

Patient Safety and the Legal System: Trials and Tribulations

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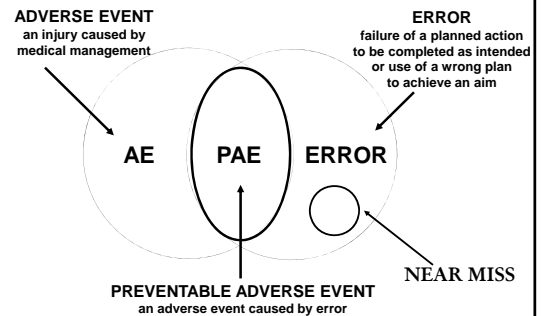
Agenda

- Patient Safety 101
- Current legal system
- Proposed alternatives
- Limited no fault system - NICA

Patient Safety 101

1. Incidence of Medical Errors
2. Reasons for Medical Errors

Key Definitions



IOM – November, 1999



44,000-98,000 (3.7% error rate) deaths annually (more die each year than the entire Vietnam War, or motor vehicle accidents or breast cancer).

Lucian Leape, MD

Leading Cause of Death 1999

1. Cancer — 156,485
2. Heart disease — 115,827
3. Medical errors 98,000
4. Injuries — 46,045
5. Suicide — 19,549
6. Cerebrovascular disease — 18,369
7. Diabetes — 16,156
8. Respiratory disease — 15,809
9. Chronic liver disease and cirrhosis — 15,714
10. HIV/AIDS — 14,017

Sources: U.S. Department of Health and Human Services, National Center for Health Statistics, *Health, United States, 2002*, Table 33, p. 132 — deaths for causes;

To Err is Human – To Delay is Deadly
Consumer Reports, SafePatientProject.org 2009

“Despite a decade of work, we have no reliable evidence that we are any better of today. More than 100,000 patients still needlessly die every year... We have failed to make the systemic changes in health care needed to end preventable medical harm.”

Jim Guest, President
Consumers Union

**A million deaths is a statistic;
A single death is a tragedy.**

Joseph Stalin

Patient Safety 101

1. Incidence of Medical Errors
2. Reasons for Medical Errors

REASONS FOR ERRORS

- HUMAN FALLIBILITY
- COMPLEXITY OF MEDICINE
- SYSTEM DEFICIENCIES
- VUNERABILITY OF DEFENSE BARRIERS

**Human
Fallibility**

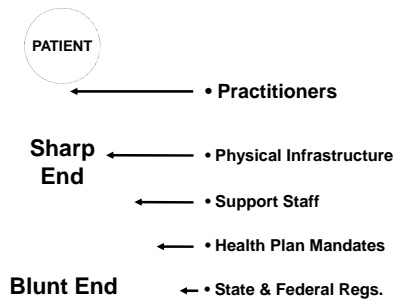
COMPLEXITY

“...modern health care is the most complex activity ever undertaken by human beings.” Ken Kizer

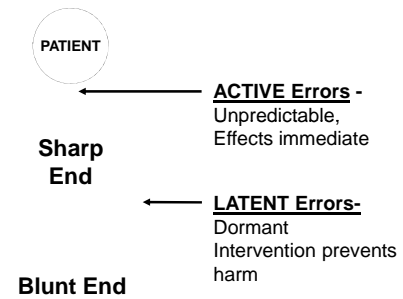
- Highly complicated technologies
- Panopoly of powerful drugs
- Widely differing professional backgrounds
- Unclear lines of authority
- Highly variable physical settings
- Unique combinations of diverse patients
- Communication barriers
- Care processes widely vary
- Time pressured environment

SYSTEM DEFICIENCIES

Working at the Sharp End



Working at the Sharp End



Examples of Latent Errors

- Staffing ratios
- Communication
- Engineering
- Purchasing
- Accounting
- Laboratory
- Pharmacy
- Telephone
- Credentialing
- Peer review
- Security
- RN&MD competency
- CME
- Medical records
- Paging systems
- Information services

Complications Associated with Decreased RN Staffing

- Urinary Tract Infection
- Pneumonia
- Gastrointestinal Bleeding
- Shock
- Deep Vein Thrombosis
- Sepsis

NEJM 2002

Correlation of Staffing Ratios to Risk of Death

- 1:4.....Ideal Staffing
- 1:57% Increase
- 1:6.....14% Increase
- 1:7.....23% Increase
- 1:8.....31% Increase

JAMA 2002

Balancing personal accountability with system failures

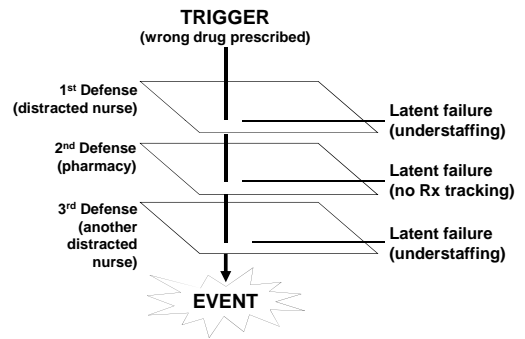
Latent system errors do not absolve the individual but makes error recognition and mitigation *everyone's* responsibility!

“Ritz Carlton Credo”
“Just Culture”

DEFENSIVE BARRIERS

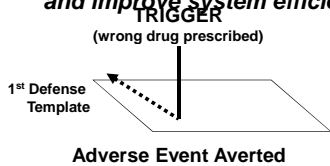
“SWISS CHEESE” THEORY

Defensive Barriers

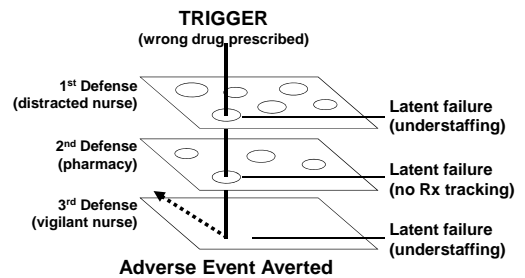


Defensive Barriers

Standardized approaches can reduce variability and improve system efficiency



Defensive Barriers



Reason J Human error: Models and Management, *BMJ*, 18 March 2000.

Defense Barriers

- Professional Communication
- Training
- Quality Management
- Knowledge
- Information technology
- Credentialing
- Peer review
- Protocols, pathways, policies
- Redundancy
- Forcing functions

Strategies to Improve Patient Safety

Individual Focus

~~■ Try harder — Punishments and Rewards~~

System Focus

- Forcing Functions, Reminders at the POC
- Reduce Complexity
- Eliminate Latent Errors
- Decrease vulnerability of defensive barriers

ASK "WHAT HAPPENED"
NOT "WHO DID IT"

"Adverse outcomes are *system deficiencies*, not human error. Most medical errors are not committed by incompetent or negligent practitioners."

David Shapiro, MD, JD

Current Legal System

Purpose of torts

- Compensate injured party
- Punish party at fault
- Deterrent to prevent recurrent substandard care
 - Individual or enterprise

Purpose of Patient Safety Interventions

- Compensate injured party
- "Just Culture"
- Change the medical system to prevent future recurrence

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Malpractice Liability and Medical Error Prevention- Strange Bedfellows

Michelle Mello, JD, Ph.D., M.Phil.

Tort System

- Punitive
- Individual Focus
- Adversarial Process
- Privileged information

Patient Safety

- Nonpunitive
- System Focus
- Cooperative Process
- Transparency

Barriers to Tort as Deterrence

- Liability insurance not experience rated
- Cost externalization
- Unreliable - Lack of correlation of actual negligence and litigation
- Lack of Consistency - Physicians view the professional liability system as capricious

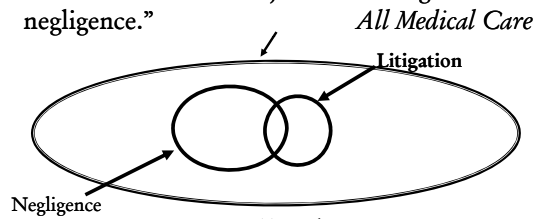
ATR Judicial Hellholes - 2010

“Places where judges systematically apply laws and court procedures in an unfair and unbalanced manner, generally against defendants in civil lawsuits”

- South Florida
- West Virginia
- Cook County, Illinois
- Atlantic County, NJ
- New Mexico Appellate Court
- New York City

Harvard Medical Practice Study

“...Malpractice suits correlate poorly with the actual occurrence of injuries resulting from negligence.”



Brennan TA, et al NEJM 1996

Harvard Medical Practice Study

	Negligence	Adverse event	Adverse event & Negligence
Plaintiff Verdict	42%	46%	55%
Mean Payment	\$28,000	\$98,000	\$67,000

“the severity of the patient's disability, not the occurrence of an adverse event or an adverse event due to negligence, was predictive of payment to the plaintiff.” Brennan TA, et al NEJM 1996

Disability	None	Temporary	Permanent
Plaintiff Verdict	42%	29%	88%
Mean Payment	\$29,000	\$39,000	\$201,000

Defensive Medicine

“When doctors order tests, procedures, or visits, or avoid high risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice liability.”

Office of Technology Assessment
U.S. Congress, July 1994

Defensive Medicine (cont.)

- Fear of litigation – Emotional impact
- Physicians may not be aware they are being defensive
- Defensive medicine may, in some cases, be beneficial.
- < 8% diagnostic procedures are consciously defensive

Reducing Defensive Medicine OTA, July 1994

- Decrease malpractice concerns via traditional tort reform
- Change malpractice laws in conjunction with health system reform
- Practice guidelines to define legal standard of care
- Demonstrations projects to limit physician involvement in litigation process

Patient Safety & Professional Liability “Two Sides of the Same Coin”

- Liability Reforms –Will reduce economic losses and stabilize Premiums
 - Caps on Non-Economic Damages
 - Collateral Source Offset
- Patient Safety Initiatives
 - decrease hazards,
 - fewer patient injuries,
 - fewer compensable events

Alternatives to the Tort System for Medical Errors

Alternatives Dispute Resolution

- Health Courts
- Mediation & Binding Arbitration
- Enterprise Liability
- Guidelines as Affirmative Defense
- Pre-trial Screening Panels
- Disclosure and Early Offer Programs
- Designated Compensable Events (No Fault)

Disclosing Health Care Injury

If Error contributed to health care injury:

1. Compassionate & truthful explanation (apology)
2. Remedies available
3. Steps to reduce likelihood of similar injuries

National Patient Safety Foundation
Statement of Principle, 2000

Disclosure & Offer Programs

Mello M & Gallagher T, NEJM April 2010

	Financial Comp.	May still sue	Negligence as Threshold
Reimburse model (3R's)	Preset Limit	Yes	Not Necessary
Early Settlement	No Limit	No	Yes
Health Courts	No Limit	Limited Judicial Appeal	Yes

Comparison of U.S. Medical Malpractice and N.Z. No-fault Systems

	U.S.	N.Z.
Eligibility	Negligence	Treatment injury
Expert advisers	By parties	By ACC
Decision maker	Lay jury	Admin. panel
Time to resolve	Years	Weeks - months
Admin Costs	High	Low (<10%)
Insurance costs	High	< \$1000 USD
QI process link	Theoretical	Direct

FLORIDA BIRTH RELATED
Neurological Injury Compensation Act
January, 1989

Neurological Injury Compensation Act

- A. Development and Implementation
- B. Impact of NICA-15 Years Later
 1. Economic
 2. Ethical
- C. Future Considerations

Neurological Injury Compensation Act-FS 766.301

Legislative Findings and Intent:

- “Any birth other than a normal birth frequently leads to a claim against the attending physician.”
- “The cost of birth related neurological injury claims are high and warrant the establishment of a limited system of compensation irrespective of fault.”

NICA – Inclusion Criteria

- Live Birth
- Birth Weight
 - > 2500 grams singleton
 - > 2000 grams multiple birth
- Oxygen Deprivation or Mechanical Injury
- Occurring During
 - Course of Labor
 - Delivery
 - Resuscitation Immediately after Delivery
- Resulting in Permanent and Substantial Mental and Physical Impairment
- Excludes Genetic & Congenital Anomalies

NICA Funding

- Initial capitalization from State Funds
- \$5000 per participating obstetrician
- \$250 from all other licensed physicians
 - Limited exceptions (VA, Military, Retired, Volunteers)
- \$50/birth from every OB facility
- “Backstop funding” from professional liability insurance (up to 0.25%)

“Tort Reforms” Incorporated in NICA

- \$100,000 cap on non-economic damages
- Administrative judge (not a jury)
- Collateral source offset
- Structured Payout
- Limitation on Attorney’s Fees
- Shortened Statute of Limitations
 - General Statute – 7 years
 - NICA Statute- 5 years

Neurological Injury Compensation Act

A. Development and Implementation

B. Impact of NICA – 15 Years Later

1. Economic
2. Ethical

C. Future Considerations

ECONOMIC

NICA reduced obstetrician’s premiums and increased patient benefits

NICA IS EFFICIENT: Most of premium dollars go patient

(Data from K. Shipley, NICA; R. White, EPIC)

	NICA	TRADITIONAL TORT SYSTEM
TRANSACTION COSTS (Atty. and Admin. Fees)	17%	61%
PATIENT BENEFIT	83%	39%

Economic – Physicians
Turner Consulting
2007

	Participating Obstetrician	Non- Participating Physician
Annual Premium Reduction	\$55,900- 95,500	\$1,400

EFFICIENT

Rapid Claim Resolution

	Time to Resolution (Days)
NICA (Paid Claims)	148
Comparable Tort Cases	591

ETHICAL & EQUITABLE

“IT’S THE RIGHT THING TO DO”

**NO FAULT
SYSTEM.....**

Not an adversarial system

CAUSES OF FETAL INJURY
93 NICA CLOSED CASES
(Stalnaker, 1997; Shipley 2003)

	Percent
Non Reassuring Fetal Heart Rate	46
Meconium Aspiration	14
Uterine Rupture	14
Suboptimal Care	9
Operative Delivery with ICH	9
Shoulder Dystocia	5
Abruptio Placenta	3

New York Post Editorial

William Tucker, February 10, 2003

What is truly shameful is the way plaintiff's bar has used cerebral palsy to grow rich... Cerebral palsy is a condition for which no one is to blame. Yet the plaintiff's bar continues to ravage doctors and hospitals because that's where the money is... *Malpractice suits over cerebral palsy are a cynical, unprincipled exploitation of nature's tragedies.*

Neurological Injury Compensation Act

- A. Development and Implementation
- B. Impact of NICA-14 Years Later
 - 1. Economic
 - 2. Ethical
- C. Future Considerations

Future of NICA

Governor's Academic Taskforce,
February, 2003

- "The legislature should maintain the NICA program because of its success and should further consider and study the issues for broadening the NICA program.."
- Lower birth weight criteria
- Change proof of injury from "mental *and* physical impairment" to "mental *or* physical impairment"

Future of NICA

FL OB/GYN Soc. & NICA Proposal

- Explicit coverage for Erb's Palsy
- Enroll NICA beneficiaries in KidCare Program
- Protect NICA Trust Fund

Conclusions

- Medical Errors are usually the result of system deficiencies not negligent practitioners
- Current tort system frequently impedes meaningful system analysis and improvement
- There is no ideal alternative to the tort system
- A very limited no fault alternative in Florida and disclosure and early offer programs places the patient interests first