so as to avoid the capricious nature of a thoroughly unreasonable jury verdict in either direction.

A key problem is that today's system gives little guidance of any use to decision makers for the as yet undocumented elements of compensation—future medical and wage loss, as well as non-monetary losses such as pain and suffering. Nor does the liability system have any way to assure that like injuries receive similar awards and that larger injuries regularly receive larger compensation. Each case is tried in isolation, and each element of compensation must be established from the ground up.

High variability and unpredictability of awards promotes disputes, which raise costs for lawyers, many kinds of specialized experts, and so on. The ever-present possibility of a very large award seems to be a key motivation for malpractice claimants to hold out for jury verdicts and also influences settlements made in "the shadow of" potential verdicts. Nationally, only about 20 percent of verdicts favor medical liability claimants, but high jury awards make such low success rates still worthwhile for plaintiff's attorneys. This compares with a success rate at trial of about 50 percent in auto accident cases, which have lower average awards.

The basic principle for compensation should be that patients' monetary losses are reasonably compensated. Washington residents with preventable medical injuries should not have to bear any out-of-pocket costs. Patient-oriented compensation should coordinate benefits with other compensation sources, such as sick leave and health insurance, to assure this result. Available benefits should be similar to what well-insured Washington residents finance for themselves. State policy makers may well want to add some benefits for preventable injuries that are often left uncovered by insurance and public programs, such as extended rehabilitation, transportation, and some level of custodial assistance.

In addition, Washington state will need to decide whether and how much to allow for pain and suffering payments. Worldwide, few injury compensation systems cover such non-monetary aspects of injury. Pain is real, however, and Washington state residents are probably willing to finance some pre-measured levels of payout that are proportionate to the severity and duration of pain or loss of enjoyment of life. If good benefits are provided quickly after an injury, early rehabilitation should help patients recover faster and to higher levels of functioning.

A number of additional approaches could increase the fairness, consistency, and predictability of payouts. One method is to pay for future losses over time, as they occur, rather than as a lump-sum in advance (the latter is the standard liability approach today). Many existing non-liability mechanisms pay for losses only as they arise, including the Virginia and Florida programs for severely neurologically impaired newborns

injured by the birth process. Paying losses as they occur protects injured patients and caregivers alike against under- or over-estimating future needs.

If the new system continues to make current lump-sum payments for some or all future losses, it should regularly adopt and consistently apply to all cases more systematic estimates for future price inflation for medical and other health services needed in "out years". It also should apply the discount rates needed to reduce future losses to current value. Any of several fair processes for developing and updating the estimated rates could be used.

Designers of the new system also should consider ways to standardize the calculation of certain elements of loss. For example, allowances for lost wages can be standardized as a certain percentile of statewide wages. Some standardization is particularly appropriate for injured children and other claimants with little work history; adjudicating such cases entirely from scratch inevitably promotes unfair differentials. Not dissimilarly, wage replacement for those injured who have a work history may reasonably be less than 100 percent in light of the injured person's lack of work-related expenses and the tax-free nature of injury compensation. Allowances for pain and suffering can also be standardized in the interests of fairness.

Structuring Compensation for Predictability and Consistency

Basic standard:

- Pay net out-of-pocket costs of covered losses—medical, wage-loss, and other reasonable costs
- Schedule any allowances for non-monetary losses, based on severity and duration of injury

Further design issues:

- Whether to pay for future losses in advance or as they occur
- How to standardize estimates of the current value of future losses

None of the potential elements of compensation mentioned here needs to be adopted as an inflexible schedule that lacks recognition of individual circumstances. The new approaches can create ranges of reasonableness or targets. The looser the guidelines, the more closely payments can be tailored to match the specific losses of each patient, but the greater the likelihood that the parties will not agree on compensation and an adversarial hearing will be required to resolve the case. If compensation calculations are more tightly constrained, they will be more predictable and more likely to produce agreement, but they will be less able to take individual circumstances into account.

The system's developers must strike a balance that best serves the interests of Washington residents.

Even with controlled payouts, injured people will fare better on average under a new patient-oriented system. More claims will be discovered and paid. Payouts will come faster and with less investment of claimants' own time. Legal and other transaction costs will fall substantially, raising net compensation.

All these ways to improve the fairness and consistency of compensation will also improve patient safety by increasing predictability and generating reliable economic incentives to prevent injury. Less unexpected variation in payouts and much shorter "tails" of open claims awaiting trial or settlement can also generate considerable savings in non-compensation costs.

One academic medical center, for example, adopted a policy in 2002 of admitting errors up front and negotiating early settlements with patients. It has reduced its average time to close a case from more than three years to less than one year, and it has cut its number of open cases by more than half.

All of these factors likely will decrease the "risk premium" now charged by liability insurers, reduce the need for high-cost reinsurance, and dampen the current swings between over- and under-pricing premiums and between over-and under-reserving claims for medical liability. As a result, cyclical medical liability insurance crises will be ameliorated.

Alternative Dispute Resolution (ADR)

Fundamentally, the new system will promote ***undisputed*** compensation. It is meant to operate much more like health or disability insurance than like liability insurance.

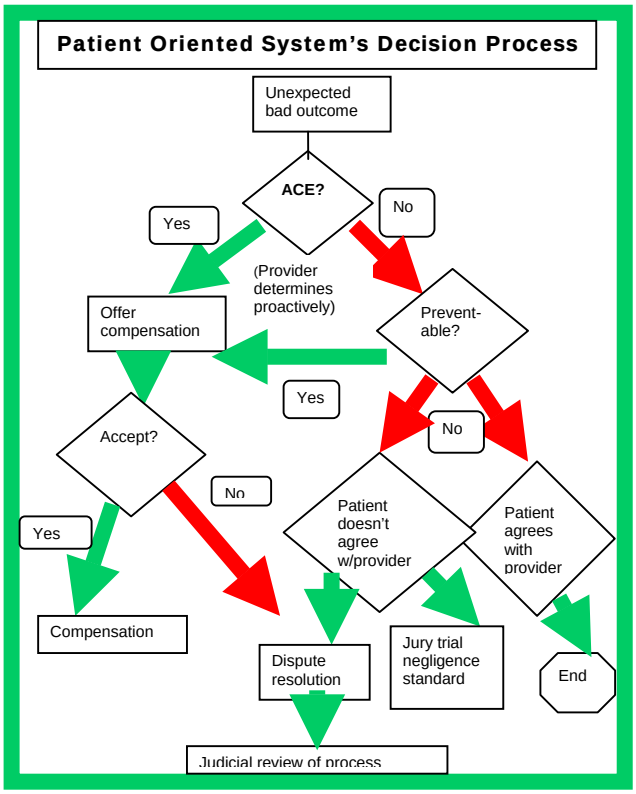
The occurrence of an ACE or other preventable injury should normally be quickly followed by an objective determination of eligibility for compensation and a non-litigious agreement to pay for reasonable losses, past and future. Compared with the current adversarial system of litigation, this will save much time, cost of adjudication, and unpleasantness.

Injured patients and their providers could potentially disagree in three areas:

- Whether or not a particular injury is compensable as an ACE
- Whether a non-ACE nonetheless qualifies for compensation under the general standard of preventability
- Whether the amount of compensation offered is reasonably related to the losses already suffered or yet to come

The new patient-oriented system will be designed to minimize such disputes. Differences on compensation will be narrowed by the guidelines and other means described in the preceding section. Moreover, disputes about compensation are qualitatively different and easier to resolve than conflicts about liability.

In the new system, providers will have a duty to report preventable events. Failure to report should enable the patient to immediate have a choice of either using the alternative dispute resolution system or opting for a jury trial.



Disagreements about ACEs will be reduced by making the set of ACEs as comprehensive as clinically and scientifically possible and each ACE as clearly delineated as the drafters can make them. ACE listings will be changed over time to keep pace with advances in medicine that affect avoidability of injury, and to correct imprecision in wording.

The type of ultimate decision-maker used can help reduce the number of disputes as well as their costs, monetary and non-monetary. Decision-making on ACEs, non-ACEs, and compensation can be made more consistent and predictable by using an experienced decision-maker that issues written determinations to help guide future cases. Juries—and even judges hearing isolated cases—are not such entities, so an alternative must be used.

When the patient and provider cannot quickly bridge any differences on their own, mediation should generally be used first to try to achieve a mutually agreeable resolution, with more formal dispute resolution used only thereafter, if needed. Graphing the process shows the importance of proactive identification and mediation, with dispute resolution only needed for a small number of claims.

Mediation

Mediation, when properly crafted to the particulars of the problem and the setting, can help almost any system work better—today's courtroom-based liability or any alternative. Use of mediation has increased for medical malpractice claims, but it could be used far more extensively. It is often undervalued for being "only" voluntary and not a mandatory reform. It is also taken too often to refer to "settlement negotiation," whereas its most effective forms drive toward resolution rather than just financial settlement.

Mediation can quickly resolve many disputes, typically at reduced cost, and even prevent injuries from escalating into formal disputes. Its key advantages are promoting cooperation and greater freedom to craft more appealing resolutions than the limited monetary options of conventional disputes. Injured patients typically want more than money, sometimes even instead of money—recognition of and explanation for their problems, an apology, and acceptance of accountability in the form of concrete actions to avoid similar problems in the future. Early intervention before adversarial postures have hardened can promote success.

Mediation can work better where parties want to maintain a relationship rather than break it and punish the other side. Mediation has been shown to work even where parties have very different views of the severity of an injury—and its likely monetary costs. To work well, a mediation orientation that seeks win-win solutions needs to supplant the "we-win-you-lose" mentality of adversarial approaches, which may call for using different personnel as mediators. Some pioneers report very high rates of successful mediation, even under the shadow of conventional liability. Mediation's focus on agreement and fixing problems also parallels patient-safety approaches to problems. Indeed, by allowing a confidential and candid discussion of the event, its causes, and its effects, mediation is more consistent with the search for improvement than almost any adversarial process can be.

Sometimes even mediation will fail, and an ultimate decision-maker will be needed to reach a final result. To support the shift in focus of the new system, this arbiter should be an alternative to traditional litigation. Washington residents designing their new patient-oriented system should consider several mechanisms of alternative dispute resolution (ADR). These possibilities include private arbitration, a medical court, and an administrative forum similar to workers' compensation. Such alternatives should be far friendlier to patients and less threatening to doctors and other practitioners than is the medical liability system, even if reformed.

Arbitration

Arbitration is a reasonable way to resolve disputes that cannot be mediated or otherwise settled. Arbitrators are independent neutral professionals who hear evidence under more expeditious rules of procedure and evidence, then quickly render full judgments. Arbitration's administrative costs are substantially less than the conventional medical liability process. In many U.S. industries and in most industrialized nations, arbitrators rather

than courts resolve disputes. Federal and state statutes facilitate arbitration, which is normally agreed to by private contract.

The most promising approach for health care may be what many Kaiser Permanente health plans have done for generations. Patients and providers agree to final, binding arbitration when they agree to participate in the plan. That way, dispute resolution can be part of an organized continuum of ways for the plan and its practitioners to address perceived shortcomings in care. Patients can instead agree to arbitration at the time of service, separately with each unintegrated provider, in the same way that they give informed consent for care. Where parties have agreed to arbitrate, court appeals should be allowed mainly to correct clear misbehavior by parties or arbitrators. Nonbinding arbitration risks becoming merely a duplicative stage in a protracted, courtroom-bound legal dispute, especially in "big ticket" cases.

Like any process, arbitration can be well or poorly run, so accountability needs to be maintained through documentation of performance. Arbitration should visibly meet the needs of all parties for a speedy, reliable, and fair resolution by independent decision makers in a transparent process. Arbitration's decision makers are expert, neutral and take a measured approach to evidence. Shifting from courtrooms to arbitration can make medical practitioners more cooperative with compensation and attendant safety inquiries. Arbitration appears to reduce average payouts and the variability of results while slightly increasing the volume of claims—both consistent with the perspective of this issue brief—although good data are sparse.

Arbitration need not be the exclusive remedy, but may be available to agreeing parties even where the default mode of dispute resolution is medical courts or administrative adjudication.

Specialized Medical Courts

Specialized medical courts are another alternative that more closely resembles the current system yet attempts to remedy some of today's failings. The courts would be staffed by full-time judges who would handle no other types of cases. They would hear and decide medical injury claims without juries. Like judges today, they would enjoy independence from the parties to the dispute and from the rest of state government. Unlike today's judges, they would be more expert in resolving medical disputes. They would acquire expertise with training and augment it over time with experience; some may come with medical credentials.

Shifting medical injury compensation from conventional courts to more knowledgeable decision makers aims to make decisions more expert, more reliable, faster, and less expensive. A key goal, say promoters of the concept, is prompt and expert winnowing out of non-meritorious claims. They point to the precedent of expert courts for tax disputes, and formerly for admiralty cases. Specialized medical courts have not as yet been tried, but some specialization often occurs today among administrative law judges, such as those who hear appeals from the agencies that run specific payment programs.

Expert Administrative Agencies

Expert administrative agencies could totally replace today's medical liability claims resolution system with a more accessible system run by specialized public administrators. In the late 1980s, organized medicine proposed such an administrative agency to make determinations based on standards of fault. The approach is more commonly suggested to implement the standard of

preventability endorsed by this issue brief. Such systems simplify determinations of responsibility for compensation, limit damage allowances—especially for non-monetary compensation—and avoid an adversarial judicial process.

Two existing models of administrative compensation exist in U.S. health care: Virginia and Florida administrative agencies provide compensation in lieu of medical liability to infants born live with severe, birth-related neurological injury due to oxygen deprivation or mechanical injury. Independent administrative law judges resolve disputes. The federal Vaccine Compensation Program is another model. It bars suits and automatically pays for listed adverse side effects of childhood vaccines, somewhat like ACEs. Its disputes are resolved before special masters working with federal judges of the U.S. Court of Federal Claims, somewhat akin to a medical court.

Evidence from these programs shows reasonable compensation with low overhead—but no discernable impact on safety, indeed no mechanisms to improve safety. A much broader system would not only improve compensation but would also generate more injury information, rely more on experience rating, and build in more technical expertise—all expected to improve safety, as Workers' Compensation has done for employees.

ADR as a Fallback

These ADR options should be secondary to more proactive ways of compensating injuries. Unlike medical liability dispute resolution, ADR in a patient-oriented system is not the central mechanism of compensation. Rather it's a fall-back mechanism invoked only for those cases not easily resolved under the more open and fair ACE- and disclosure-based processes. Even a non-medical liability dispute-based system, if it passively relies on claimants to bring claims, can expect to suffer the same under-disclosure as medical liability. Another point is that over-relying on ADR would raise overhead costs; all claims going into ADR must be separately investigated and settled or adjudicated, case by case. This raises administrative costs and can lead to inconsistent results across cases, although less so than the current system. ACEs and other measures need to be implemented in tandem with ADR.

In order to ensure fairness, judicial review of the process would be available to patients, after an alternative dispute resolution ruling. An appeal of the arbitrator's decision should be allowed to review allegations that the process was arbitrary and capricious.

Use of mediation, and alternative dispute resolution alternatives, such as binding arbitration, medical courts, and expert administrative agencies, are fall back mechanisms for the new prevention-based system. Regardless which model is used it should be based on the following guiding principles:

- Efficient
- Economical
- Accurate
- Consistent
- Concentrated expertise

A Patient Safety Representative

The new patient-oriented system will allow most claims to be resolved without any adversarial hearing or lawyers for either side. ACEs and clear rules and guidance on compensation will facilitate this result. Yet many patients may want assistance with the process, because health care providers and insurers possess greater expertise and resources than patients do. Additionally, the old system has created an adversarial legacy of non-disclosure that will take time to change.

A new kind of patient representative could help patients access and navigate the new compensation system, especially for cases that do not clearly qualify as ACEs or where injuries are profound. This person would help patients investigate events, assess patients' injuries, and receive prompt and reasonable compensation. The representative would assemble and review the relevant medical records, obtain additional information from patients and health care providers, and hire medical experts if needed to provide information as well as opinions about the claim.

Representatives can give clients an objective, unbiased assessment of a potential claim's merits and the extent of compensation. They can work collaboratively with providers toward solutions that can include non-monetary remedies such as explanations, and patient safety improvements.

A patient representative who is experienced and professional, and who can work constructively with providers, can minimize the need for an adversarial hearing. When a lawyer is needed to resolve a case, the representative could help the patient obtain good legal representation at fair terms. The representative should be motivated to use legal services only where lawyers add value, so litigation serves the compensation system rather than drives it.

This patient representative role requires a new set of abilities and incentives. Representatives must serve the interests of clients, but in a non-adversarial way as much as possible. Providers should come to trust the performance of the patient representatives so they will not hesitate to refer patients and potential claims to them.

A model for this role is the third-party administrator (TPA) employed by large, self-insured health care organizations to manage their medical malpractice claims. Most TPA personnel are former nurses. They deal with plaintiffs' lawyers as well as interact directly with claimants who have not engaged a lawyer. They hire and manage the cost of defense counsel. TPAs add value by resolving cases better and more efficiently than health care organizations can with the sole help of defense counsel.

When a new compensation system is pilot tested, it would be useful to include a demonstration of this new type of patient representative to gain experience with the service.

Consideration should be given to new models for providing patient representatives. Funding and organizational mechanisms are needed that will produce patient representatives who will best support the goals and functions of the new compensation system. The goal is to provide patient representatives who will provide value to patients and who providers will be able to work with productively to resolve claims in an efficient, fair, and respectful manner.

Maintaining Affordability

The new patient-oriented system is designed to compensate more injuries, as preventability is a more reliable standard than negligence. The likely increase in the number of valid claims raises concern that the new system's total ***internal*** cost might be higher than the aggregate premiums now paid by caregivers, including self-insurance and similar mechanisms.

The total ***societal*** cost of preventable medical injuries, by contrast, would likely drop due to the administrative efficiencies of the new system, and would decline further over time as prevention improves. The societal cost of preventable medical injuries is now borne by a combination of separate sources and streams of money, of which the medical liability system constitutes only a partial share. It would be infeasible for the already-stressed medical liability system to assume a greater share of injury costs, to the benefit of the other compensation systems.

Other Sources of Support for Medical Injuries

Medical benefits
- Employer supplied health coverage
- Individual health coverage
- Federal Medicare program
- State-Federal Medicaid program
- State-Federal Children's Health Insurance Program
- State General Assistance-Medical programs
- Federal Veterans Benefits

Income replacement benefits
- Employer supplied paid sick leave
- Employer supplied disability coverage
- Individual disability coverage
- Federal Social Security Disability program
- Federal Supplemental Security Income program

Medical and income replacement
- State Workers' Compensation programs

Miscellaneous assistance (for those rendered unemployed, indigent)
- State/Federal Unemployment Compensation,
- Temporary Assistance for Needy Families, etc.

New system costs will be controlled in a number of ways.

First, the administrative overhead of the system will be much lower. Reduced disputation and faster claim resolution will save money. Considerable efficiencies will be achieved by minimizing disputes and the use of lawyers on both sides and, when lawyers must be employed, by harnessing them to serve only the purposes they are needed for and paying them fairly for the work they perform. The academic medical center, mentioned earlier in the report, that adopted a policy of early settlement of valid cases has cut its legal costs in half.

Second, having more predictable decision makers and better standards for compensation including the use of ACEs, will reduce the number of invalid claims made and paid.

Third, having better decision makers, dropping medical liability's emphasis on proving blame, and adding guidance on compensation awards will create greater consistency and equity of awards.

Fourth, the new patient-oriented system will coordinate better with all the non-

liability forms of compensation that pay for most medical injuries today. Such non-liability payers as health and disability insurance deliver compensation very efficiently and need to continue as the primary payers, while the new system covers patients' net out-of-pocket reasonable costs. Thus, the new patient-oriented system will begin to coordinate medical-injury benefits with other payers, much as the latter already coordinate among themselves.

The function of coordination as proposed here is to maintain the efficiency of non-liability compensation while using the new patient-oriented system to fill in gaps and generate new patient-safety information. Over time, all payers of injury compensation will reap savings from the lower rates of injury that will follow from the new medical-injury system.

Fifth, the cost of the new compensation system will be directly influenced by various compensation rules and requirements, which Washington state can vary as needed to assure affordability. Some analysts have proposed requiring that medical injuries cause a minimum number of days of disability to qualify for compensation. Such a threshold would make the identification of injuries more reliable because small injuries can be hard to differentiate from effects of the underlying medical condition. A threshold also avoids the relatively high administrative costs of handling small amounts of compensation. In addition, losses such as household production might be compensated at standardized amounts, and wage losses might be compensated at 80 percent, as under disability insurance.

One study has applied defensible sets of such rules, using a preventability standard, to a representative set of medical injuries occurring in two states. The overall cost of such a system varied with the rules, but some sets of rules produced cost estimates in the same range as the then-current malpractice system in those states.

The precise cost of instituting a new compensation system in Washington state depends on many of its features yet to be completed in detail. The system's features can be designed to keep the system affordable, but outcomes cannot be fully predicted without more precise information. Feasibility studies and a pilot project are essential, and adjustments will likely be needed before the new system

Preventing Egregious Conduct

The patient safety and compensation system we envision properly focuses on the principal type of preventable medical injuries: those caused by errors originating from complex medical systems and the actions of well-meaning, competent personnel. The new system should promote continuing education for providers on patient safety, systems redesign to make it easy for caregivers to do the right thing, and remediation of problems rather than punishment of individuals—as the Joint Commission on Accreditation of Healthcare Organizations and others have recommended. It also will be well aligned with other aspects of the medical system that can promote safety, such as medical training, board certification, and development of professional standards.

However, even with such improvements, there will remain practitioners who are impaired or incompetent, who willfully do not or cannot comply with safety processes and rules, or who grossly violate professional norms and obligations. The new system is not intended to address such "bad apples." A separate system of effective oversight and medical discipline is needed to address this type of problem.

Medical discipline needs to be enhanced—through institutional peer review, state medical boards, some combination, or another alternative. Without improvements in discipline, opponents of compensation-safety reform will retain one of their best arguments for resisting improvements over medical liability. Opinion polling shows that the public recognizes medicine's current safety shortcomings, but thinks the appropriate response is tougher litigation and discipline of physicians and other medical providers.

Enhancement seems to call for stronger relationships between state medical licensure boards and other quality monitors, as well as with caregivers and safety analysts. These individuals have the best information about low performers, but are not motivated to speak up because they fear and resent what they see as the haphazard blame finding of today's disciplinary and liability processes.

Disciplinary authorities also need to recognize the new learning that simple errors are not blameworthy and are better prevented within a proactive framework of patient safety—and non-adversarial compensation for ACEs and other preventable injuries—than within the reactive and punitive environment of traditional discipline. The Federation of State Medical Boards has begun a task force charged with finding better ways to mesh discipline and safety.

Our proposal does not address medical discipline in the depth we feel necessary. However, we have deferred further work in this area pending recommendations from Governor Gregoire's initiative on medical discipline, an effort in which Forum members are closely engaged.

Next Steps

It will take time to create a patient-oriented system that promotes safety and injury compensation, while preventing injuries and minimizing disputes.

A reasonable goal is to complete the shift to a new system before the next liability insurance crisis hits Washington state.

The process needs to begin with agreement on the general policy vision by a broad spectrum of opinion leaders in Washington state. Then, a nonpartisan process needs to be implemented to consider and select among the many options for new systems design.

As noted earlier in this paper, whatever the process selected for making final design choices, the decision makers will need to address a number of key points. Development of ACE listings is a key component of a patient-oriented system. The process of listing ACEs needs to draw on medical and patient safety expertise, again from non-advocacy sources and always with an epidemiological orientation rather than an advocacy posture. Initially, academic physicians can usefully contribute, specialty by specialty, but the final list needs to merge all specialties into one outcomes-oriented list, whose application will not vary according to which specialty or caregiver might be involved.

Feasibility Study

Once the ACE listings are reasonably complete, they need to be evaluated through what may be thought of as a "virtual demonstration." This is a focused, retrospective analysis of the likely scope and potential costs of the new system.

This feasibility study needs to occur within a large, integrated health care entity or set of related entities. The cooperating entit(ies) need to:

- Be representative of the health system at large; and
- Have good data that can be mined to assess the likely incidence of ACEs and non-ACE preventable injuries.

The data might come from various sources—quality and utilization review, incident reporting, risk management and sentinel event monitoring, and closed liability claims files. Likely costs also need to be estimated for various conditions using proxies for the anticipated compensation rules of the new system.

During this period, others need to consider implementation processes.

Pilot Project

Because this proposed new system is a wholesale change in focus, we recommend testing and refining its elements with a pilot or demonstration project. A variety of health care provider organizations could participate in such a pilot, including hospitals, integrated delivery systems, academic medical centers, or multi-specialty group practices. A prescribed set of providers and their patients would have the option to opt-in to the system before any injury occurs. As a safety mechanism, injured parties would have access to some form of judicial review after they went through the steps outlined in this paper, so that patients would feel assured that they were treated fairly. Since the demonstration project would be voluntary, initial discomfort or distrust of the new system should be minimized. This approach is consistent with the 2003 Institute of Medicine (IOM) report, "*Fostering Rapid Advances in Healthcare*."

One issue is whether to phase in the new system in stages, possibly starting with inpatient care. Any partial implementation needs to cover all care for a given type of medical services or none to avoid boundary disputes. It may be that some aspects of the new system can be implemented piecemeal, but others will require entire replacement of existing rules and processes.

In moving toward a truly patient-oriented system, decision makers will need to resist the temptation to mix, match, and compromise with different elements of reform that might deliver the appearance but not reality of reform. The new system needs to be a mandatory and total replacement for at least large sectors of the medical liability system, and document that it performs better.

Design and Implementation Issues

The following are the next steps needed to move toward a patient-oriented medical-injury system:

- Develop preventability standards for medical injuries:
  - ACEs and the process for creating and approving them for use
  - Rules for case-by-case determinations for non-ACEs
- Create compensation standards; need to weigh tradeoffs, especially on future losses and non-monetary compensation
- Choose a mix of alternative dispute resolution mechanisms to be available; develop them for implementation
- Determine the desirability of new patient representatives and flesh out provisions
- Create incentives and mechanisms for productive use of new data to improve safety
- Participate in the development of Governor Gregoire's egregious conduct initiative
- Design new system funding flows, with attention to insurability and overall affordability
- Design and conduct a preliminary feasibility study, with retrospective review
- Conduct one or more opt-in pilot projects to test and refine system elements
- Consider other phasing and implementation issues

End Results of Reform

We are confident that over time a comprehensive overhaul of our medical liability system will greatly benefit all Washington residents as:

- Fewer preventable medical injuries will occur.
- Compensation will go to a greater share of patients with preventable injuries—faster, more consistently, and more cost-effectively.
- The system will be sustainable over time, and its costs will be more predictable.
- Accountability and perceptions of accountability for preventable medical injuries will be improved.
- Patients and providers will trust the system to produce good outcomes and to treat them respectfully and fairly.
- Discipline of bad or dangerous doctors is strengthened.

Creating a new system will not happen overnight, and implementation will call for good monitoring and some mid-course corrections. However, the changes proposed here will put Washington state on track toward a 21st century patient-oriented system to promote patient safety and medical injury compensation.

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