Disclosure & Early Offer: How it Started, where it is Going.

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The Good Old Days

Sudden Death during an Operation.—A most melancholy event happened lately in the surgical practice of M. Dupuytren, which involves some curious physiological and surgical considerations. On the 19th November, 1822, a fine young woman (Alexandrine Poirier) came to the Hotel Dieu, for a tumour of some size, situated on the posterior and lateral part of the neck. From its hardness, renitency, and insensibility, M. Dupuytren ascertained that it was of a cellulo-fibrous nature, and proposed its removal, to which the young woman consented. The operation was performed on the 22d of November, with all the skill and dexterity of that celebrated surgeon. No arteries were cut that required the ligature, and consequently, there was very little hemorrhage. Neither were there any muscles or large nerves divided. Just, however, as he was proceeding to separate the last shreds of attachment, and turn the tumour out, he was surprised to hear a somewhat prolonged hissing noise (sifflement prolongé) similar to that produced by the re-entrance of air into a vessel from which it had been exhausted. The operator stood for an instant astonished, and observed, that, were it not for the distance of the knife from the air passage, he would have thought that he had made an opening into it. He had scarcely said the word, when the young woman cried out that she was dying, and instantaneously dropped down on the floor a lifeless corpse, to which all their efforts could not restore the slightest symptom

First published:
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The Good Old Days

of animation. This happened in the presence of nearly 400 spectators, and the body was examined next day, in the presence of full as many, with the most rigorous minuteness.—Every part of the body was carefully dissected; but there was not a particle of morbid structure any where to be found. An examination of the heart, however, disclosed the cause of the melancholy catastrophe. The right auricle was distended like a bladder with air, which rushed out when cut open, without any admixture of blood. Fluid blood was found in the other cavities of the heart, as also in the different vessels. Great quantities of air were found in all the vessels. There was no other unnatural appearance in any part of the body.

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We have not the smallest doubt, that Dupuytren was perfectly correct in his conclusion, that air had rushed in through one of the veins of the neck, and thus caused instant death. It is, perhaps, the only case on record of the kind, and so unlikely to happen often, that it can be no serious objection to any operation on the neck or other part of the body. We think it is a pathological fact, however, which bears on the physiology of the circulation. It proves that the heart acts as a sucking as well as a forcing pump, otherwise air would never have passed from a cut vein in the neck down into the right chambers of the heart. It is highly probable, that, in consequence of the morbid state of the parts, the mouth of the cut vein had remained patulous, and thus readily admitted the air.
Medico-Chirurg. Review.

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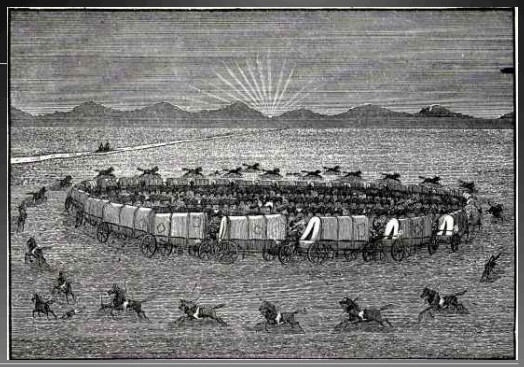
What Happened?

- Before ~1840, medical malpractice cases were rare
- After 1840, the number of actions against doctors for violating standard of care causing patient injuries increased.
  - Mohr JC. American medical malpractice litigation in historical perspective. *Jama*. Apr 5 2000;283(13):1731-1737.
- Doctors now needed malpractice insurance and soon could not work without it.
- The insurance companies, financially at risk, determined what could and couldn't be told to patients.



Professionalism?

- Are we proud that we let risk managers and insurers behave this way on our behalf?
- Is this transparent? Does it support patient care?
- Is this professional?

Professionalism?

How is Such Behavior Rationalized?

- In medical risk management, the only reason that deny & defend has predominated until recently is the certain belief that to do otherwise would have caused financial disaster.
- Why is this? (Who's fault is this?)
  - Plaintiff's attorneys
  - Contingency payment system
  - Irrational juries

This Outlook is Changing

Dec 1999

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MEDICINE AND PUBLIC ISSUES

Risk Management: Extreme Honesty May Be the Best Policy

Steve S. Kraman, MD, and Ginny Hamm, JD

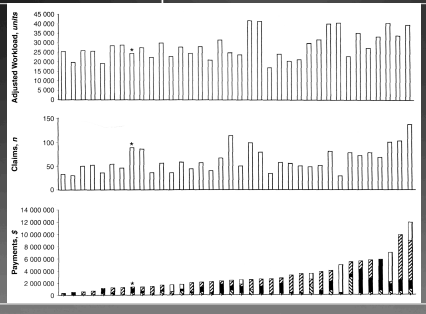
This paper reviews a humanistic risk management policy that includes early injury review, steadfast maintenance of the relationship between the hospital and the patient, proactive full disclosure to patients who have been injured because of accidents or medical negligence, and fair compensation for injuries. The financial consequences of this type of policy are not yet known; however, one Veterans Affairs medical center, which has been using humanistic risk management since 1987, has had encouragingly moderate liability payments. The Department of Veterans Affairs now requires such a policy for all of its facilities; therefore, comprehensive experience may be only a few years away.

Ann Intern Med. 1999;131:963-967.

sulted in awards to the plaintiff. Of the 90 awards made, the median amount was $463 000, 26 exceeded $1 million, and 12 exceeded $10 million.

Under the Federal Tort Claims Act (6), the United States is not liable for punitive damages. However, federal judges have wide discretion in determining awards. The upper limit on the size of an award is determined by the plaintiff's claim and by the applicable state law of damages. In cases that involved egregious negligence and resulted in awards of millions of dollars, we inferred that the high assessments were substitutes for punitive awards. Press and DeFrances (5) found that a mean of more than 2 years was spent in litigation in each of

Financial Consequences - 7 Yrs.



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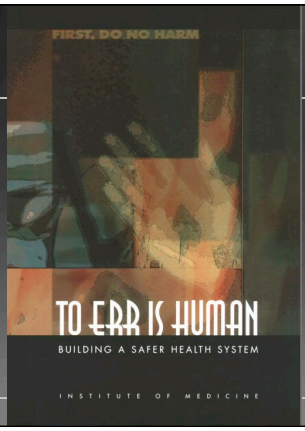


How it Started

- Risk Management Committee – 1987
- Damage control: case dossiers to protect facility
- Wrongful death case involving a med error – family did not know and had no way of knowing
- Decision to "do the right thing"
- Disclosure
- Settled within several weeks at fair (reasonable) cost.

Since Then…

- First case seemed successful, felt right
- Followed this model since then
- Analyzed financial impact and published results (1999)

What We Did. . .

- Practitioners and others identify ***potentially*** compensable incidents
- Case and peer reviews determine:
  - Standard of care violation?
  - Medical error?
  - Patient injured or worse?
- Involve practitioners in reviews and discussions
- Come to consensus re: need for disclosure
- Make open and honest disclosure
- Discuss settlement options

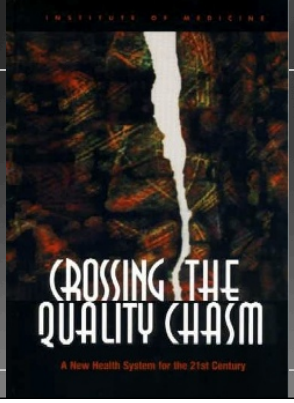
Disclosure: What Did We Tell Them?

- The facts
  - Directly
  - Sympathetically
  - Completely
  - Accepting full responsibility (apology)
  - Describing what we have done to prevent future incidents.

What Else?

- Advise them to retain an attorney experienced in malpractice litigation to represent them.
- Why?
  - Reassures patient of fair treatment (Avoids "buyer's remorse.")
  - Reassures us that we can negotiate with someone who understands damages.
  - Regardless of our good intentions, we were VA employees with a primary responsibility to our employer. The patient should have his own advocate.
- If they didn't want a lawyer, we negotiated directly with them

Mar 2001



On	PAGE 62	... The need for **transparency**. The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a ...
On	PAGE 63	... **Transparency**: Your care will be confidential, but the care system will not keep secrets from you. You can know whatever you wish to know about the care that ...
At the bottom of	PAGE 67	... **Transparency** is necessary....
At the bottom of	PAGE 79	... Rule 7: Need for **Transparency**...
At the bottom of	PAGE 79	.... In the current system, concern about the burden of reporting and oversight, litigation, and blame has generated conflict and mistrust and cast **transparency** in its most negative light, resulting in resistance to disclosure of all kinds....
On	PAGE 80	..., improving the health care system cannot wait for such change to occur. Some organizations have successfully implemented programs of increased **transparency** despite the liability risk (Peterkin, 1990). Indeed, some evidence shows that open disclosure of errors may decrease the likelihood of malpractice ...
On	PAGE 80	... In the future health care system envisioned by the committee, **transparency** is the route to accountability--the identification of who is responsible both financially and clinically for the actions of health care ... aggregate (non-personally identifiable) research data and information about the quality of care. A health care system that operates under a rule of **transparency** will be more patient-centered and safer because patients will be able to recognize outdated and wrong information and to share in information that ...

Followed by:

- "Transparency" becomes buzzword
- JCAHO (2001) requires hospitals to disclose the "unanticipated outcomes" to patients/families
- Press and commentators focus on apology
- "Sorry" becomes buzzword
- Apology exclusion laws passed in (about) 36 states
- Several hospital and healthcare systems announce adoption of disclosure practices, often associated with a public disclosure.

Hospitals and Hospital Systems Reporting Adoption of Disclosure Practices

- Univ. of Michigan
- Indiana Methodist Hospital
- Univ. of Tampa Med. Ctr.
- Johns Hopkins Hosp.
- Rush Univ. Med. Ctr.
- Methodist Hospital (Omaha)
- Stanford Med. Ctr.
- Shands Med. Ctr. (Gainsville)
- Park Nicollet Hospital (Minnesota)
- Tampa General
- Minneapolis Children's Hospital
- Virginia Mason Medical Ctr (Seattle)
- VA Healthcare System
- Harvard Affiliated Hospitals
- Catholic Health Initiatives
- Catholic Health West
- Kaiser-Permanente
- Geisinger Health System

Univ. of Michigan

- Began a program styled after Lexington's in 2003
- Claims, average litigation and attorney fees and ave. time to case completion decreased and remained down.

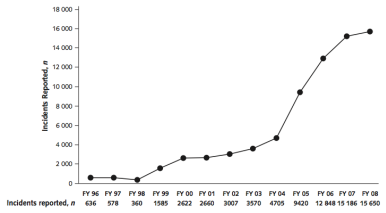
University of Michigan

- Published in 2010*, reporting remarkable decreases in suits, costs, trials and time to resolution. Also, as we had 11 years before, they linked the openness of such a program with patient safety benefits due to reduced need for secrecy surrounding errors.

*Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Annals of internal medicine. 2010;153(4):213-21.

Univ. of Michigan

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.

University of Illinois

- 2011, the Univ. of Chicago published details about their risk management and patient safety program* using similar concepts and processes as the Univ. of Michigan and the Lex VA.
- Their program was only two years old when published. Did not report amounts but did claim no increase in either number of suits or payouts.

* McDonald TB, Helmchen LA, Smith KM, Centomani N, Gunderson A, Mayer D, et al. Responding to patient safety incidents: the "seven pillars". Quality & safety in health care. 2010;19(6):e11.

Disclosure Initiatives in Other Countries

- Canada
- United Kingdom (NHS Redress, passed 2006, relaunched 2009)
- Wales (NHS Redress) 2008
- Australia (piloting different models)
- New Zealand (No fault since 1970s)

Copic's 3 Rs Program

- ***Recognize, Respond, Resolve***
- Numerous anecdotes of patient gratitude and MD satisfaction
- Patients usually continue to see same physician
- $30,000 cap on payments
- Patients do not waive their right to sue
- Exclusions: Death, written demand for money, hiring an attorney…

MACRMI

Massachusetts Alliance for Communication and Resolution following Medical Injury

- Started in 2012
- *"MACRMI is a Massachusetts alliance of patient advocacy groups, teaching hospitals and their insurers, and statewide provider organizations committed to transparent communication, sincere apologies and fair compensation in cases of avoidable medical harm."*

MACRMI

Massachusetts Alliance for Communication and Resolution following Medical Injury

"Mission:

MACRMI is committed to the implementation of Communication, Apology, and Resolution (CARe) following medical injury. Prompt recognition of, and response to, medical injury, along with appropriate compensation to the patient or family, has demonstrated potential to improve patient safety, reduce medical costs, and enhance fairness and transparency in health care. It is, simply, the right thing to do."

More info at: http://www.macrmi.info/about-macrmi

Advocacy Groups

- MITSS (Medically Induced Trauma Support Services)
- Mothers Against Med Errors
- Pulse of NY
- Jeni D Safer-Healthcare
- Justin's Hope
- SorryWorks Coalition
- Citizens for Patient Safety.
- Etc…

Academics

- Since 1999, >400 peer-reviewed studies, reviews and commentaries published in the medical literature alone (more in the legal literature). Virtually all supportive, many claiming, with little supportive data, cost savings. Some arguing, with ***no*** data, increased costs.

Do We Need More Research?

- Too few data points to know the eventual financial consequences of adopting a disclosure and early offer practice rather than deny & defend.
- Too few data points to know the eventual consequences of adopting "Thou shalt not steal" rather than "go ahead and steal."
- It isn't a science question. It is a decision on how to behave.
- It involves administrative competence.

Administrative Competence*

- *Risk management is a pragmatic, businesslike and unsentimental system based first on working hard to know the difference between reasonable and unreasonable care and next, resolving to take advantage of no one and allowing no one to take advantage of you.*

*Paraphrased from Boothman and Kraman: http://www.sorryworks.net/article31.phtml

Obstacles

- Disbelief
  - Starry-eyed liberals
  - May work but only in certain hands
- Some published research suggests that disclosure practices could cost more by inviting many more claims
- Defense attorneys are trained to defend, not coddle
- Lots of money at stake. Who gets blamed if we try this and it doesn't work?
- People who sue and their lawyers don't deserve our respect or compassion.

What Disclosure and Early Offer is ***Not***

- Only comes into play when an actual error (std. of care violation) is made and damage is done.
  - (The legal standard that, if proven in court, would result in an award)
- When the doctor or hospital has done no wrong:
  - Still be transparent
  - Maintain professional relationship with patient
  - Try to correct erroneous impressions of wrongdoing
  - Cooperate with patient's attorney
  - Decline any settlement

Questions?