Disclosing Medical Errors to Patients: What Have We Learned?

Allen Kachalia, MD, JD
Chief Quality Officer, Brigham Health
Associate Professor of Medicine, Harvard Medical School

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BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

Overview

1. Hypothetical Case
2. Disclosure: Definitions and Background
3. What Does the Evidence Tell Us?
4. Current Developments
5. Conclusions

Day #1 - Initial Presentation

- Kate, a healthy 54 year old woman, presents to the emergency department (ED) with a fever, headache, and generalized malaise

- Work-up includes negative lumbar puncture and chest x-ray. Slightly elevated peripheral white count

- Sent home with diagnosis of a “viral syndrome”

Day #2 - Back Again

- Feeling “worse”
- Returns next day to the emergency department

Day #2 - Evaluation

- Seen by a resident who reviews previous days labs but does not realize culture results were drawn
- Resident staffs ED attending, but does not mention patient had presented earlier
- The ED attending performs a routine exam
- More bloodwork is drawn and she is sent home

Day #3 - Sepsis

- Presents for a third time to the ED
- Hypotensive with sepsis
- Placed on pressors and mechanical ventilation and admitted to the ICU team

Review of the Lab Data

- Looking back through the lab results from two days ago, you see that the original blood cultures (drawn on Day #1) had turned positive yesterday

- From what you can see, no one had been notified, nor had anyone checked

Treatment

- Antibiotic therapy tailored to the culture results

- Kate makes a full recovery

Is There a Dilemma Here?

- The family does not suspect any wrong doing
- The family thanks the team for saving Kate's life
- Imaging that you're on the clinical team: In your professional estimation, intubation could have been avoided if antibiotics had been started on Day #2

Do You Disclose?

- Key Questions
  - Does the family need to be told?
  - Who tells them?
  - What should they be told?
  - What good will it do?
  - What are the repercussions?

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Know the Differences in: Apology, Disclosure, & Disclosure and Offer

- Apology:
  - Showing remorse over the harm;
  - Showing remorse over the event/error; and/or
  - Taking responsibility for the error

- Disclosure:
  - Explaining what happened in an event
    - Does not require taking responsibility

- Disclosure and Offer:
  - Explaining what happened in an event and offering compensation
    - Compensation can be in response to taking responsibility or measure of good faith

The Case for Disclosure

- Heightened attention to medical error has resulted in calls for more disclosure to support:
  - Ethical obligations
  - Transparency
    - Patient preference
    - Trust in patient/doctor relationship
    - Culture to improve patient safety

The Big Barriers and Debate

- Key barriers:
  - Talking about error
  - Liability risk (and reporting)
- Genuine disagreement on disclosure's effect on liability
  - Handing over "blank check"

    vs
  - Meeting patient desire for sincerity and honesty
- Very limited data on direct effect

Consequences of Lawsuits – Not Just Financial

- Liability premium increases or inability to get coverage
- The stress of being sued
  - Feeling of blame/shame
  - Not to talk about it
  - Distraction from clinical practice
  - Depositions
  - Uncertainty (for a long time)
- Reporting to the state board
- Reporting to insurance
- Reporting to the federal government

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Ethical Responsibilities

- Fiduciary Duty
  - Patient interests outweigh doctor's interests
- Autonomy
  - Right to make informed decisions on care
- Equity
  - If erroneously injured, entitled to compensation

What Do Patients Want?

Survey of Health Plan Members in New England (1000 respondents)	
Want to know about error regardless of outcome	91%
Reasonable to expect an error in medical care	81%
Want to know about error as soon as discovered	98%
Expect financial compensation	67.8%
Want some type of discipline for doctor	38.8%

Source: Mazor, Annals 2004

Doctor's Views

National Survey of Physicians and Public	
Disclosure for errors should be required	Doctors 77% Public 89%
Reporting should be confidential and not released to public	Doctors 86% Public 34%

Source: Blendon NEJM 2002

The Challenge

Physicians' Attitudes And Behavior Regarding Communication With Patients

	Weighted results		
Physicians should:	**Sample size**	**Completely agree (%)**	**Somewhat agree or disagree (%)**
Disclose all significant medical errors to affected patients	1,768	65.9	34.1
Fully inform all patients of benefits and risks of procedure or course of treatment	1,809	88.7	11.3
Never tell a patient something that is not true	1,798	82.8	17.2
Disclose financial relationships with drug and device companies to their patients	1,800	64.6	35.4
Never disclose confidential patient health information to an unauthorized individual	1,802	91.4	8.6
In the past year how often have you:	**Sample size**	**Never (%)**	**Rarely, sometimes, or often (%)**
Told an adult patient or child's guardian something that was not true?	1,811	89.0	11.0
Described a patient's prognosis in a more positive manner than warranted?	1,809	44.8	55.2
Not fully disclosed a mistake to a patient because you were afraid of being sued?	1,812	80.1	19.9
Intentionally or unintentionally revealed to an unauthorized person health information about one of your patients?	1,808	71.6	28.4

Source: Iezzoni, *Health Affairs*, 2012

Doctor's Views

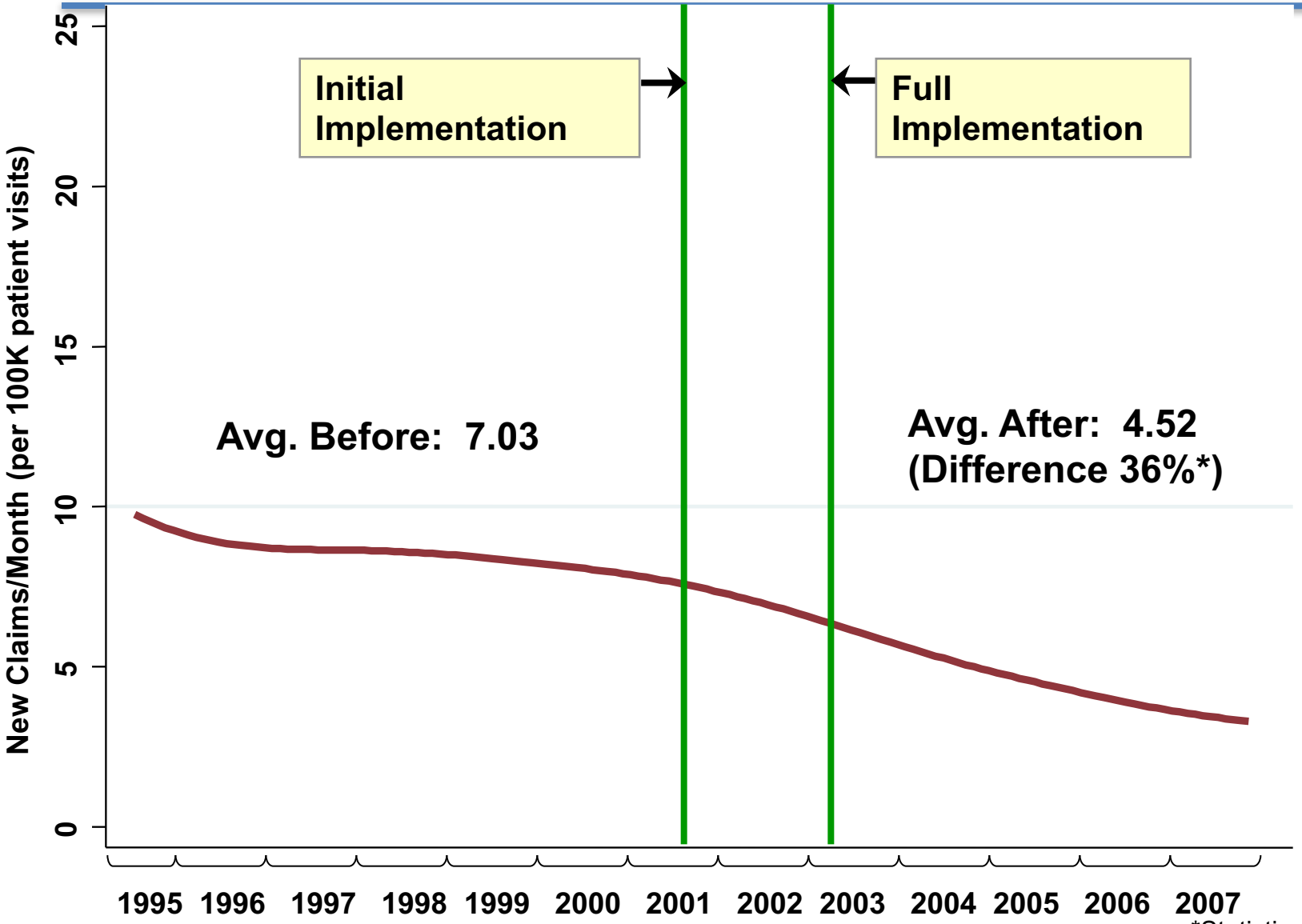
Findings from Focus Groups	
Definition of error	Much narrower than patients
Disclose trivial harm	No need to do so
Disclose near misses	No need to do so
Concerns	Liability and reputation

Source: Gallagher, JAMA 2003

Medical Error Disclosure Program at the University of Michigan

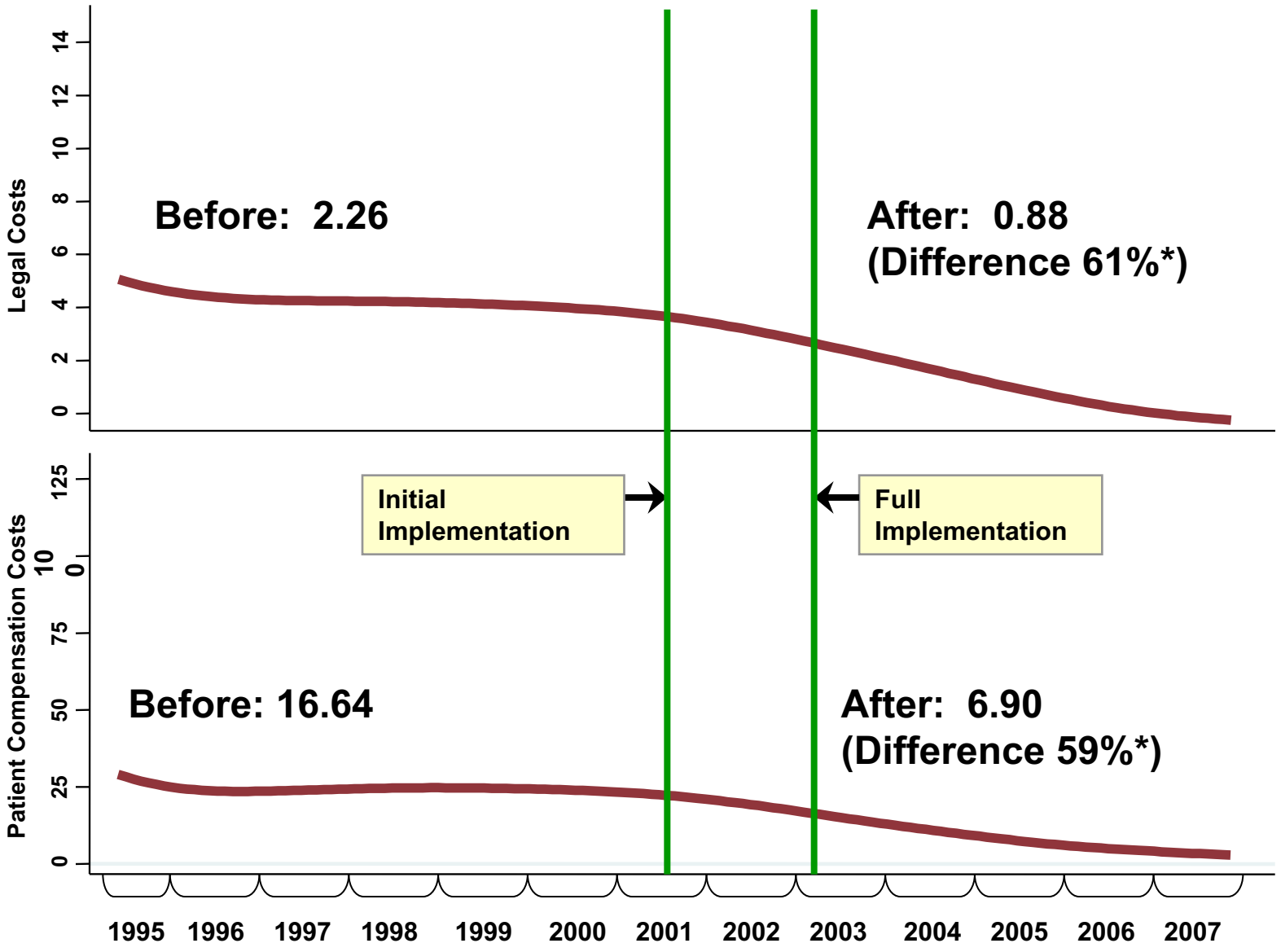
Source: Clinton H and Obama B. N Engl J Med 2006;354:2205-2208

Results - New Claims Per Month



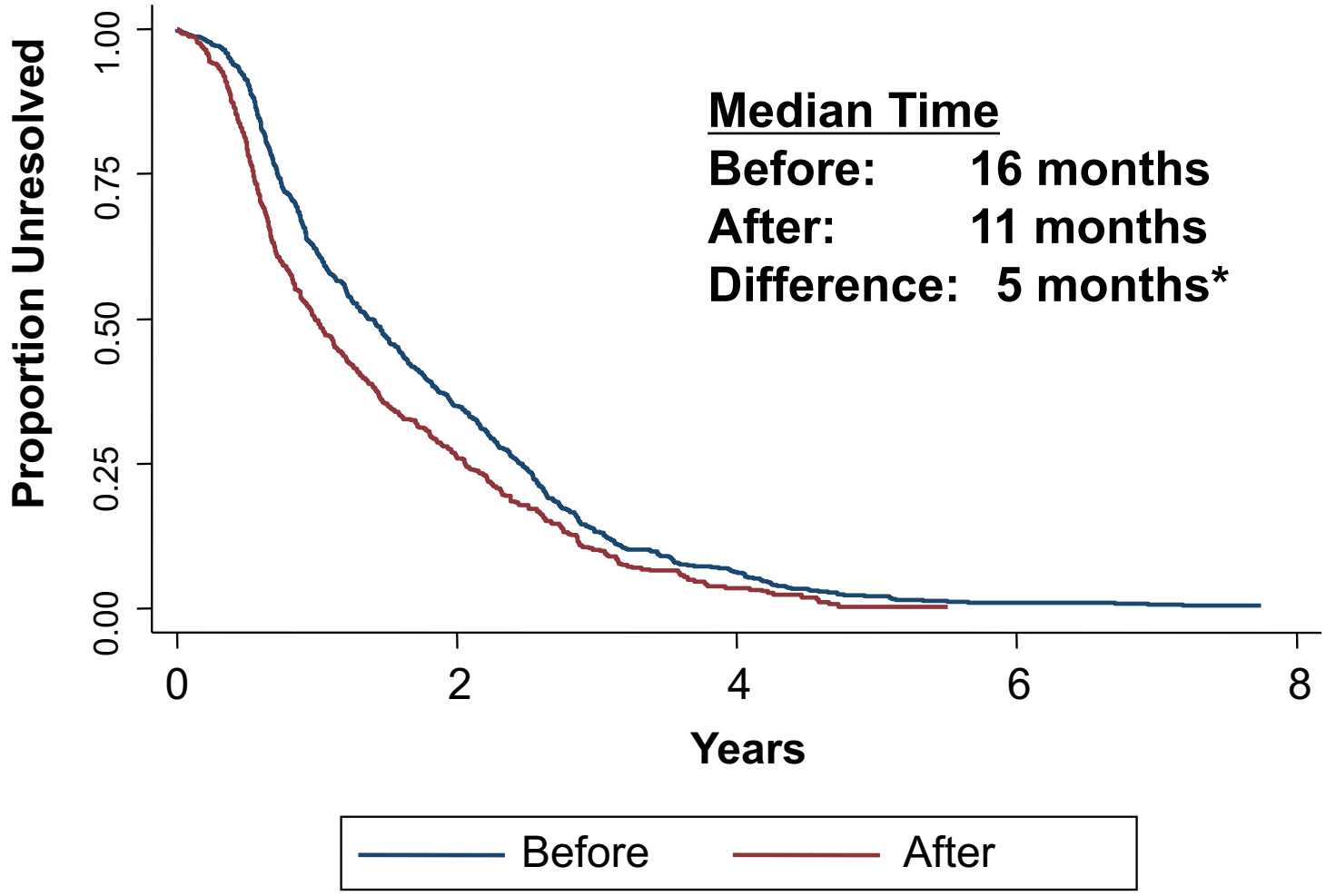
*Statistically significant

Results – Liability Costs



*Statistically significant

Results – Time to Resolution



*Statistically significant

Available Outcomes Data: The University of Michigan Experience

- Mean & median total liability costs decreased significantly
- Patient compensation costs decreased significantly
  - Average payout per lawsuit**: $405,921 vs. $228,208** ($p<0.01$)
  - Costs did not change significantly for non-lawsuit claims
- Overall legal costs decreased significantly ($p<0.01$)
- From 2001-2007, other insurers in the same state:
  - Paid less claims (24% vs. 43% at the Univ of Michigan)
  - Had increasing legal costs
  - Had flat compensation costs

Disclosure and Malpractice Liability

- No studies have directly or definitively shown the overall effect of what happens to liability with disclosure
- We do not know how many more claims would occur with disclosure
- We do know: Patients want to hear about errors and ethical obligation exists
- Greater disclosure may help improve patient safety

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Demonstration Projects

Medical Liability Reform and Patient Safety

Demonstration Grants

The demonstration grants for Patient Safety and Medical Liability Initiative support the implementation and evaluation of evidence-based patient safety and medical liability projects. The Agency for Healthcare Research and Quality (AHRQ) funded seven demonstration grants for a total amount of $19.7 million.

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These seven grants include a variety of models that meet one or more of the patient safety and medical liability reform initiative goals, including:

- Reducing preventable harms.
- Informing injured patients promptly, and making efforts to provide prompt compensation.
- Promoting early disclosures and settlement, through a court-directed alternative dispute resolution model.

Timothy McDonald, M.D., J.D., University of Illinois at Chicago, IL, $2,998,083

The project is designed to fill the evidence gap regarding the impact on patient safety and litigation rates of programs that feature improved communication with patients, transparency, disclosure of adverse events, early offers of compensation, and learning from mistakes. It will evaluate the impact on Medical Liability Reform and Patient Safety outcomes of extending an existing disclosure program from an academic hospital setting to diverse hospitals in the greater Chicago area.

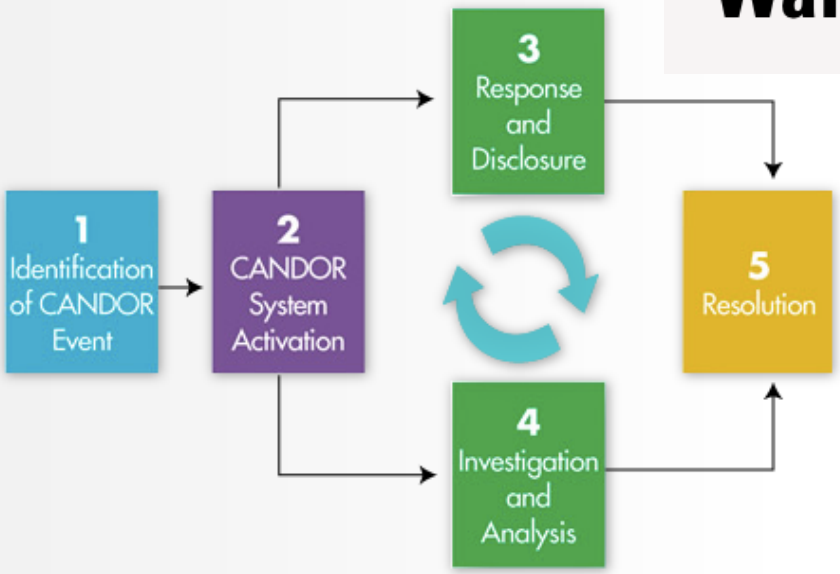
Stanley Davis, M.D., Fairview Health Services, Minneapolis, MN, $2,982,690

New AHRQ Toolkit

The Michigan Model: Medical Malpractice and Patient Safety at UMHS

Since 2004, the U-M Health System has been in the national spotlight for its innovative approach to medical errors, mishaps and near-misses -- and their potential legal consequences including malpractice suits. We call it the Michigan Model.

Hospitals Can Break Through the 'Wall of Silence' with New Toolkit



Communication and Resolution Programs Growing

Lessons from Implementation

- Will need strong leadership support for resourcing and addressing legal/financial fears
- Need to coach providers through the disclosure process – Institutional program
- Need to support providers involved in the event
- Conversations should happen early – even if cause not known
- Plan for many conversations – this is process – not a one time event. Need to stay true to principles of transparency

Trust Can Be Easy to Lose

What Are Legislatures Doing?

- Some are requiring disclosure to patient or family in specific circumstances (CA, FL, MA, NJ, NV, OR PA, VT)

- But can you actually mandate it?

Facilitating Communication and Resolution

Levers	Notes
"I'm Sorry" Laws	• Can encourage openness at time of event • Vary greatly by state • Not a free pass to say anything (inconsistent statements admissible) • But are they compatible with transparency?
"Cooling Off" Periods	• Required notice time meant to give parties time to settle
Oregon Reform – Mediation	• Enable medication. Bill deems settlement are "not a payment resulting from a written claim or demand for payment"
NPDB Reporting Requirement Changes	• Proponents advocating for change to law or its interpretation • But what about the NPDB's purpose of tracking "bad" doctors?

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Conclusions

- The push for disclosure continues to grow
  - Transparency to improve safety
  - Ethical imperative
- Barriers include liability + reputation (human nature)
- Data indicate that programs can reduce liability outcomes
- Hard to do: Success requires leadership + programmatic support

The End -- Thank you!

For questions, please contact:

Allen Kachalia at:

akachalia@bwh.harvard.edu

Appendix

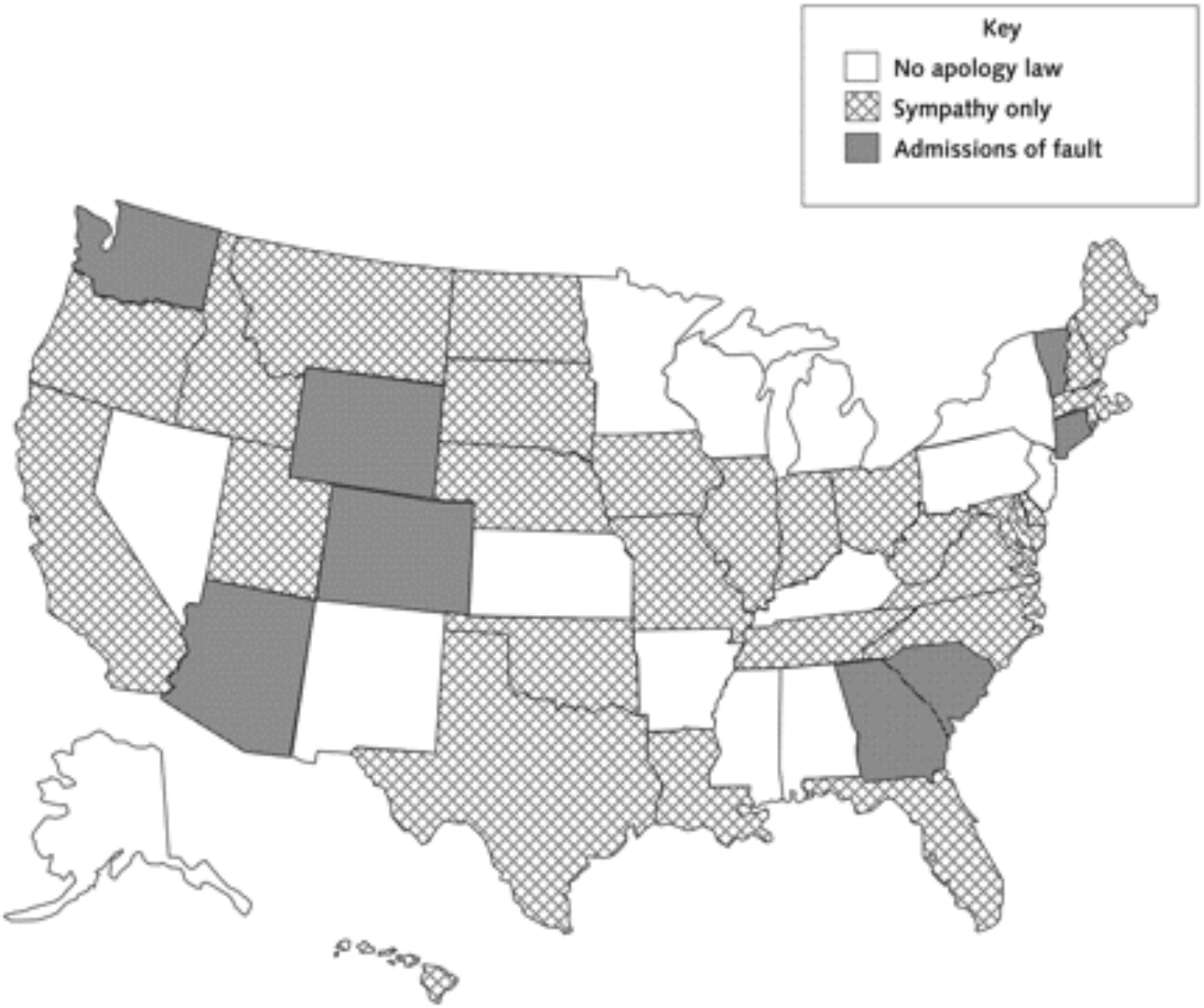
What To Do About Others' Errors?

Clinical Situation	Potential Strategy
Error by another clinician in same hospital	Notify Safety / Risk - Disclose together
Trainee error	Notify Safety / Risk – Attending + trainee
Error at another institution	Notify Safety / Risk - Institutional leadership after discussion with other institution

Is Communication and Resolution Enough?

- Can help with many of the factors ailing the liability system
  - Patient access to compensation
  - Time to resolution
  - Overhead costs
- But:
  - Are these programs transportable to other setting?
  - Will institutions disclose enough?
    - Drop in percentage of paid claims
  - What about the cases in which there is still a genuine dispute?

Types of Apology Laws by State



McDonnell, W.A., et al. "Narrative Review: Do State Laws Make it Easier to Say "I'm Sorry?"" Ann Intern Med 149(11): 811-5, 2008.

What Do Patients Want?

Survey of Patients at Internal Medicine Clinic	
Do they want to know about mistakes?	98% wanted acknowledgement of some form with minor, moderate or serious errors
Moderate Errors Sue if told? 12% Sue if find out? 20%	Major Errors Sue if told? 60% Sue if find out? 76%

Source: Witman, 1996

Lawsuits and Disclosure

Study	Results
Survey of families who had filed suit for perinatal injuries (Hickson, 1992)	1 in 4 families suing due to failure of complete honesty or misleading behavior
Adoption of a policy of full disclosure in VAMC (Kraman, 1999)	Institution moved from being from top quartile into the lowest quartile of its peer group
Survey of patients and families filing suit in England (Vincent, 1994)	Over 60% sued for desire of an explanation or because they felt ignored and/or neglected

Current Disclosure Programs

- "Disclosure" programs can also vary
  - Reimbursement Model: Some will make offers for cases with lesser harm (and no attorney involvement).
    - Do not also close out the possibility of a claim later on.
    - Usually does not trigger reporting
  - Some will only disclose the error
    - Offers do not automatically follow
  - Early Settlement Model: Some will disclose and make an offer of compensation, if at fault
    - Can trigger physician reporting depending on how settled