Federal Liability Protection for Emergency Care

August 23, 2013
Agenda

Welcome and Introductions
• Danielle Lazar, MA, Senior Research Associate, Urgent Matters
• Sarah Hoper MD, JD, EMRA Legislative Advisor

The Health Care Safety Net Enhancement Act
Robert A. Bitterman, MD, JD, FACEP

Medical Malpractice Safe Harbors
James F. Blumstein, University Professor of Constitutional Law and Health Law and Policy, Vanderbilt Law School

Safe Harbors and the Practice of Emergency Medicine
Kevin M. Klauer, DO, EJD, FACEP, Chief Medical Officer, EMP, Ltd., Director, EMP PSO, Asst Clinical Professor, MSUCOM
Asking Questions

The question and answer period of the webinar will be interactive. We have scheduled approximately 10 minutes for questions at the end of the presentation. To submit a question, simply type your question in the designated area in the right hand column of the screen at any time during the webinar. If your question is not selected to be answered during the webinar, you can re-submit your question via email to info@urgentmatters.org.
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Federal Liability Protection for Emergency Care: The Health Care Safety Net Enhancement Act

Robert A. Bitterman, MD, JD, FACEP
Objectives

• What are the elements of this legislation?
• How would it work?
• What medical services does it cover?
• What are the implications of utilizing the EMTALA and Federal Torts Claims laws?
• Will the Act achieve its intended goal?
Introduction

- Medical liability climate
- Burdens of federal law - EMTALA
- Lack of hospital ED on-call specialists
- Diminished access to emergency care
Health Care Safety Net Enhancement Act of 2013

- H.R. 36 / S.961
- Congressional intent:
  Improve access to emergency medical services by providing liability protection for emergency care provided pursuant to the federal mandate of EMTALA
- Historical perspective ...
Legislative Legalese

• Amends the Public Health Service Act
• Deems certain providers ‘employees’ of the government
• Only for care provided pursuant to EMTALA
• Provides liability coverage under the Federal Torts Claims Act (FTCA)
“Deemed Status”

• Only providers as defined by the statute
• Must apply – annually
• HHS must approve application – annually
• Voluminous data must be provided on risk management programs, polices & procedures, credentials, etc.
• Must still maintain own malpractice insurance
Services Covered

• Only services mandated by EMTALA; and
• ‘Post stabilization services’, defined as:
  • Services ‘related to’ the condition treated under EMTALA; and
  • Services provide after the patient is stabilized in order to maintain the stabilized condition or to improve or resolve the condition of the patient
EMTALA Services Covered

- Medical screening examination
- Stabilizing treatment
- Transfer of an unstable patient
- Determination of whether the patient has an ‘emergency medical condition’ is key (EMC)
Post Stabilization Services Covered

• Must be ‘related to’ the diagnosed EMC; and
• Provided after the EMC is stabilized to maintain the stabilization or improve or resolve the ‘condition of the patient’
• EMTALA’s definitions really matter!
Federal Torts Claims Act (FTCA)

- Different than dealing with insurance carrier
- FTCA folks decide whether to defend a claim
- Provider has no say in how case is settled
- National Practitioner Data Bank issues
- FTCA has right to recover losses from ‘covered’ provider under some circumstances
Ramifications

- Violations of EMTALA = illegal acts
- Various claims of liability = different processes, different law, and different courts, defense agencies, and legal counsel
- Limited services are covered / protected
- Funding subject to appropriations process
"The doctor is in court on Tuesdays and Wednesdays."
Conclusions

• Federal mandate – federal liability protection is a step in the right direction
• Acknowledgement of the problem
• Low probability of providers participating
• Unlikely to encourage specialists to provide more ED on-call coverage
Questions?
Federal Liability Protection for Emergency Care

Medical Malpractice Safe Harbors

James F. Blumstein
University Professor of Constitutional Law and Health Law and Policy
Vanderbilt Law School
August 23, 2013
Medical Malpractice Doctrine: A Brief Primer

• Different Ways of Thinking About Medicine and Their Implications
  – The Professional Paradigm
  – The Market-Based Economic Paradigm
Medical Malpractice Doctrine: A Brief Primer

• Conventional Tort Doctrine vs. Professional Negligence Doctrine
  – Conventional Tort Doctrine: The Reasonable Prudent Person Standard
  – Professional Negligence Doctrine: The “Customary Practice” Standard
Medical Malpractice Doctrine: A Brief Primer

• Elements of a Typical Medical Malpractice Case
  – Customary Practice (or Accepted Practice) Standard
    • Establishing the Standard
    • Use of Expert Testimony to Establish Standard of Care
  – Breach of Standard?
  – Causation
  – Damages
The Problem of Uncertainty

• Clinical Uncertainty and Its Embarrassing Implications
• Structural Uncertainty
• Implications
A Response to Uncertainty

• *Ex Ante* Standards: In General
• The Problems With Traditional *Ex Ante* Standards/Guidelines: A Medical Malpractice Perspective
  – Traditional Guidelines Reflect Professional Paradigm
  – Broad and Flexible
  – Wide Range for Clinical Judgment and Discretion
  – Implications for Medical Malpractice Liability
A Response to Traditional Guidelines: “Safe Harbors”

- Narrowly Targeted – Not Comprehensive or Excessively Ambitious
- Prescriptive and Precise Within Defined Scope of Practice
- Single Applicable Guideline Upon Which Physician Can Rely
Prospects and Pitfalls

• Doability as a Practical Matter?
  – The Science
  – The Law (Drafting)

• Introduction of Cost Considerations Into Clinical Decisionmaking
Prospects and Pitfalls

• The “Asymmetry” Problem
  – Safe Harbors As Evidence of the Standard of Care?
  – Safe Harbors As the Standard of Care?
Prospects and Pitfalls

• Implementing Safe Harbors as the Standard of Care
  – Role of Quality Improvement Organizations (QIOs)
  – Standard-setting Authority of QIOs
  – The Updating Concern
  – QIO Liability?
Conclusion

• Traditional Medical Malpractice Reform Focuses on Remedies
  – Damages Caps
  – Limitations on Scope of Damages Recovery

• Safe Harbors Approach Focuses on Improving Existing System of Liability
  – Addresses Problem of Clinical Uncertainty
  – Addresses Problem of Structural Uncertainty
Safe Harbors and the Practice of Emergency Medicine

Kevin M. Klauer, DO, EJD, FACEP
Chief Medical Officer, EMP, Ltd.
Director, EMP PSO
Asst Clinical Professor, MSUCOM
EPIC FAIL
Only moments away
Number of encounters for each fatality

Regulated Hazards

- Health Care (HAZARDOUS: >1/1000)
- Driving (REGULATED)
- Scheduled Airlines (ULTRA-SAFE: <1/100K)

Unregulated Hazards

- Mountain Climbing
- Bungee Jumping
- Chemical Manufacturing
- Chartered Flights
- European Railroads
- Nuclear Power
Why?  
Reason’s ‘Swiss cheese’ model of organizational accidents

Some holes due to active failures
Other holes due to latent conditions

Successive layers of defenses
Human error: models and management James Reason
BMJ 2000;320:768
Quality/Utilization/Liability

- Maintaining or Improved Quality
  - Outcomes?
- Reduced Utilization
- Increased liability

- The simple physics of medicine
Provider Interests

- Quality
  - Pride?
- Utilization
  - Economics?
- Liability
  - Pride & Economics
Alternatives

• If you can’t swim don’t get in the water
• Do it better and safer
• Mitigate risk
  – Foreseeable risk from Unforeseeable outcomes
  – Unforeseeable: Global v. Individual
What makes patient selection/prediction nearly impossible?

• #1 History
• #2 Variation in disease presentation
  – Physical findings
  – Diagnostic variability
• #3 Translation of data: Population-Based
LIMITATIONS OF APPLYING SUMMARY RESULTS OF CLINICAL TRIALS TO INDIVIDUAL PATIENTS

The Need for Risk Stratification

David M. Kent, MD, MS
Rodney A. Hayward, MD

THERE IS GROWING AWARENESS THAT THE RESULTS OF randomized clinical trials might not apply in a straightforward way to individual patients, even those in the trial. Although randomization theoretically ensures the comparability of treatment groups overall, there remain important differences between individuals in each treatment group that can dramatically affect the likelihood of benefiting from or being harmed by a therapy. Averaging effects across such different patients can give misleading results to physicians who care for individual, not average, patients.

The limitations of subgroup analyses—the conventional means for exploring differences in treatment effect based on patient characteristics—are well appreciated. Because patient characteristics influence disease severity, it is possible that the effect of a treatment may vary with the characteristics of patients. The differences in patients enrolled in different trials or those treated in different settings can also result in variable benefit and harm. These differences may be due to random errors in treatment assignment or to confounding variables that were not accounted for in the trial design. The lack of information on these variables can result in a misunderstanding of the treatment effect.

For example, consider a hypothetical trial in which we compare two treatments for a disease. In the trial, we observe a significant difference in survival between the two groups, with the treatment group having a higher survival rate than the control group. However, when we analyze the subgroup of patients who were smokers, we find that the treatment group has a lower survival rate than the control group. This suggests that the treatment is less effective in smokers than in non-smokers.

Therefore, we cannot simply apply the results of a clinical trial to all patients. Instead, we need to consider the characteristics of the patients in the trial and how those characteristics might affect the treatment effect. This is known as risk stratification.

Risk Stratification

David M. Kent, MD, MS
Nicky D. Shah, PhD

All models are wrong, but some are useful.

George Box

A fundamental contradiction of evidence-based medicine (EBM) is that evidence is derived from groups, whereas medicine is applied to individuals. Individual differences from average group effects is an example of the fallacy of division. Even in a randomized trial, benefit in a summary rate does not imply that the probability of benefit is greater in a subgroup than in the overall population. Consider the use of aspirin for prevention of coronary heart disease (CHD). Based on a comprehensive pooled analysis of 6 trials including more than 90,000 patients, guide lines agree that use of aspirin is helpful for high-risk patients (ie, those with a 20% or greater 10-year risk of CHD), but not for lower-risk patients. The American Heart Association (AHA) guidelines recommend targeting aspirin to patients with a 10-year risk of CHD higher than 10%.

The Framingham Risk Score (FRS), the Atherosclerosis in Communities (AIC) risk score, and the Reynolds Risk Score (RRS) are validated models that estimate CHD risk. Although all incorporate similar cardiac risk factors, the FRS and AIC score were developed using population-based cohorts; the RRS was derived from the Physicians’ Health Study (for men) and the Women’s Health Study (for women). However, applying each of these 3 risk models in a nationally representative population showed that 39% of men and 21% of women exceed the AHA threshold for aspirin therapy using one model but not the other.

In conclusion, the results of clinical trials should not be applied to all patients. Risk stratification is necessary to determine the most appropriate treatment for each individual patient.

REFERENCES


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The Law of Unintended Consequences

GOOD INTENTIONS
bad results
Examples

• Chest Pain

• Pulmonary embolism
Chest Pain

• ACS or not?
• MACE rate 1-2% Despite what we do
  – Highly sensitive troponin
  – CPUs
  – Coronary CTA
  – Etc., Etc.
Pulmonary Embolism

- To follow PERC or not to ....
- Good risk stratification tool?
- Population’s vary
- Approximately <2% miss rate (Initial study)
- THE PULMONARY EMBOLISM RULE-OUT CRITERIA (PERC) RULE DOES NOT SAFELY EXCLUDE PULMONARY EMBOLISM
  – 5.4% Miss Rate
Safe Harbors: A Viable Solution

• First Steps ..... 

Doctors win first safe harbor against ACA use in liability suits

“This legislation provides that lawsuits cannot be brought against health care providers based simply on whether [they] followed national guidelines created by the health care law,” Dr. Gingrey stated in an email. “This bill reinforces my belief that medical decisions must be made between patients and their doctors. The practice of medicine is not one-size-fits-all. It must be protected from policies or rules that may threaten a physician's ability to treat patients according to their specific needs.”
Safe Harbors: A Viable Solution

• Next steps .....
Safe Harbors: A Viable Solution

Next steps ..... 

The word “safe” in “safe harbor” suggests stronger legislation, to make guidelines conclusive evidence of appropriate care. This would go farther than Maine’s legislation or Senator Wyden’s bill. If safe harbors created an irrebuttable presumption, plaintiffs simply could not contend that the guidelines are wrong and that a jury should instead believe a different standard articulated by an expert witness.
Safe Harbors
May not be the only solution...
But a critical factor to guideline acceptance

Thank you