

# The Negligence Standard and Medical Error Causation: What the Evidence Tells Us

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## Today's discussion

1. Malpractice claims as a source of data about medical errors
2. Three empirical discoveries that cast negligence and tort processes into doubt
3. Policy implications

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## Malpractice Insurers' Medical Error Prevention and Surveillance Study (MIMEPS)

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## Sample of insurers

- 5 Insurers (2 Northeast, 1 Mid-Atlantic, 1 Southwest, 1 West)
- Coverage:
  - 33,000 physicians
  - 61 acute care hospitals (31 academic, 26 non-academic)
  - 428 outpatient facilities


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## Sample of claims

- Claims selected randomly in 4 clinical categories which collectively account for ~80% of claims:
  - Operative (n=444 claims reviewed)
  - Obstetrics (n=335)
  - Missed or delayed diagnosis (n=429)
  - Medication-related (n=244)
- Target number at each site based on annual claims volume


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## The error judgment process

1. Was there an adverse outcome? 
2. What caused the adverse outcome?
 

Rate the likelihood that a failure of \_\_\_\_\_ contributed to the adverse outcome.

1-----2-----3-----4-----5

Highly Unlikely      Somewhat Likely      Highly Likely
3. Was the adverse outcome due to error? 
4. Clinical details of error

*In light of your responses to the above questions and all other relevant information in the claim file, indicate your confidence that the adverse outcome resulted from one or more errors.*

- o Little or no evidence (END REVIEW)
- o Slight to modest evidence (END REVIEW)
- o Not quite likely; less than 50-50 but close call (END REVIEW)
- o More likely than not; more than 50-50 but close call
- o Moderate/strong evidence
- o Virtually certain evidence

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## Finding 1: Medical error causation is multifactorial and complex

Contributing factors	% of all error-related injuries
<b>Individual factors</b>	<b>96%</b>
Error in judgment	70%
Failure of vigilance/memory	57%
Lack of technical competence/knowledge	48%
<b>System factors</b>	<b>56%</b>
Teamwork/communication	40%
Other	20%
<b>Patient-related factors</b>	<b>39%</b>

## Finding 1: Medical error causation is multifactorial and complex

Number of contributing factors:	
Mean (median)	3.14 (3)
≥4	35%
≥5	19%
Number of involved clinicians:	
Mean (median)	1.96 (2)
≥3	25%
≥4	7%

## Challenges for tort processes

- o Newtonian model of causation doesn't fit well
  - More of a causal "web"
- o The "but for," "substantial factor," and "proximate causation" tests of tort causation are too crude

## Finding 2: It is difficult to isolate individual failures from "systems"

- o Individual failures contribute to most errors, but they are precipitated or amplified by systems failures.
- o Injury severity was higher among claims with individual+system factors vs. individual factors only (7.3 vs. 6.8, p<0.01)

## Challenges for tort processes

- Negligence standard disproportionately focuses on individual failures
  - Institutional defendants only pay in 1/4 of cases
  - Doctrinal barriers
- System doesn't distinguish well between cases with and without system factors
  - Institutions no less likely to pay in cases without vs. with system factors

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## Finding 3: The best opportunities to avoid injuries are at the system level

- Focus on individual negligence misdirects the deterrent signal to individuals who may be relatively powerless to effect the needed changes

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## Need to shift the focus to institutions

- Greater possibilities for enterprise liability
  - Exclusive corporate liability model
  - Joint liability model
  - Channeling
- Greater institutional role in responding to injuries and claims
  - Disclosure
  - Offers of compensation

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## Doctrines and processes should reflect the realities of how medical errors happen

- Negligence is too narrow
  - Need alternatives that incorporate system factors and consider what should happen in well-designed *environments* of care
- Causation analysis should be transformed
  - Look beyond proximate causes
  - Experts may be better able to analyze the causal web than laypersons

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## Summary

- Medical error causation is complex; individual failures can't easily be separated from problems with the environments in which individuals work.
- Tort doctrine and processes assume a much simpler view of the world.
- Liability reform could give institutions greater "skin in the game" and produce more just outcomes.

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## Further reading

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- Mello MM, Studdert DM. Deconstructing negligence: the role of individual and system factors in causing medical injuries. *Georgetown Law J* 2007 (in press – available from author).
- Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Accuracy of the medical malpractice system: relationship between claims, errors, and outcomes of litigation. *N Engl J Med* 2006;354:2024-33.
- Studdert DM, Mello MM. When tort resolutions are "wrong": predictors of discordant outcomes in medical malpractice litigation. *J Leg Stud* 2007 (In press – available at the web link below).
- All papers from the Malpractice Insurers Medical Error Prevention and Surveillance project are listed at <http://www.hsph.harvard.edu/faculty/michelle-mello/current-projects/>