

**Oregon Health Policy Board  
Medical Liability Task Force**

**Wednesday, September 8, 2010  
1:00 - 4:00 pm**

**Wilsonville Training Center, Room 112  
29353 Town Center Loop East, Wilsonville, OR**

**DRAFT AGENDA**

Time	Item	Lead	Action Item
1:00 pm	Call to Order	J. Michael Alexander Joseph Siemenczuk Co-chairs	
1:00 pm	Review and Draft Summaries for July and August Meetings	Co-chairs	x
1:10 50 min	Presentation of Straw Recommendation on Health Courts Discussion	Lynn-Marie Crider  Co-chairs	x
2:00 60 min	Staff Presentations: ➤ Evidence-Based Guidelines in Oregon ➤ Evidence-Based Guidelines Safe Harbors Grant Discussion	Jeanene Smith Dave Pass  Lynn-Marie Crider  Co-chairs	
3:00 60 minutes	Conversation with Allen Kachalia ➤ Evidence-based guidelines safe harbors ➤ Disclosure and offer programs (esp. evidence of affect on liability costs and public policy supports) ➤ Health courts	Allen Kachalia, MD, JD, researcher, clinician,	
4:00	Adjourn	Co-chairs	x

**Exhibit Materials:**

01. Agenda
02. Meeting #2 Draft Summary (revised)
03. Meeting #3 Draft Summary
04. Draft recommendations on health courts
05. Background on the Health Resources Commission
06. Background on comparative effectiveness research, practice guidelines, the CEBP, the HRC, and the HSC
07. Summary of Evidence-Based Guideline Grant Project
08. Summary of safe harbor experiments
09. Bio for Allen Kachalia
10. Kachalia et al, "Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program," *Annals of Internal Medicine*, August 17, 2010.

**Medical Liability Task Force  
Meeting #2 Summary  
(as amended at 8/4/10 Meeting)**

Wednesday, July 7, 2010  
1:00-3:00 pm

Work Group Members in Attendance

Michael Alexander, Co-Chair  
Joseph Siemieniczuk, Co-Chair  
Rick Bennett  
Jeffrey Bildstein  
Janet Billups  
Jim Dameron  
Scott Gallant  
Robert Holland  
Jodie Mooney  
Laura Potter  
Christoffer Poulsen  
Mark Stevenson  
Lawrence Wobbrock

Work Group Members Absent

Craig Fausel  
Peter Bernardo

OHPR Staff in Attendance

Jeanene Smith  
Lynn-Marie Crider

OHFB Liaison Representative in Attendance

Chuck Hofmann

Meeting Summary (**actions in bold**)

*Review of meeting summary*

**The meeting summary was approved.**

Review of the meeting summary provoked discussion of whether or not task force members had reached agreement on language framing the issue they wish to address. It was agreed to include language addressing need for improving the medical liability system to better advance patient safety concerns, reduce expenses (including costs associated with defensive medicine and administrative cost), and more effectively compensate individuals who are injured as a result of medical error. Staff was asked to circulate proposed language capturing the agreement by e-mail after the meeting.

### ***Priorities for Task Force attention***

Co-chair Joe Siemienczuk recommended the task force address four issues and recognize that it is unlikely the task force will address the rest of a list of proposals that have been discussed in the past. (See the Discussion Draft marked #3 in the materials.) Priority topics would be:

- Disclosure and offer programs
- Health courts
- Evidence-based guideline safe harbors
- Extension of rural medical liability insurance subsidy program

Janet Billups said she didn't want to take anything off the table. She agreed with the co-chairs' proposed priorities but felt some of the other topics might appropriately come into the discussion as priority issues were discussed. No one objected to the priorities identified or to Ms. Billups' suggestion.

Addressing the questions to be addressed in considering the priority concepts, Jim Dameron noted that the group should ask whether the proposals are feasible now and whether they require legislative or constitutional change.

Laura Potter suggested that patient safety should be the #1 concern.

Joe Siemienczuk asked staff to revise the list and the questions consistent with the discussion.

Scott Gallant proposed that the task force not study extension of the rural medical liability insurance subsidy program since a legislative interim committee was studying it. Others agreed. Mr. Gallant suggested the task force could weigh in for continuing the program but shouldn't duplicate the interim committee's work. Rick Bennett suggested the task force should not comment without study. A decision was made to pull the extension of the rural medical liability program out of the list of priorities but separate it from the list of non-priority items, marking it "Reserve for possible study and comment."

### ***Disclosure and offer programs***

Jodie Mooney described the experience of PeaceHealth in the Eugene area with early disclosure and offer. The program was developed in the context of PeaceHealth's internal policy regarding transparency and Medicare, Joint Commission, and Oregon Patient Safety Commission reporting and disclosure requirements. PeaceHealth has developed a sentinel event policy as well as a preventable event policy that governs non-billing for services associated with sentinel events. If the investigation shows that negligence has occurred and a patient has been harmed as a result then PeaceHealth seeks to resolve the case even if no claim has been asserted or filed. A similar process occurs for adverse events resulting in harm that do not fall out as "sentinel events" per se.

She described an example:

- A patient had a procedure. The physician ordered a drug to be given post-procedure. It was not given. Harm resulted.
- PH investigated, discovered what happened, concluded that negligence occurred, and developed a plan to prevent similar events from happening in the future.

- PH told the patient.
- Jodie talked to the patient, suggesting that he might want to get a lawyer.
- She met with the patient and lawyer, explained what happened, and explained the policy changes PH had put in place to prevent recurrences. She offered to enter into a mediation process to reach an agreement for compensation.
- A settlement was reached in mediation—before any claim or suit was filed.

If there is a legitimate question about whether or not an error occurred or harm was caused, no offer of compensation is made. PeaceHealth uses the early offer and disclosure approach for cases involving sentinel events.

As a self-insured entity, PeaceHealth has encountered challenges using this approach when a sentinel event or other legitimate compensable event involves someone not employed by the facility, such as an independent physician.

There was discussion on the following issues:

- Will disclosure policies generate more claims?
- Will it save money?
- Is a disclosure policy limited to sentinel events really disclosing anything to patients that they don't know? Should facilities be encouraged to disclose incidents that patients may not be aware of, such as the fact that a proper reading of a film would have produced an earlier diagnosis of a life-threatening condition?
- Could disclosure and offer programs be strengthened by applying them to a broader set of adverse events?
- Could disclosure and offer programs be developed for ambulatory settings?
- How widespread is early disclosure in Oregon facilities?
- Could we assess compliance with the reporting requirements of the Oregon Patient Safety Commission—which apply only to serious events—by comparing the medical liability claim reports to the reports to the Patient Safety Commission?
- Are there particular types of claims that are most amenable to early resolution?
- Could disclosure be required?
- Can these programs be implemented where a professional or a facility is insured rather than self-insured? Do the cooperation clauses in insurance policies preclude physicians from disclosing errors to patients? Could insurers be forbidden to cancel a policy because a physician discloses an error?

The Task Force will discuss this issue further next meeting.

### ***Other***

Larry Wobbrock distributed a reading list. He would like it to be included in the record. [Staff note: The list is attached to this meeting summary.]

The meeting was adjourned at 3:05 pm.

The next committee meeting is scheduled for:

August 4, 2010 from 1-4 pm in Wilsonville. (NOTE: CHANGE IN MEETING TIME.)

**READING LIST**

**From Lawrence Wobbrock, Medical Liability Task Force Member**

“The Medical Malpractice Myth,” Ezra Klein, Slate, 7/11/06

<http://www.slate.com/id/2145400/>

“Critique of October 9, 2009, CBO Letter to Senator Hatch on Medical Malpractice Issues,” Center for Justice and Democracy

<http://www.centerjd.org/archives/issues-facts/CJDCBOCritiqueF3.pdf>

“CBO’s Analysis of the Effects of Proposals to Limit Costs Related to Medical Malpractice (“Tort Reform”),” Director’s Blog, Congressional Budget Office, 10/12/09

<http://cboblog.cbo.gov/?p=389>

“Liability = Responsibility,” Tom Baker, The New York Times, 7/11/09

<http://www.nytimes.com/2009/07/12/opinion/12baker.html>

“I’m a doctor. So sue me. No, really.” Rahul K. Parikh, M.D., Salon, 10/27/09

[http://www.salon.com/news/opinion/feature/2009/10/27/malpractice\\_reform](http://www.salon.com/news/opinion/feature/2009/10/27/malpractice_reform)

“Baby, I Lied. Rural Texas Is Still Waiting For The Doctors Tort Reform Was Supposed To Deliver,” Suzanne Batchelor, The Texas Observer, 10/19/07

<http://www.saynotocaps.org/newsarticles/baby%20i%20lied.htm>

“The Cost Conundrum. What a Texas Town Can Teach Us About Healthcare,” Atul Gawande, The New Yorker, 6/1/09

[http://www.newyorker.com/reporting/2009/06/01/090601fa\\_fact\\_gawande](http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande)

“Atul Gawande: The Cost Conundrum Redux,” Atul Gawande, The New Yorker, 6/23/09

<http://www.newyorker.com/online/blogs/newsdesk/2009/06/atul-gawande-the-cost-conundrum-redux.html>

Medical Malpractice and the American Jury: Confronting the Myths about Jury Incompetence, Deep Pockets, and Outrageous Damage Awards”. Neil Vidmar. 318 pp. Ann Arbor, University of Michigan Press, ISBN 0-472-10639-2.

The Medical Malpractice Myth. Tom Baker. 214 pp. Chicago, University of Chicago Press, 2005. ISBN 0-226-03648-0.

“Estimating a Bargaining Model with Asymmetric Information: Evidence from Medical Malpractice Disputes,” Holger Sieg, The Journal of Political Economy, Vol 108, No 5, 10/2000

<https://www.msu.edu/~conlinmi/teaching/EC860/signallingscreening/siegJPE2000.pdf>

“The Economic Consequences of Medical Injuries,” William Johnson, M.D., The Journal of the American Medical Association, Volume 267, 5/13/92

<http://jama.ama-assn.org/cgi/reprint/267/18/2487>

“The Influence of Standard of Care and Severity of Injury on the Resolution of Medical Malpractice Claims,” Taragin, MI. Ann International Medicine, 1992; 117; 780-4.

“Claims, Errors, and Compensation Payments in Medical Malpractice Litigation,” David M. Studdert. The New England Journal of Medicine. 354:19; 5/11/06.

<http://content.nejm.org/cgi/content/full/354/19/2024>

“Nadler: Malpractice Suits Are Not Frivolous”, Rep. Jerrold Nadler. Roll Call. 6/21/10.

[http://www.rollcall.com/features/Health-Care-Next-Steps\\_2010/health\\_care/47488-1.html](http://www.rollcall.com/features/Health-Care-Next-Steps_2010/health_care/47488-1.html)

**Medical Liability Task Force**  
**Meeting #3 Summary**  
Wednesday, August 4, 2010  
1:00-4:00 pm

Work Group Members in Attendance

Michael Alexander, Co-Chair  
Joseph Siemienczuk, Co-Chair  
Rick Bennett  
Jeffrey Bildstein  
Janet Billups  
Jim Dameron  
Scott Gallant  
Robert Holland  
Jodie Mooney  
Laura Potter  
Christoffer Poulsen  
Mark Stevenson  
Lawrence Wobbrock

Work Group Members Absent

Chuck Hoffman  
Craig Fausel

OHPR Staff in Attendance

Jeanene Smith  
Jeannette Nguyen-Johnson

Meeting Summary (actions in bold)

*Review of meeting summary*

**The meeting summary was approved with the provision that Jodie Mooney's suggestions will be incorporated.**

*Presentation of Straw Plan Discussion: Recommendations on Disclosure and Offer Programs*

Jeanene Smith discussed the straw recommendations on Disclosure and Offer Programs. The straw recommendations have been prepared by staff for the Task Force to react to.

Issues raised included the following:

- There is a tension between the fact that facilities voluntarily opt-in to the Patient Safety Commission's error reporting system and the fact that facilities that opt in do make a commitment to report. Facilities that have committed to report do so far less than 100% of the time.

- Mandatory disclosure could save litigation cost and get more people compensated.
- The Patient Safety Commission rules do not specify what the required written notification to the patient means. Enforcing the existing disclosure requirement wouldn't necessarily result in the type of full disclosure that really makes litigation less expensive.
- Reporting could be mandated but early offers cannot.
- The experience of the VA is that early offers save money for facilities.
- Disclosure and offer is more easily implemented in an integrated delivery system.
- The excess liability fund concept raises many issues including how it would be financed, the fate of injured patients if the fund is not adequately funded, the possibility that it undermines incentives for physicians, and the possibility that it just grows the dollars that can be accessed by plaintiffs.

After discussion, it was the sense of the group that the excess liability fund concept included in point 3 of the straw recommendation does not get to the goals of the committee for improving the liability system and should be eliminated from consideration.

There will be further discussion to shape a recommendation on this issue.

### ***Health Courts Presentation***

Ambia Harper, JD, of the organization Common Good made a presentation based on a slide deck included in the meeting materials. Common Good is a proponent of health courts.

Issues raised in questioning included the following:

- Will an administrative adjudication system increase reliability (that is, consistency) of liability determinations or compensation amounts?
- Will it reduce use of experts?
- Would it be perceived as fairer?
- Do we know what an administrative system with neutral experts would cost?
- Doesn't the health courts idea include a component of compensation caps?

Among the opinions expressed by the speaker were these:

- Patients should have a high level of access to whatever information a facility collects about adverse events.
- The standard used in Scandanavian health courts is preventability or avoidance with the use of best practices.
- The premise of the program is that if outcomes of litigation are more consistent then physicians will feel more comfortable making good clinical decisions—rather than practicing defensive medicine.
- Pilots could be done using a consent-based arbitration approach. A patient would sign an arbitration agreement when admitted to a hospital for care, for example. So, the health court would be exclusive for those patients. Patients should not be

- given a right to opt out after the injury. Birth injuries may be fertile ground for this approach.
- There is funding for a planning for a pilot in New York.

Task Force members debated the constitutionality of any system that included an element of fault.

Some felt that there is a need for a well-designed and evaluated pilot approach to determine whether more patients get compensation and physicians have more confidence in the system before going full bore. The design should allow patients to know what kind of system they are entering and what compensation may be obtained through it. Others felt a voluntary pilot could not be done.

Any recommendation should provide guidance for design of a program or pilot but acknowledge the barriers to design of a successful program or pilot.

The Task Force will discuss this issue further before any recommendation is agreed upon.

The meeting was adjourned at 4:05 pm.

The next committee meeting is scheduled for:  
September 8, 2010 from 1-4 in Wilsonville. (NOTE: CHANGE IN MEETING DATE.)

## Alternative Recommendations on Health Courts

Note: This document offers three alternative recommendations the Task Force might make to the Health Policy Board and the Legislature. Staff recommends adoption of Alternative #1 only.

### **Alternative #1 (staff recommended) – Rely on other states to pilot this concept**

**Health courts are an intriguing idea if they result in compensation of more individuals injured as a result of encounters with the health care system; promote patient safety by overcoming physician/facility reluctance to disclose medical errors and increasing participation in efforts to avoid future errors; and reduce collateral costs, including defensive medicine.**

**Oregon should keep a careful eye on pilots and other initiatives that emerge in other states but should not implement health courts—even on a pilot basis—until persuasive evidence demonstrates that a health court program would accomplish two or more of the Task Force’s three key objectives. When the evidence supports such a finding, serious consideration should be given to implementing health courts on a mandatory basis statewide.**

Rationale: An Oregon pilot is not feasible, and the health courts concept is not ready to go live on a statewide basis.

- It is not feasible to build the administrative apparatus that would support health courts that produce consistent decisions without more volume than Oregon could funnel into a voluntary pilot.
- It is not feasible to pilot mandatory health courts in Oregon because an exclusive administrative remedy for medical negligence is unlikely to survive a constitutional challenge unless the threshold for compensation is lowered significantly as part of a comprehensive remedial scheme.
- It is not feasible to pilot health courts in Oregon because a pilot will not achieve a measurable shift in physician culture and hence will not reduce defensive medicine or support increased openness of medical error reporting. The required cultural shift could result only from major, across-the-board changes in the liability system.

### **Alternative #2 – Do feasibility study of carve-out**

**Oregon should study the feasibility of creating a carve-out for no-fault compensation for birth injuries or other highly costly claims in which fault is often a difficult question to resolve. A carve-out could be modeled on the Virginia and Florida birth injury programs. Although Oregon’s volume may be too low to support a carve-out, it may be possible for Oregon to join another state’s system.**

Arguments for:

- A carve out would result in compensating more injured patients.
- Eliminating the negligence standard may improve patient safety by promoting more open discussion of how to prevent targeted serious injuries.
- By narrowing the issues in a claim to causation, rather than negligence, collateral costs of the liability system will be reduced.

Arguments against:

- A carve-out would be likely increase total compensation costs in the system by compensating more individuals.
- Oregon does not have enough volume to support a carve-out.

### **Alternative #3 – Develop pilot program**

**Oregon should develop a pilot program that allows patients to opt in to an alternative dispute resolution system that would involve the classic elements of health courts: specialized judges, access to neutral experts, written decisions, a schedule of benefits, exclusive remedy for patients who opt in [post-injury?] to the system after full disclosure of the differences between the standard litigation system and the pilot administrative system. Careful consideration should be given to whether or not to set a reduced threshold for compensation (e.g., an avoidability standard in lieu of a negligence standard).**

Arguments for:

- If Oregon ever wants to establish health courts, the value proposition needs to be demonstrated. A pilot is the way to do that.

Arguments against:

- A voluntary program will not demonstrate value because individuals with large, clear claims will opt for the traditional system.

## Tools for thinking through the health courts issue

### Key characteristics of health courts:

- specialized judges
- neutral experts
- written decisions
- schedule of benefits
- reduced threshold for compensation (e.g., no-fault or avoidability standard)
- exclusive remedy (variations below)
  - exclusive remedy for claims that are compensable under the standard (Va and Fla birth injury programs) OR
  - exclusive remedy for individuals entering into arbitration agreement when seeking care (NY pilot) OR
  - exclusive remedy for individuals opting in post-injury (Federal law concept)

### Key advantages from perspective of proponents:

- Consistency of results on liability (which, it is proposed will reduce defensive medicine)
- Efficiency - Quicker recoveries, lower litigation costs
- Fairer compensation – Increased numbers of individuals recover and greater consistency of amount of recovery
- Improve patient safety (as a result of broader reporting of errors due to reduced adversarial culture)
- Reduced malpractice premiums
- Greater physician accountability (as a result of feedback loop with the claims apparatus?)

### Key disadvantages from perspective of opponents:

- Compensation schedules are backdoor caps on recovery and may reduce recoveries for injured patients
- Health courts carry a danger of pro-physician bias
- To the extent health courts include procedural safeguards of courts, cost savings may not be as great as projected
- Because many medical errors are unique, the quest for consistency may be illusory
- Defensive medicine and reluctance to report are deeply entrenched and unlikely to change quickly due to changes in the legal apparatus for adjudicating claims

## FACT SHEET: Health Resources Commission

**Background:** In 1991 Senate Bill 1077: established the Health Resources Commission in order to develop a process for deciding on the allocation of medical technologies in Oregon. The Oregon Health Resources Commission was created in 1991 by statute section 2, chapter 470:

*"The Health Resources Commission shall develop a medical technology assessment program that addresses the introduction, diffusion and utilization of medical technologies and their associated services and shall make recommendations regarding the program's implementation."*

2001 Senate Bill 819 creates a Practitioner Managed Prescription Drug Plan requiring that it ensure:

*"Decisions concerning the clinical effectiveness of prescription drugs are made by licensed health practitioners, are informed by the latest peer-reviewed research and consider the health condition of a patient or characteristics of a patient..."*

The Health Resources Commission is charged with conducting these evaluations alongside the existing medical technology assessment program. The goals of the Commission are:

- Encourage the rational and appropriate allocation and use of medical technology in Oregon through its analysis and dissemination of information concerning the effectiveness of medical technologies and their impact on the health and health care of Oregonians.
- Assure Oregonians access to high quality, effective health care, whether that care is provided by the state or through the private sector.
- Work towards integration of evidence-based practices into the clinical setting.

**Composition:** The Commission is composed of 11 Governor-appointed members including four physicians, two pharmacists, a consumer representative and representatives of labor, hospitals, the insurance industry and business. The Commission has three subcommittees charged with evaluating evidence in their respective areas (Technology, Mental Health and Pharmaceutical).

**Process:** The Commission partners with OHSU's Center for Evidence-based Policy (CEbP) to review the medical literature to determine the effectiveness of certain groups of prescription drugs and to evaluate evidence for effectiveness of medical technologies. This is through

- The Drug Effectiveness Review Project (DERP) for a consortium of 14 states plus Canada
- The Medicaid Evidence-based Decision making project (MED project) for a consortium of 11 states,

Utilizing Oregon's membership in the CEbP's programs; exhaustive systematic literature reviews are conducted using Oregon's Evidence-based Practice Center (EPC) on topics of interest identified by the member states. These extensive reviews of the clinical literature are then used by the HRC's subcommittees consisting of local experts in evaluating evidence for evidence-based findings in a public process.

The Commission bases its findings and recommendations on the evidence from original research, meta-analyses, review articles, published clinical guidelines (if available), public input, information from the manufacturer, and any pertinent socioeconomic articles as well as on the collective clinical expertise and experience of panel members and their knowledge of current accepted medical practice in Oregon. The HRC also participates in special projects including participation in an international workgroup evaluating a group of medications referred to as “biologicals” which have significant potential impact to healthcare for Oregonians.

**Accomplishments:**

- 75 Pharmaceutical Classes reviewed with ongoing annual review and update as warranted
- Wide range of Technology topics reviewed including:
  - Reduced Intensity Stem Cell Transplantation
  - Negative Pressure Wound Therapy
  - Vagal Nerve Stimulation for Treatment of Depression
  - Evidence for the Effectiveness of Treatments for Autism Spectrum Disorders
  - Bariatric Surgery for Morbid Obesity
  - Stereotactic Surgery
  - Anterior Cruciate Ligament Surgery
  - Interleukin 2
  - Ventricular Assist Device
  - Spinal Fusion
  - Laser Photoreactive Surgery
  - Pallidotomy and Deep Brain Stimulation for Parkinson's Disease
- Reorganization to improve workflow in order to meet the increasing demand for reviews
- Improved coordination with stakeholders to allow for optimal scheduling of topic coverage
- Incorporation of HRC conclusions and recommendations has resulted in savings of millions of dollars while assuring effective healthcare for Oregonians.

**Outreach:** The reports generated by the Health Resources Commission are made available to policymakers; both public and private, practitioners, and the public through various channels. The Commission maintains a website which contains all of the current reports completed at:

[http://www.oregon.gov/OHPPR/HRC/Evidence\\_Based\\_Reports.shtml](http://www.oregon.gov/OHPPR/HRC/Evidence_Based_Reports.shtml)

**Contact:**

David Pass M.D., HRC Director

Phone: 503-373-1985

E-mail: [HRC.info@state.or.us](mailto:HRC.info@state.or.us)

## Health Resources Commission-Function

“The Health Resources Commission shall develop a medical technology assessment program...”

1991 Statute Section 2, Chapter 470

## Health Resources Commission- Composition

- 4 physicians, 1 in family practice
- 1 representative of hospitals
- 1 insurance company representative
- 1 business representative
- 1 representative of labor organizations
- 1 consumer representative
- 2 pharmacists, 1 in retail pharmacy

## Health Resources Commission- Process

- Evaluates topics of interest to the OHA
- In partnership with the Center for Evidence-based Policy at OHSU the HRC performs high quality evidence evaluations utilizing the most current accepted methodological standards and affords opportunity for public input at several steps in the process.

3

## HRC Process- CEBP

- Full systematic literature search
- Studies meeting inclusion criteria undergo quality assessment using standardized methods.
- If inadequate evidence then “Best Practices” approach
- Draft report prepared and made available for public and professional (technical advisory committee) comment
- Final Draft academic evidence report completed.
- Report to HRC

4

## HRC Process- Subcommittee

- Draft HRC subcommittee report prepared from CEbP report extracting academic findings in clinical context.
- HRC subcommittee evaluates reports (CEbP and HRC draft) and forms conclusions based on the information in the report.
- Public input
- Final subcommittee Draft prepared
- Subcommittee draft to HRC for final evaluation

## HRC Process- Commission

- Commission reviews subcommittee report
- Opportunity for public input
- Commission discussion
- Commission recommendation to accept/modify or return report to subcommittee for further work.

## HRC- selected topics completed

- Reduced Intensity Stem Cell Transplants
- Negative Pressure Wound Therapy
- Vagus Nerve Stimulation Therapy for Depression
- Bariatric Medicine
- Bariatric Surgery (used by HSC to develop guideline for Medicaid/Prioritized List)

## HRC Output-for more information

- HRC reports are publicly available on our website:  
[http://www.oregon.gov/OHPPR/HRC/EvidenceBased Reports.shtml](http://www.oregon.gov/OHPPR/HRC/EvidenceBasedReports.shtml)
- Information is available throughout the OHA for use as the evidence base in their decision making processes

## Oregon's Medical Liability and Patient Safety Planning Grant Project

Objective: To craft a broadly supported legislative proposal that establishes a method for adopting evidence-based clinical practice guidelines for addressing recurrent clinical situations out of which significant numbers of patient injuries and/or medical liability claims arise and links the legal standard of care to compliance with the guidelines.

The change should:

- Provide physicians with greater clarity about the standard of care expected of them and assure them that if they adhere to the guidelines, they will not be found liable for harm resulting from failure to do something that is inconsistent with the guidelines.
- Provide patients with greater protection from substandard care.
- Reduce medical liability claims.

Planning Period: September 2010 to September 2011 (for the 2013 Legislative Session)

Funding: Agency for Healthcare Research & Quality, US Department of Health & Human Services

Activities:

1<sup>st</sup>. Identification of recurrent issues in medical errors and/or claims.

OHPR and the Patient Safety Commission will identify medical errors (or alleged medical errors) that occur frequently or result in high liability costs, using databases secured from the Patient Safety Commission, the Oregon Medical Board, the National Practitioner Data Bank, and Oregon medical liability insurance carriers.

2<sup>nd</sup>. Analysis of the root causes of claims arising from these recurrent issues.

The Patient Safety Commission will examine closed claims records for claims involving the recurrent issues to (a) determine the root causes of injuries and (b) assess (to the degree possible) whether injuries might have been prevented by adherence to practice guidelines describing the appropriate clinical decision or processes of care.

3<sup>rd</sup>. Narrow the clinical issues with potential value for the guidelines project.

OHPR and the Patient Safety Commission, in consultation with others, will study the results of the data review and root cause analysis to narrow the clinical issues where improvement in outcomes might result from adherence to practice guidelines.

4<sup>th</sup>. Examination of the evidence.

The CEBP will examine the peer-reviewed literature and well-regarded practice guidelines to determine whether there is sufficient evidence to support guidelines addressing the issues identified by OHPR and the Patient Safety Commission.

5<sup>th</sup>. Collaborative process for liability reform design.

OHPR will convene a broad-based group of consumers, patient advocates, medical professionals, and legal professionals to:

- Examine the results of the research to determine whether guidelines might be useful in avoiding patient injury.
- Examine the historical precedents for safe harbor legislation for lessons learned.
- Review and seek consensus on design issues involved in developing a legislative concept including:
  - How will guidelines be used—as a shield, a sword, or both? Put another way, do the guidelines supplant the traditional community standard of care or are they simply a defense to a claim based on deviation from the traditional standard of care?
  - How and by whom should guidelines be selected for special status in the medical liability system? Based on what criteria?
  - How can it be assured that the guidelines will remain up to date and not hold up desirable innovation?
  - Should the concept be piloted in particular communities or should the experiment be undertaken statewide with respect to particular issues?
  - How would success be measured? Is there publicly reported data available on the measures of success? If not, how will data be obtained?

5<sup>th</sup>. Design an evaluation plan

OHPR will develop an evaluation plan to measure the success of the proposed modification of the standard of care, which may include a recommendation to collect additional data.

6<sup>th</sup>. Implementation

If a concept is developed and it has broad-based support, the process of developing guidelines would probably begin and might well be completed by the time the Legislature considers a bill to implement the program.

## Practice Guidelines in State Medical Liability Law

---

The states of Florida, Maine, Minnesota, and Vermont each at one time sought to give state-endorsed clinical practice guidelines a special position in the medical liability system, creating “safe harbors” for physicians.

### **Florida**

*Health Insurance Reform Act* — Fla. Stat. sec 408.02 (1992)

Effective dates: October 1, 1994 – October 1, 1998

Lead Agency: Florida Agency for Health Care Administration

**Project Description:** The law established a demonstration project. Physician participation was voluntary. A participating physician was able to use evidence of compliance with state-endorsed practice guidelines to establish an affirmative defense to a liability claim. The issues to be addressed by guidelines were to be selected based on data reported by hospitals. They were to include diagnostic-imaging centers, radiation therapy services, clinical laboratory services, physical therapy services, comprehensive rehabilitative services, and mammography services. One of the guidelines addressed use of cesarean procedures. Twenty percent of eligible physicians participated in the pilot.

**Statutory Language:** “A participating physician who is named as a defendant in a cause of action accruing on or after October 1, 1994, but before October 1, 1998, may introduce evidence of compliance with the practice parameters as an affirmative defense to a liability claim.” Fla. Stat. Ann. § 408.02(9)(e) (1998).

**Evaluation:** Current AHCR staff could not provide any information regarding how the demonstration project was evaluated but recalled that the project did not accomplish what had been hoped. The project was phased out “as the need to keep practice guidelines up-to-date became clearer” and national clinical-specialty organizations developed guidelines that “held precedent.”

### **Maine**

*Medical Liability Demonstration Project* — Me. Rev. Stat. Ann. tit. 24 § 2971-2978 (1989)

Effective: January 1, 1992 – December 31, 1999

Lead Agencies: Maine’s Bureau of Insurance and the Bureau of Licensure in Medicine

**Project Description:** The law created a demonstration project. Physician participation was voluntary. The project originally applied to three specialties: Anesthesia, Emergency Medicine, and Obstetrics/Gynecology, and was later amended to include Radiology. Four medical specialty advisory committees were appointed to develop guidelines and risk management protocols in each of the four specialty areas. Each advisory committee was asked to “establish standards of practice designed to avoid malpractice claims and increase the defensibility of the malpractice claims that are pursued” A total of 20 guidelines were adopted. Participating physicians were allowed to use adherence to applicable guidelines as an affirmative defense in medical malpractice trials and pretrial proceedings. The majority of eligible physicians participated.

Statutory Language: “In any claim for professional negligence against a physician or the employer of a physician participating in the project established by this subchapter in which a violation of a standard of care is alleged, only the physician or the physician’s employer may introduce into evidence, as an affirmative defense, the existence of the practice parameters and risk management protocols developed and adopted pursuant to section 2973 for that medical specialty area.” Me. Rev. Stat. Ann. tit. 24 § 2975(1) (1989)

Evaluation: The concluding evaluation was conducted by the firm of Milliman & Robertson. They analyzed Maine Bureau of Insurance databases of closed claims for five years prior to the demonstration project and five years during the demonstration project. They concluded that the demonstration project did not appear to have impacted Maine’s claim or claim settlement costs. They noted that “only one claim in the database utilized adherence to the clinical guidelines as an affirmative defense (...in this particular case the plaintiff was able to prove through expert testimony that the physician did not adhere to the guidelines).”

### **Minnesota**

*Health Care Cost Containment Law* — Minn. Stat. Ann. § 62J (1992)

Effective Dates: August 1, 1993, or 90 days after the date the commissioner approves the applicable practice parameter, whichever is later.

Lead Agency: Commissioner of Health

Project Description: The law established a Practice Parameter Advisory Committee to advise to advise the commission on adopting guidelines. The law also established a Health Care Analysis Unit to “develop, adopt, revise and disseminate” guidelines. Practice guidelines approved by the health commissioner were an absolute defense for providers facing allegations that they did not comply with accepted practice standards.

Statutory Language: “(a) In an action against a provider for malpractice, error, mistake, or failure to cure, whether based in contract or tort, adherence to a practice parameter approved by the commissioner of health under subdivision 2 is an absolute defense against an allegation that the provider did not comply with accepted standards of practice in the community. (b) Evidence of a departure from a practice parameter is admissible only on the issue of whether the provider is entitled to an absolute defense under paragraph (a).” Minn. Stat. § 62J.34[3] (1992)

Evaluation: Legislation was repealed in 1995.

### **Vermont**

*Vermont Health Care Reform Law* — Vt. Acts 160 [adjourned session], § 46 (1991)

Effective Dates: [Research continues.]

Lead Agency: [Research continues.]

Project Description: The law established a framework for achieving universal access. The provisions related to implementations of guidelines were tied to the passage of a universal access law, which had not passed as of 1996. One provision would have permitted the use of practice guidelines as evidence to determine whether the standard of care had been met.

Statutory Language: [Research continues.]

Evaluation: [Research continues.]

## REFERENCES

Hyams, Andrew L., Shapiro, David W., and Troyen A. Brennan, Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective, *Journal of Health Politics, Policy and Law*, Vol. 21, No. 2, Summer 1996.

LeCraw, Linda L., "Use of Clinical Practice Guidelines in Medical Malpractice Litigation." *Journal of Oncology Practice*, Vol. 3, No. 5, 2007.

Matthews, J. Rosser, Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish, *Journal of Health Politics, Policy and Law*, Vol. 24, No. 2, April 1999. Copyright © 1999 by Duke University Press.

United States General Accounting Office, *Medical Malpractice: Maine's Use of Practice Guidelines to Reduce Costs*, October 1993.

Milliman & Robertson, Inc., *Evaluation of Medical Malpractice Tort Reform*, Maine Bureau of Insurance, October 2000.

Conversations with state staff in Florida.

State statutes.

Allen Kachalia is an academic hospitalist in the Department of Medicine at Brigham and Women's Hospital in Boston, Massachusetts. He obtained his law degree from the University of Pennsylvania and medical degree from Washington University in St. Louis. He completed his residency and a year as chief resident in internal medicine at the University of Michigan.

He is currently clinically active, regularly teaching and attending on the hospital wards with medical students and residents. His academic and administrative activities focus on improving the quality and safety of patient care in the hospital and outpatient settings. He is currently the Medical Director for Quality and Safety for Brigham & Women's Hospital. His research pursuits include improvement of quality and safety in health care and legal issues in medicine, such as malpractice system reform and disclosure. He also holds an appointment at the Harvard School of Public Health where he teaches a course on the Law and Clinical Medicine.

# Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program

Allen Kachalia, MD, JD; Samuel R. Kaufman, MA; Richard Boothman, JD; Susan Anderson, MBA, MSN; Kathleen Welch, MS, MPH; Sanjay Saint, MD, MPH; and Mary A.M. Rogers, PhD

**Background:** Since 2001, the University of Michigan Health System (UMHS) has fully disclosed and offered compensation to patients for medical errors.

**Objective:** To compare liability claims and costs before and after implementation of the UMHS disclosure-with-offer program.

**Design:** Retrospective before–after analysis from 1995 to 2007.

**Setting:** Public academic medical center and health system.

**Patients:** Inpatients and outpatients involved in claims made to UMHS.

**Measurements:** Number of new claims for compensation, number of claims compensated, time to claim resolution, and claims-related costs.

**Results:** After full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100 000 patient encounters (rate ratio [RR], 0.64 [95% CI, 0.44 to 0.95]). The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100 000 patient encounters

(RR, 0.35 [CI, 0.22 to 0.58]). Median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Average monthly cost rates decreased for total liability (RR, 0.41 [CI, 0.26 to 0.66]), patient compensation (RR, 0.41 [CI, 0.26 to 0.67]), and non–compensation-related legal costs (RR, 0.39 [CI, 0.22 to 0.67]).

**Limitations:** The study design cannot establish causality. Malpractice claims generally declined in Michigan during the latter part of the study period. The findings might not apply to other health systems, given that UMHS has a closed staff model covered by a captive insurance company and often assumes legal responsibility.

**Conclusion:** The UMHS implemented a program of full disclosure of medical errors with offers of compensation without increasing its total claims and liability costs.

**Primary Funding Source:** Blue Cross Blue Shield of Michigan Foundation.

*Ann Intern Med.* 2010;153:213-221.

For author affiliations, see end of text.

[www.annals.org](http://www.annals.org)

Ethical obligations and patient safety principles support prompt disclosure of harmful medical errors (1–4). Disclosure can strengthen trust in the patient–physician relationship and is widely acknowledged as the “right thing” for hospitals and physicians to do (5–8). However, fears that disclosure will invite new claims or complicate subsequent litigation can inhibit the impulse to disclose (9–11). In practice, disclosure may not occur as frequently as we might hope (10–15).

Whether more disclosure will increase or decrease liability remains unclear. Some physicians and risk managers worry that admitting a medical error may amount to handing over a “blank check” and invite lawsuits and disputes about compensation amounts (16). Others counter that prompt disclosure may actually reduce liability because patients primarily seek the facts, a sincere apology, a commitment to prevent the error from recurring, and fair compensation (17, 18). The debate continues amid a lack of widely generalizable data on disclosure’s effect on liability (19, 20).

In 2001, the University of Michigan Health System (UMHS) launched a comprehensive claims management model with disclosure as its centerpiece (17). Emphasizing transparent communication, the UMHS program has received national attention for its process of disclosure with offer of compensation for harmful medical errors (1, 8). To better understand the relationship between disclosure and malpractice liability, we evaluated the effect of the UMHS

program on liability-related performance (**Appendix**, available at [www.annals.org](http://www.annals.org)).

## METHODS

### The Claims Model

The current UMHS claims management program has been described in detail (17). In brief, before 2001, UMHS pursued a traditional approach to risk and claims management. Once received, claims for compensation were typically assigned to a defense counsel. A claims management committee would ultimately review all claims and advise on settling or going to trial.

In July 2001, UMHS began responding to all open and new malpractice claims by admitting fault and offering

See also:

#### Print

Editors’ Notes . . . . . 214  
 Editorial comment . . . . . 266  
 Summary for Patients . . . . . I-28

#### Web-Only

Appendix  
 Appendix Figure  
 Conversion of graphics into slides

**Context**

The University of Michigan Health System performs active surveillance for medical errors, fully discloses found errors to patients, and offers compensation when it is at fault.

**Contribution**

This analysis found a decrease in new legal claims, number of lawsuits per month, time to claim resolution, and costs after implementation of the program of disclosure with offer of compensation.

**Caution**

Similar findings were reported in Michigan generally through the latter part of the study period.

**Implication**

A disclosure-with-offer approach to medical errors did not increase legal claims and costs at a large U.S. health system during the past 10 years.

—The Editors

compensation when an internal investigation reveals medical error. If an investigation reveals no error, UMHS provides the reasons for its conclusion and vigorously defends a claim, if necessary. In April 2002, UMHS began linking the investigation process with peer review and quality improvement efforts.

By February 2003, the disclosure program was fully integrated with patient safety efforts. The program now identifies patient injuries through various means, including reporting by employees, patients or family members, or patients' attorneys. It uses experienced risk managers with clinical backgrounds to lead investigations and mediate patient concerns as facts are collected, care quality is evaluated, and conclusions are disclosed. The UMHS emphasizes honesty and transparency with patients and staff, regardless of whether events resulted from error, and encourages staff to enlist risk management in the disclosure process.

Settlements, if made, generally occur in the institution's name, in line with common practice at many institutions with closed medical staffs (Appendix). Consequently, reporting of individual caregivers in medical malpractice claims in the National Practitioner Data Bank is rare. However, full claims histories are maintained and reported for each involved caregiver, as required.

**Design**

We used a before–after approach to evaluate the UMHS program. The study period included claims reported to risk management from 1 July 1995 to 30 September 2007, with 1 July 2001 as the date of initial implementation of the disclosure program and 1 February 2003 as the date of full implementation. We categorized claims on the basis of their date of reporting. The institu-

tional review board from the University of Michigan approved the study protocol.

**Data Sources and Measures**

We linked 2 data sets, the UMHS risk management database (which contains claims-related performance data, such as injury and disposition dates, disposition status, and liability costs) and the Clinical Information & Decision Support Services database, to assess 4 primary study measures: number of new claims, number of claims receiving compensation, time to claim resolution, and claims-related costs.

We defined a claim as any request for compensation for an unanticipated medical outcome whether initiated by the patient (or a family member or attorney) or by disclosure. We were unable to categorize the source of the claim (patient- or family-initiated vs. UMHS-initiated) because UMHS opted not to distinguish between the sources upon initiation of its program. We attempted to determine the number of lawsuits that had resulted from disclosure but could not reliably do so. Claims counts are by occurrence regardless of the number of caregivers named. We excluded service recovery claims (those brought by patients without an attorney and compensated for less than \$5000) because payments for those claims primarily serve to restore patient relations rather than redress a harmful error. We also excluded off-site claims (those involving a UMHS physician at a non-UMHS facility) because off-site locations frequently lacked a formal disclosure program.

We calculated the monthly rate of new claims by using the number of claims in a month (based on report date) for the numerator and the number of patient encounters in that month as the denominator. Patient encounters were defined as the sum of hospital discharges and outpatient visits for that month.

We defined total liability costs as the sum of all patient compensation and legal costs incurred by UMHS. Patient compensation costs included amounts paid to the patients (or families) and lien holders. Total legal costs were primarily defense attorney and expert fees but also included lawsuit-associated items, such as filing fees. Because costs are presented here as a portion of clinical operating revenue, we adjusted them to 2007 U.S. dollars by using the cost of medical care from the U.S. Bureau of Labor Statistics. We calculated the monthly liability cost rate by using total costs (by claim report date) in a given month as the numerator and total operating revenue in that month as the denominator.

**Statistical Analysis**

To evaluate differences in the rate of claims in the periods before and after disclosure, we used negative binomial generalized linear models (GLMs) with a log link. Rate ratios (RRs) were calculated by comparing the rate of claims before implementation of the disclosure program with that after full implementation. For the main analyses, only those claims that were reported and closed before the

initial implementation of the policy (1 July 2001) were included in the period before the program (reference group). We included claims that were reported after the full implementation of the policy (1 February 2003) in the period after disclosure. We used a locally weighted, scatterplot smoother (lowess) to display trends over time. Piecewise regression with linear splines was used to assess the difference in trends before and after initial implementation of the disclosure program (1 July 2001).

We conducted survival analyses to assess the time to claim resolution. Kaplan–Meier estimators of the survivorship function were plotted for claims reported before the initial implementation of the disclosure program (1 July 2001) and those reported afterward. A Cox proportional hazards regression model was used to calculate hazard ratios for the difference in resolution rates after versus before (reference group) implementation of the program; visual inspection of the survival curves suggested no violation of the proportional hazards assumption. We adjusted for patient age, sex, inpatient status, and whether the claim went to trial.

To assess the differences in costs of the program before and after disclosure, we used GLM with a gamma distribution and log link. At the time of analysis, 36 claims that had been filed during the study period remained open (that is, cases that had not been closed as of 31 March 2008); we included the costs for these open claims in the statistical analyses, as incurred as of 31 March 2008.

Two sensitivity analyses were conducted for the cost data. The first excluded outliers in the GLM. Outliers were determined by calculating costs that exceeded the product of 1.5 and the limits of the interquartile range (IQR). The second sensitivity analysis used the date of the initial implementation of the disclosure program (1 July 2001) as the cut point for the before-versus-after comparison. In addition, we included all claims on the basis of the date of the reported claim, regardless of disposition status.

All analyses were 2-tailed, with an  $\alpha$  level of 0.05. We performed analyses in Stata SE, version 10.0 (StataCorp, College Station, Texas).

### Role of the Funding Source

Blue Cross Blue Shield of Michigan Foundation funded this study. The funding source had no role in the

design, conduct, analysis, or decision to submit this manuscript for publication.

## RESULTS

### Total Claims

The UMHS risk management claims database contained 1131 claims for the study period after excluding service recovery ( $n = 33$ ) and off-site cases ( $n = 145$ ). Mean patient age was 40.4 years (SD, 20.7) at the time of injury; 87% of patients were white, 52% were women, and 55% were inpatients.

Of the 1131 total claims, 633 were asserted before and 498 after implementation of the disclosure-with-offer program. Of the claims made before implementation, 632 were closed as of 31 March 2008 and 319 (50.5% [95% CI, 46.5% to 54.4%]) were compensated, compared with 463 closed and 198 (42.8% [CI, 38.2% to 47.4%]) compensated after program implementation ( $P = 0.012$ ). This averaged 53.2 paid claims per year before and 31.7 after the program began.

### Claims Rates

The monthly rate of new claims decreased from 7.03 (CI, 5.98 to 8.08) per 100 000 patient encounters before initial program implementation to 4.52 (CI, 3.96 to 5.08) after full implementation (RR, 0.64 [CI, 0.44 to 0.95]) (Table 1). The trend in monthly rate was stable before ( $-0.002$  [CI,  $-0.050$  to  $0.046$ ];  $P = 0.935$ ) but decreased after the program was initially implemented in July 2001 ( $-0.061$  [CI,  $-0.082$  to  $-0.040$ ];  $P < 0.001$ ), which was a statistically significant before–after difference ( $-0.059$  [CI,  $-0.110$  to  $-0.008$ ];  $P = 0.023$ ) (Figure 1).

Changes in rates of claims before and after program implementation were statistically significant only for claims that resulted in a lawsuit. The UMHS experienced 232 lawsuits (38.7 per year) before and 106 (17.0 per year) after program implementation. A decrease was still evident, assuming all cases that were open at the end of the observation period (1 before and 35 after implementation) resulted in lawsuits, with 233 lawsuits (38.8 per year) before and 141 lawsuits (22.6 per year) after program implementation. Monthly lawsuit rates decreased from 2.13 (CI, 1.58 to 2.67) per 100 000 patient encounters before initial

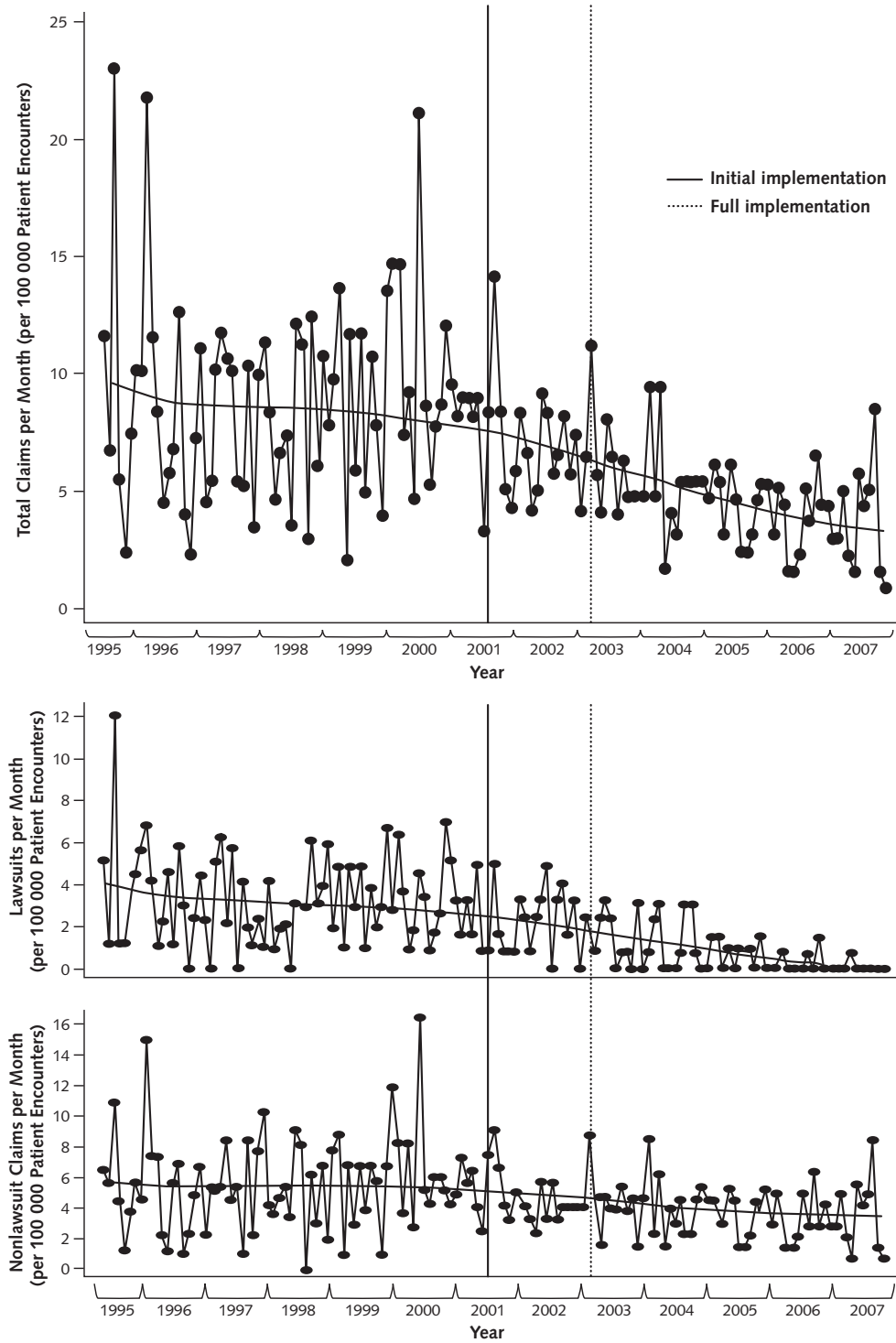
**Table 1. Monthly Rates and Incidence Rate Ratios of New Claims Before and After Full Implementation of the University of Michigan Health System Disclosure-With-Offer Program**

Variable	Mean Monthly Rate (95% CI)*		Rate Ratio (95% CI)†	P Value
	Before	After		
Total claims	7.03 (5.98–8.08)	4.52 (3.96–5.08)	0.64 (0.44–0.95)	0.025
Lawsuits	2.13 (1.58–2.67)	0.75 (0.47–1.03)	0.35 (0.22–0.58)	<0.001
All other claims	4.90 (4.17–5.63)	3.77 (3.27–4.26)	0.77 (0.52–1.14)	0.191

\* Number of claims in 1 mo per 100 000 patient encounters.

† Rate after full implementation compared with rate before program began (reference group).

Figure 1. Monthly rates of new claims before and after implementation of the University of Michigan Health System disclosure-with-offer program.



implementation to 0.75 (CI, 0.47 to 1.03) per 100 000 patient encounters after full implementation (RR, 0.35 [CI, 0.22 to 0.58]) (Table 1). The trend in monthly rates of lawsuits before and after initial implementation of the program demonstrated a significant change (difference in trend, -0.028 [CI, -0.054 to -0.001];  $P = 0.04$ ) (Figure 1).

In contrast, there was no change in the rate of claims that did not result in a lawsuit after the program was fully implemented (RR, 0.77 [CI, 0.52 to 1.14]) (Table 1), with no significant change in trend after initial implementation (difference in trend, -0.031 [CI, -0.070 to 0.007];  $P = 0.108$ ).

Our primary analyses counted only claims reported and closed before initial program implementation as “before” claims, but findings were similar when we compared rates of all claims reported before and after initial program implementation, independent of time of disposition (RR for all claims, 0.59 [CI, 0.41 to 0.83]; RR for claims resulting in lawsuits, 0.34 [CI, 0.23 to 0.51]; and RR for claims not resulting in lawsuits, 0.73 [CI, 0.51 to 1.04]).

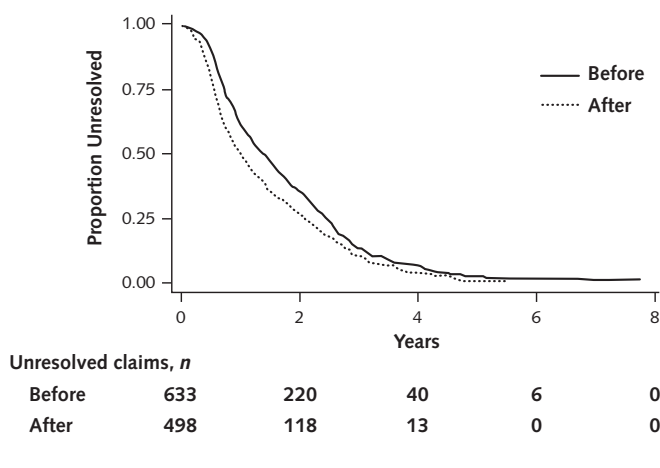
### Time to Resolution

Median time to claim resolution was 1.36 years (IQR, 0.72 to 2.44 years) before initial implementation and 0.95 year (IQR, 0.55 to 1.96 years) after initial program implementation (Figure 2); the rate of resolution increased after program implementation with an adjusted hazard ratio of 1.27 (CI, 1.11 to 1.45;  $P < 0.001$ ). No effect modification by site (inpatient vs. outpatient) occurred.

### Liability Costs

Median and mean total liability costs decreased after full program implementation (RR for mean costs, 0.41 [CI, 0.26 to 0.66];  $P < 0.001$ ), attributable to decreases in both legal and patient compensation costs (Table 2). After initial program implementation, total cost rates significantly decreased (difference in trend, -0.449 [CI, -0.806 to -0.092];  $P = 0.014$ ) as did legal (difference in trend, -0.066 [CI, -0.111 to -0.022];  $P = 0.004$ ) and patient compensation (difference in trend, -0.383 [CI, -0.715 to

**Figure 2. Time to claim resolution before and after implementation of the University of Michigan Health System disclosure-with-offer program.**



-0.050];  $P = 0.024$ ) costs (Figure 3). Although the total costs associated with lawsuits decreased after full implementation (RR, 0.27 [CI, 0.13 to 0.54]), the total costs for nonlawsuit claims did not (RR, 0.81 [CI, 0.47 to 1.38]) (Table 2).

In a sensitivity analysis excluding outliers, results were qualitatively similar for claims overall (RR, 0.66 [CI, 0.44 to 0.98]), type of claim (RR for lawsuits, 0.35 [CI, 0.21 to 0.58]; RR for nonlawsuits, 0.77 [CI, 0.52 to 1.14]), and type of costs (RR for legal costs, 0.43 [CI, 0.26 to 0.70]; RR for patient compensation, 0.45 [CI, 0.31 to 0.67]). We also found similar results in a sensitivity analysis by using the date of initial rather than full program implementation as the before-after marker (data not shown).

The average cost per lawsuit significantly decreased from \$405 921 before to \$228 308 after initial program implementation (RR, 0.40 [CI, 0.24 to 0.68];  $P = 0.001$ ). Costs did not change for nonlawsuits (RR, 1.27 [CI, 0.73 to 2.23];  $P = 0.397$ ). This pattern was similar when time

**Table 2. Monthly Rates of Liability Costs Before and After Full Implementation of the University of Michigan Health System Disclosure-With-Offer Program**

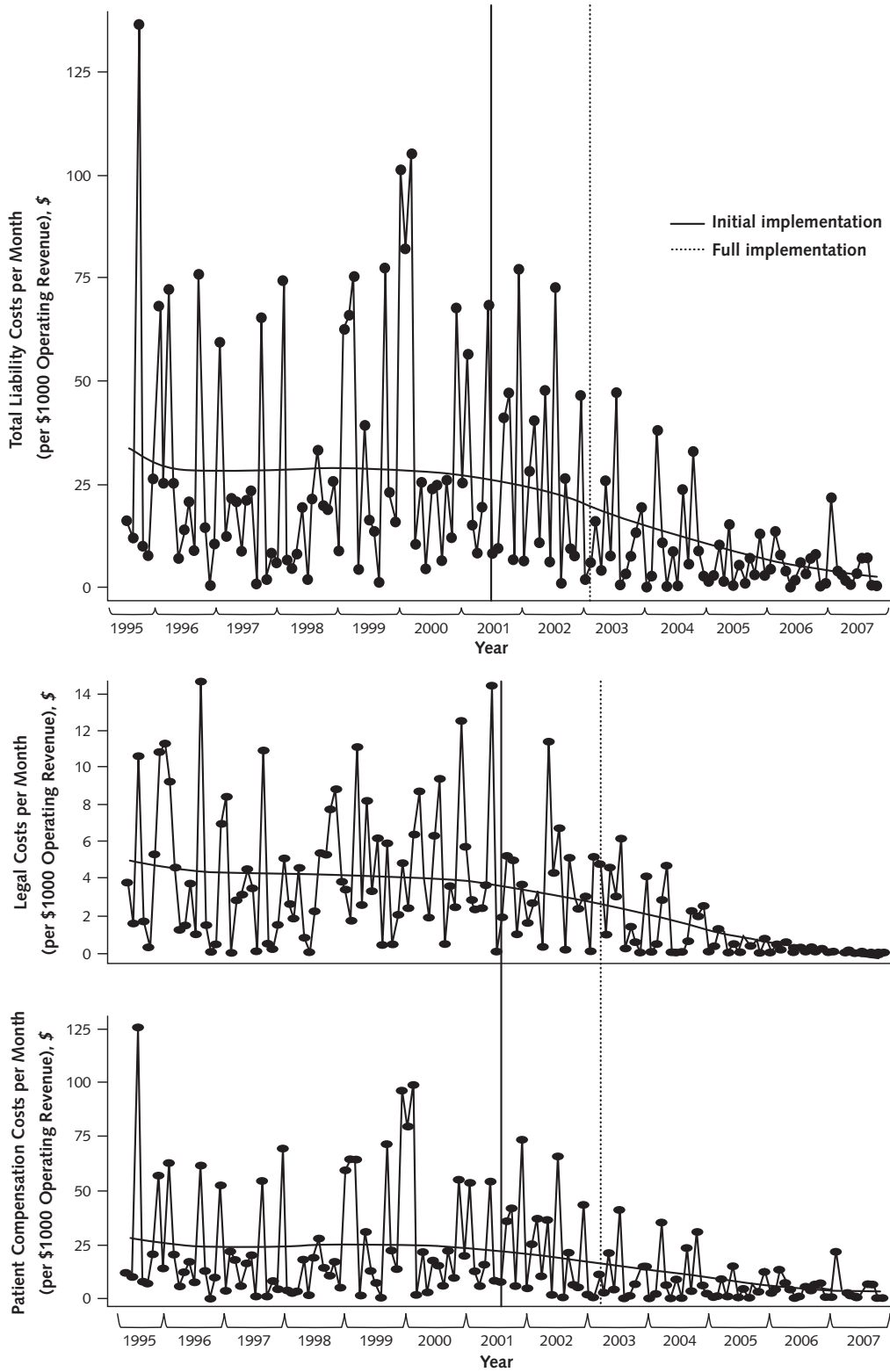
Category	Median Cost Rate (IQR)*		Mean Cost Rate (95% CI)*		Rate Ratio (95% CI)†
	Before	After	Before	After	
All liability costs	8.48 (3.24–21.48)	4.00 (1.16–9.31)	18.91 (12.61–25.21)	7.78 (5.14–10.42)	0.41 (0.26–0.66)
Type of claim					
Lawsuit	4.06 (0.02–13.95)	0 (0–3.65)	13.85 (8.26–19.43)	3.71 (1.46–5.95)	0.27 (0.13–0.54)
Nonlawsuit	1.02 (0.13–5.95)	2.45 (0.29–5.61)	5.06 (3.07–7.04)	4.07 (2.55–5.60)	0.81 (0.47–1.38)
Type of costs					
Patient compensation	7.88 (2.11–19.09)	3.56 (1.07–8.00)	16.64 (10.90–22.38)	6.90 (4.51–9.30)	0.41 (0.26–0.67)
Legal	0.95 (0.18–2.87)	0.19 (0.01–0.89)	2.26 (1.46–3.06)	0.88 (0.48–1.27)	0.39 (0.22–0.67)

IQR = interquartile range.

\* Costs in 1 mo per \$1000 operating revenue.

† Generalized linear models comparing average monthly costs after full implementation with average monthly costs before implementation (values <1.0 represent a decrease in costs).

Figure 3. Monthly rates of legal and patient compensation costs before and after implementation of the University of Michigan Health System disclosure-with-offer program.



trends were considered, with a significant decrease for lawsuit costs (before–after change in slope,  $-7848.73$  [CI,  $-14035.56$  to  $-1661.90$ ];  $P = 0.013$ ) but not nonlawsuits (before–after change in slope,  $-1119.33$  [CI,  $-3831.10$  to  $1592.45$ ];  $P = 0.416$ ) (Figure 4).

### DISCUSSION

In this analysis of changes in liability claims and costs with the introduction of a comprehensive disclosure-with-offer program at the UMHS, we detected a reduced rate of claims, primarily driven by a decrease in the number of lawsuits; lower liability costs; and shorter time to resolution after the program was started. These findings demonstrate that it is possible to implement a disclosure-with-offer program without increasing liability claims and costs.

Other providers and insurers have undertaken disclosure initiatives or programs, but only 1 organization with a comprehensive disclosure-with-offer program, the Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky, has reported its experience (21, 22). Assessment of total malpractice payments 9 years after initiation of the program demonstrated that the medical center had moved from the top to the bottom quartile in its peer group (21). Despite these results, widespread adoption of disclosure-with-offer programs has been limited, perhaps because the Lexington VAMC program is set in a medical center gov-

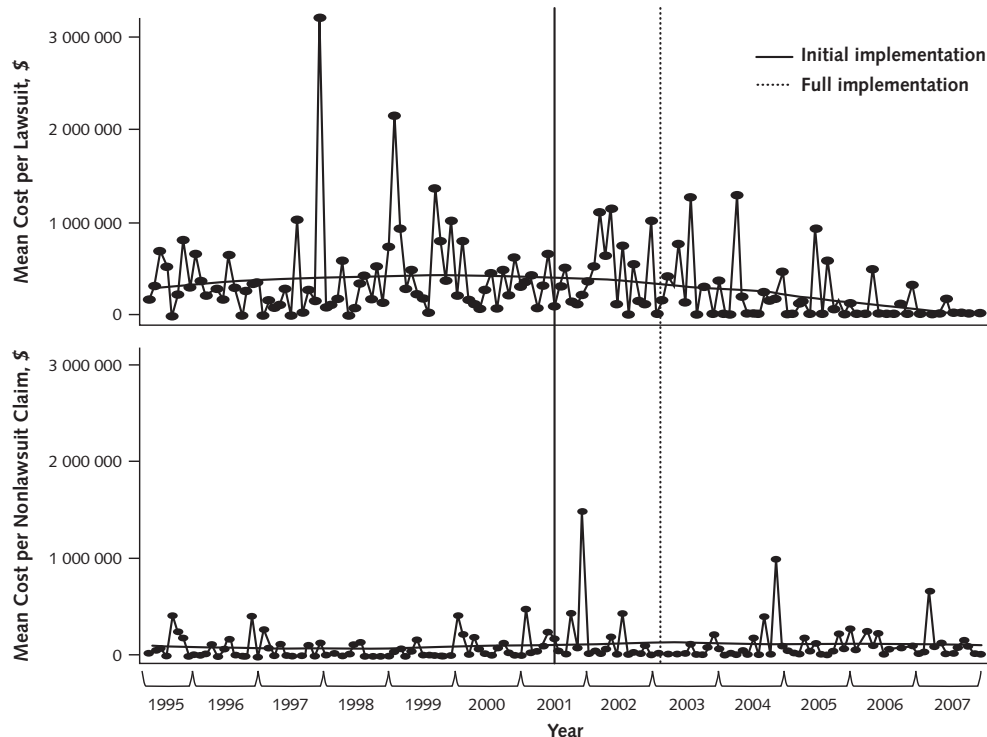
erned by the Federal Tort Claims Act and serves a population largely restricted to military veterans.

The near-absence of data on disclosure's direct effect on liability risk has led investigators to examine other indicators. For example, researchers have generated a predictive program and concluded that liability costs may actually increase with disclosure (20). Others argue that disclosure reduces lawsuits, citing surveys that suggest patients may be more likely to sue if they sense a lack of transparency (23–25). We provide empirical information on the direct liability-related consequences of a disclosure-with-offer program.

The UMHS program was designed to expedite compensation and claim resolution. Two frequent criticisms levied on the tort liability system are that only a small proportion of patients are ever compensated for negligent injury and that the time to obtaining compensation is excessively long (26). Our finding that time to claim resolution was shorter with the disclosure program suggests that the program seems to address the latter criticism. Quicker resolution can be important, especially for patients sustaining disabling injuries.

Our finding that fewer patients were compensated during the disclosure period may raise concerns that disclosure is not practiced with every case of error. This analysis, however, did not identify the specific factors that

**Figure 4.** Mean costs per claim before and after implementation of the University of Michigan Health System disclosure-with-offer program.



might account for the finding. Plausible explanations include a general decrease in claims for compensation, fewer injuries as a result of patient safety efforts, or patient satisfaction with an apology and honesty. In light of the University's transparency, patients (and their lawyers) may also be less likely to seek compensation if they believe they are getting the "real story" when UMHS denies that an error occurred. The UMHS's stance not to settle nuisance claims may also decrease the number of paid claims.

A program of disclosure with offer of compensation may also address another criticism of the malpractice system, namely its high administrative expenses (26, 27). After implementation, mean legal expenses for UMHS decreased by about 61%. Part of these savings were probably offset by the increase in the UMHS risk management budget needed to more proactively address claims internally, but the risk management expenses were more reflective of greater resources dedicated to the improvement of patient safety rather than administration of the disclosure program. Moreover, decreases in transactional costs for patients are also apparent. Not only can the shorter time to resolution translate to lower legal expenses for patients, many plaintiff attorneys now take cases on an hourly basis (as opposed to the more expensive contingency basis) in claims in which the UMHS has admitted error.

In addition to addressing some of the problems with the malpractice system, the disclosure program is compatible with other patient safety needs. Experts have called for greater reporting of errors as an important part of delivering safe and high-quality care (28–30). Despite UMHS directly linking its patient safety reporting systems to an open-disclosure risk management program (which could theoretically discourage reporting), the number of reported incidents increased tremendously (**Appendix Figure**, available at [www.annals.org](http://www.annals.org)).

Our analysis has several limitations. The state of Michigan's implementation of malpractice reform in 1994 (7 years before UMHS adopted its disclosure program) may have promoted a general decrease in liability claims and costs in the state. The legislation included caps on noneconomic damages, a 6-month compulsory presuit notice period, and new expert witness foundation requirements (31–34). However, Michigan was not considered immune to the most recent liability crisis (35).

Our study did not include a concurrent control to allow the disentanglement from secular trends. However, it is possible to glean some limited insight about what may have happened in the absence of a disclosure program. The UMHS outperformed its own actuarial models (based on external factors and UMHS claims experience before the disclosure program) by demonstrating a savings of approximately 39% from predicted total costs from 2003 to 2008. The UMHS actuarial modeling also demonstrated a relatively stable claims rate from 1995 to 2001 that was predicted to continue through 2008. Actual experience

demonstrated a claims rate that was more than 25% lower after the disclosure program.

State trends, through data submitted largely by commercial carriers insuring individual Michigan physicians, demonstrated declining numbers of reported claims from 2000 through 2007, with about 4.5 years from claim opening to closure (36). The UMHS experience compared favorably during this period: decreasing claims but with shorter resolution times. Aggregated national data from 20 physician insurer companies of claims closed from 2001 to 2008 revealed a relatively stable percentage of claims receiving payment (24% to 32%) and compensation costs, whereas legal expenses increased by about 28% (37). For claims opened during this period, UMHS compensated approximately 43% and had decreasing compensation and legal costs.

In addition, the UMHS approach of accepting systems-level responsibility with regard to the National Practitioner Data Bank reporting may affect applicability. For disclosure programs that do not adopt this approach, the willingness of physicians to settle may be limited. Finally, because the UMHS program is one of disclosure with offer (and not disclosure alone), this analysis does not necessarily inform on the liability results for providers that opt to disclose but not offer compensation.

Limitations notwithstanding, the study results have important implications. First, a medical center can implement a disclosure-with-offer program without increasing malpractice costs. Second, a disclosure program may address some of the main shortcomings of our current liability system, namely shortening long waits for compensation and decreasing administrative expenses. Third, disclosure may actually reduce another inefficiency of the malpractice system: preventing both meritorious and nonmeritorious claims from becoming expensive lawsuits. Fourth, the lower number of paid claims after implementation may suggest that disclosure with offer may not always ensure that injured patients receive compensation. This finding, however, may challenge past assumptions that everyone who had a harmful error expects compensation. The openness and accompanying patient safety efforts may satisfy patients for whom litigation was formerly their only alternative.

In an era of calls for greater transparency in health care, disclosure is often cited as a practice necessary to physician ethics and patient safety. The UMHS experience demonstrates that disclosure with offer can be conducted—in a setting similar to many other centers in the United States—without exacerbating liability costs. We hope that this study will encourage further disclosure efforts, as well as the detailed evaluation of their effects.

From Brigham and Women's Hospital, Boston, Massachusetts, and Ann Arbor Veterans Affairs Medical Center, University of Michigan Health System, University of Michigan, and Center for Statistical Consultation and Research, Ann Arbor, Michigan.

**Disclaimer:** The content is solely the responsibility of the authors and does not necessarily represent the official views of the Department of Veterans Affairs or the National Institutes of Health.

**Acknowledgment:** The authors thank Vinita Bahl, DMD, MPP; Ellen Bunting, MA; and Elaine Commiskey, MS, for their invaluable efforts in supplying data essential to this study.

**Grant Support:** By Blue Cross Blue Shield of Michigan Foundation (1217.II). In addition, Dr. Saint was supported by an Advanced Career Development Award from the Health Services Research & Development Service of the Department of Veterans Affairs during a portion of the time this study was conducted. Dr. Saint is currently supported by awards R21-DK078717 and R01-NR010700 from the National Institutes of Health.

**Potential Conflicts of Interest:** Disclosures can be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M09-1494](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M09-1494).

**Reproducible Research Statement:** *Study protocol, statistical code, and data set:* Not available.

**Requests for Single Reprints:** Allen Kachalia, MD, JD, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; e-mail, [akachalia@partners.org](mailto:akachalia@partners.org).

Current author addresses and author contributions are available at [www.annals.org](http://www.annals.org).

## References

- Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *N Engl J Med*. 2006;354:2205-8. [PMID: 16723612]
- Levinson W, Gallagher TH. Disclosing medical errors to patients: a status report in 2007. *CMAJ*. 2007;177:265-7. [PMID: 17664451]
- Hospital Accreditation Standards. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2008.
- National Quality Forum. Safe practices for better healthcare 2009 update: a consensus report. Washington, DC: National Quality Forum; 2009.
- Blendon RJ, DesRoches CM, Brodie M, Benson JM, Rosen AB, Schneider E, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med*. 2002;347:1933-40. [PMID: 12477944]
- Snyder L, Leffler C; Ethics and Human Rights Committee, American College of Physicians. Ethics manual: fifth edition. *Ann Intern Med*. 2005;142:560-82. [PMID: 15809467]
- Mazor KM, Simon SR, Yood RA, Martinson BC, Gunter MJ, Reed GW, et al. Health plan members' views on forgiving medical errors. *Am J Manag Care*. 2005;11:49-52. [PMID: 15697100]
- Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med*. 2007;356:2713-9. [PMID: 17596606]
- Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint S. Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Jt Comm J Qual Saf*. 2003;29:503-11. [PMID: 14567259]
- Lamb RM, Studdert DM, Bohmer RM, Berwick DM, Brennan TA. Hospital disclosure practices: results of a national survey. *Health Aff (Millwood)*. 2003;22:73-83. [PMID: 12674409]
- Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289:1001-7. [PMID: 12597752]
- Gallagher TH, Waterman AD, Garbutt JM, Kapp JM, Chan DK, Dunagan WC, et al. US and Canadian physicians' attitudes and experiences regard-

- ing disclosing errors to patients. *Arch Intern Med*. 2006;166:1605-11. [PMID: 16908793]
- Weissman JS, Annas CL, Epstein AM, Schneider EC, Clarridge B, Kirle L, et al. Error reporting and disclosure systems: views from hospital leaders. *JAMA*. 2005;293:1359-66. [PMID: 15769969]
- Loren DJ, Klein EJ, Garbutt J, Krauss MJ, Fraser V, Dunagan WC, et al. Medical error disclosure among pediatricians: choosing carefully what we might say to parents. *Arch Pediatr Adolesc Med*. 2008;162:922-7. [PMID: 18838644]
- Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? *JAMA*. 1991;265:2089-94. [PMID: 2013929]
- Butcher L. Lawyers say 'sorry' may sink you in court. *Physician Exec*. 2006;32:20-4. [PMID: 16615399]
- Boothman RC, Blackwell AC, Campbell DA Jr, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law*. 2009;2:125-59. [PMID: 19288891]
- Wojcieszak D, Banja J, Houk C. The Sorry Works! Coalition: making the case for full disclosure. *Jt Comm J Qual Patient Saf*. 2006;32:344-50. [PMID: 16776389]
- Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint S. Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Jt Comm J Qual Saf*. 2003;29:503-11. [PMID: 14567259]
- Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of medical injury to patients: an improbable risk management strategy. *Health Aff (Millwood)*. 2007;26:215-26. [PMID: 17211031]
- Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131:963-7. [PMID: 10610649]
- Peto RR, Tenerowicz LM, Benjamin EM, Morsi DS, Burger PK. One system's journey in creating a disclosure and apology program. *Jt Comm J Qual Patient Saf*. 2009;35:487-96. [PMID: 19886087]
- Mazor KM, Simon SR, Yood RA, Martinson BC, Gunter MJ, Reed GW, et al. Health plan members' views about disclosure of medical errors. *Ann Intern Med*. 2004;140:409-18. [PMID: 15023706]
- Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*. 1994;343:1609-13. [PMID: 7911925]
- Witman AB, Park DM, Hardin SB. How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting. *Arch Intern Med*. 1996;156:2565-9. [PMID: 8951299]
- Studdert DM, Mello MM, Brennan TA. Medical malpractice. *N Engl J Med*. 2004;350:283-92. [PMID: 14724310]
- Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, et al. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med*. 2006;354:2024-33. [PMID: 16687715]
- Kohn L, Corrigan J, Donaldson M. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academies Pr; 2000.
- Mello MM, Studdert DM, Kachalia AB, Brennan TA. "Health courts" and accountability for patient safety. *Milbank Q*. 2006;84:459-92. [PMID: 16953807]
- Leape LL. Reporting of adverse events. *N Engl J Med*. 2002;347:1633-8. [PMID: 12432059]
- Mich Comp Laws §600.2169.
- Mich Comp Laws §600.1483.
- Mich Comp Laws §600.5838a.
- Mich Comp Laws §600.5856.
- Xu X, Siefert KA, Jacobson PD, Lori JR, Ransom SB. The effects of medical liability on obstetric care supply in Michigan. *Am J Obstet Gynecol*. 2008;198:205.e1-9. [PMID: 17997388]
- Office of Financial and Insurance Regulation. Evaluation of the Michigan Medical Professional Liability Insurance Market. A Market Evaluation Study issued by Commissioner Ken Ross. Lansing, MI: State of Michigan Department of Energy, Labor and Economic Growth; October 2009. Accessed at [www.michigan.gov/documents/dleg/Michigan\\_Medical\\_Liability\\_Ins\\_Rpt\\_297694\\_7.pdf](http://www.michigan.gov/documents/dleg/Michigan_Medical_Liability_Ins_Rpt_297694_7.pdf) on 1 July 2010.
- Physician Insurers Association of America. Claims Trend Analysis: A Comprehensive Analysis of Medical Liability Data Reported to the PIAA Data Sharing Project. Rockville, MD: Physician Insurers Association of America; 2009.

**Current Author Addresses:** Dr. Kachalia: Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115.

Mr. Kaufman: Department of Internal Medicine, Division of Cardiovascular Medicine, The Blue Cross Blue Shield of Michigan Cardiovascular Consortium, 2929 Plymouth Road, Suite 225, Ann Arbor, MI 48105-3206.

Mr. Boothman: University of Michigan Health System, Med Inn Building, C 201, SPC 5825, 1500 East Medical Center Drive, Ann Arbor, MI 48109.

Ms. Anderson: University of Michigan Health System, Risk Management Department, 300 North Ingalls Building, Room 8A06/SPC 5478, Ann Arbor, MI 48109-5478.

Ms. Welch: Center for Statistical Consultation and Research, 3554 Rackham Building, 915 East Washington Street, Ann Arbor, MI 48109-1070.

Dr. Saint: Ann Arbor Veterans Affairs Medical Center, Division of General Medicine, Department of Internal Medicine, University of Michigan, 300 North Ingalls Building, Room 7E08, Ann Arbor, MI 48109.

Dr. Rogers: Division of General Medicine, Department of Internal Medicine, University of Michigan, 300 North Ingalls Building, Room 7E07, Ann Arbor, MI 48109.

**Author Contributions:** Conception and design: A. Kachalia, S. Saint, S.R. Kaufman, M.A.M. Rogers, R. Boothman, S. Anderson.

Analysis and interpretation of the data: A. Kachalia, S. Saint, S.R. Kaufman, M.A.M. Rogers, R. Boothman, S. Anderson, K. Welch.

Drafting of the article: A. Kachalia, S.R. Kaufman, M.A.M. Rogers.

Critical revision of the article for important intellectual content: A. Kachalia, S. Saint, S.R. Kaufman, M.A.M. Rogers, R. Boothman.

Final approval of the article: A. Kachalia, S. Saint, S.R. Kaufman, M.A.M. Rogers, R. Boothman, S. Anderson.

Statistical expertise: S.R. Kaufman, M.A.M. Rogers, K. Welch.

Obtaining of funding: A. Kachalia, S.R. Kaufman, S. Saint, M.A.M. Rogers.

Administrative, technical, or logistic support: A. Kachalia, R. Boothman, S. Anderson.

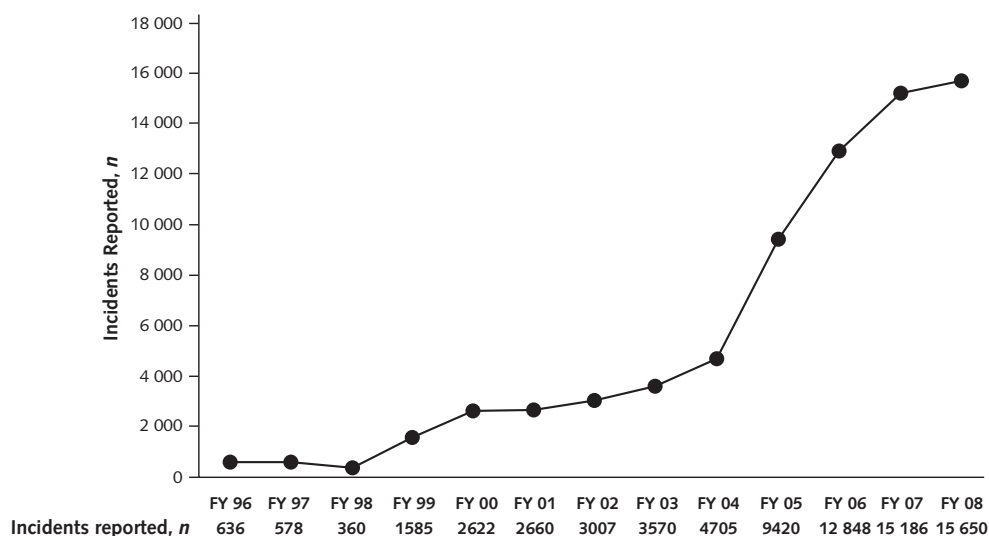
Collection and assembly of data: A. Kachalia, S.R. Kaufman, R. Boothman, S. Anderson.

## APPENDIX

### Background

The UMHS is a major public academic center located in Ann Arbor, Michigan. With few exceptions, the UMHS has a closed medical staff comprising faculty members employed by the University of Michigan Medical School, which is governed by the University's Board of Regents. The system and its employees have exclusive occurrence-based professional liability coverage provided by an established captive insurance company. Medical staff and other employees can be sued individually in the circuit courts with juries, but as an agency of the state of Michigan, the Regents may only be sued in the state's Court of Claims (which does not allow juries). For judicial economy, lawsuits are typically joined administratively but are not consolidated; separate judgments are obtained in each lawsuit that goes to verdict.

*Appendix Figure.* Number of incidents reported to University of Michigan Health System risk management, by fiscal year.



An incident is any event (whether involving injury, potential injury, or any concern) that was reported to risk management. FY = fiscal year.