Disclosing Unanticipated Outcomes to Patients: International Trends and Norms

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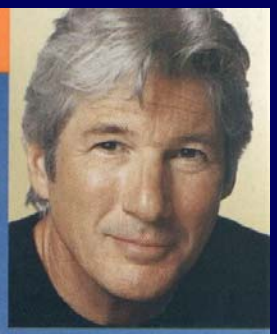
Accelerating Interest in Disclosure

- Growing experimentation with disclosure approaches
  - International disclosure programs
  - Healthcare organizations
  - Malpractice insurers
- New standards
- Laws re disclosure, apology
- Increased emphasis on transparency in healthcare generally

Cut Car Insurance 50%

rd.com

Reader's Digest



Richard Gere's surprising path to happiness

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FATAL HOSPITAL MISTAKES

How to Avoid Them

PAGE 94

Exclusive Survey

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Why Sex Only Gets Better

February 2003
$2.99

PLUS ChangeOne Diet: What Makes You Eat ▪ Daredevil Stunt Sisters ▪ Lost in the Wilderness

Solving An Almost Perfect Murder

Disclosure Performance Gap Also Increasingly Evident

- Harmful errors often not disclosed
- When disclosure does take place, often falls short of meeting patient expectations
- Little prospective evidence exits regarding what disclosure strategies are effective
- Impact of disclosure on outcomes unclear
  - Debate continues re impact of disclosure on litigation

"Listen up, my fine people, and I'll sing you a song 'bout a brave neurosurgeon who done something wrong."

International Trends/Norms

- United States
  - Disclosure policies-National Quality Forum
  - Disclosure-and-offer programs
  - State apology and disclosure laws
- Australia: Open Disclosure
- UK: Being Open
- Canada: 2008 Canadian Disclosure Guidelines
- New Zealand
- Looking forward

US Disclosure Policies

- 2001-Joint Commission policy on disclosing unanticipated outcomes
  - Virtually all US hospitals now have disclosure policy
- 2006-Harvard Consensus Statement “When Things Go Wrong”
  - Emphasized importance of accepting responsibility, apologizing
- 2007-National Quality Forum Safe Practice

NQF Safe Practices

- 30, consensus-based standards
- Harmonized with JCAHO, CMS, IHI, Leapfrog, AHRQ
- Disclosure 1 of 2 new Safe Practices
- Final report release 3/2/07
- Used in pay-for-performance
- Hospital-specific performance on each Safe Practice available on Leapfrog website

Leapfrog Hospital Ratings

Search Results: **Zip:** 98105 **Radius:** 10 Miles
Below are the results of your search. Click on the "leaps" and the circles for more details.

Survey Info | Scoring Info | Start Over

Click to Compare	Hospital Name	City	Leap1	Leap2	Leap3								Leap4				
					High Risk Treatments												
			CPOE	ICU	CABG	PCI	AAA	Esoph.	Panc.	Bariatric	Aortic Valves	NICU	Safe Practices Score	Transparency Indicator	Adherence to Never Events Policies	Leapfrog Hospital Insights Reporting Hospital	Survey Results Submitted
☑	EVERGREEN HEALTHCARE	Kirkland, WA															6/25/2007
☑	HARBORVIEW MEDICAL CENTER	Seattle, WA			NA	NA				NA	NA	NA					6/06/2007
☑	UNIVERSITY OF WASHINGTON MEDICAL CTR	Seattle, WA															6/15/2007
☑	VIRGINIA MASON MEDICAL CENTER	Seattle, WA										NA				✓	7/23/2007

Compare hospitals above: GO!

Safe Practices Score

The Safe Practices score consists of individual scores on the following 27 health care practices. The number to the right of each bar below indicates the total number of points possible for meeting each practice. The gray portion of each bar indicates the extent to which the hospital has met the standard for each practice.

(more info on scoring)

UNIVERSITY OF WASHINGTON MEDICAL CTR (website)
1959 Ne Pacific St/box 356151, Seattle, WA 98195

Practices	
Safety Culture	
Element 1: Establish leadership structures and systems	120
Element 2: Invest in performance improvement	20
Element 3: Teamwork training and skill building to promote patient safety	40
Element 4: Identify and mitigate risks and hazards	120
Nursing staff meets patients' needs	100
Non-nursing staff meets patients' needs	20
Communication Among Health Care Workers	
Timely clinical information for other caregivers and patients	84
Repeat verbal orders and critical test results	25
Prevent mislabeled x-rays	15
Discharge summary available for follow-up care	25
Use standardized abbreviations and doses	11
Doctor and Patient Communications	
Patient can repeat details of condition and treatment	4
Patient preferences are prominent in chart	4
Patient notified of problems in care delivery	25
Prevent Infections	

Overview of Disclosure Safe Practice

- Emphasizes transparency as core value
  - Risk management implications important, but secondary
- Links disclosure with performance improvement
- Articulates process of disclosure
- Details institutional disclosure support system
  - Background education for healthcare workers
  - Just-in-time coaching
  - Emotional support for patients, families, healthcare workers

Content of Disclosure

- Empathic communication of **the facts** regarding the outcome and its preventability
- Expression of regret (all unanticipated outcomes)
- Commitment to investigate and prevent future occurrences

“The Facts”

- Explicit statement about what happened
- Explanation of why event occurred and its preventability, to the extent known
- Explanation of the consequences of the unanticipated outcome for the patient’s future health

Additional Content: Feedback of Results

- Results of investigation relevant to unanticipated outcome are communicated to patient, including whether the unanticipated outcome resulted from an error or system failure, in sufficient detail to support informed decision-making by patient.

Apology

- Expression of regret appropriate for all unanticipated outcomes
- Apology when unanticipated outcome clearly caused by unambiguous error or system failure

Institutional Disclosure Support System

- Emotional support for patients, families, healthcare workers
- Disclosure education/skill building
- Provide disclosure coaching 24/7/365


Mister Boffo - By Joe Martin
THIS PROBABLY ISN'T GOING TO MEAN MUCH TO YOU...BUT WE TOOK YOUR BRAIN OUT AND MISPLACED IT!
JOE MARTIN

Apology Laws

- 35 states have adopted apology laws to date
- Protection varies widely
  - Does not mean you can't be sued if you disclose
- 7 states mandate disclosure of some events to patients
- Impact of these developments likely to be limited

University of Michigan

- In five years since implementing full disclosure program:
  - Annual litigation costs:
    - $3 million ⇒ $1 million
  - Average time to resolution of claims:
    - 20.7 months ⇒ 9.5 months
  - Number of claims and lawsuits
    - 262 ⇒ 114

COPIC

- Large Colorado malpractice insurer
- Developed “3Rs” Program in 1998
- Program seeks to promote disclosure, early offer following unanticipated outcomes
- Exclusions-patient death, attorney involvement, complaint to BME
- Patient not asked to sign waiver
- Payments not reportable to NPBD

3Rs Processes

- Event reported
- Physician and COPIC in accord as to intervention
- Doctor tells patient about program, engages in disclosure process, and puts them in touch with 3Rs administrator
- Coaching often required
- 3Rs Administrator supports physician and patient/family and reimburses upon obtaining receipts for out of pocket expenses

3Rs Program Highlights – 50 Month Financial Results (10/1/00-12/31/05)

Participants	2532	310 for all 50 months; 1713 for 38/50 months
Reported Incidents	4674	Cornerstone = Early Incident / Event Reporting
3Rs Criteria Met	2174	No incident with 3R criteria met has proceeded to full litigation
Closed with no $ Paid	1622	1235 of 2174 closed and 387 about to close with no $ paid, simply satisfactory communication
Closed with payment	500	259 closed and 241 about to be closed with payment
Sent to Claims	52	4 of 52 settled w/o lawyers, indemnity paid, & docs reported; 12 also with 3R payments (no offset, not reported)
Spent so far	$2,908,137	About 50/50 spent so far for reimbursable expenses and loss of time
Average paid per incident	$5,680	Compared to avg. severity in 2003 of $88,056, and in 2004 of $74,643, and in 2005 of $77,936
Dollar range per incident	$95 -$30,000	$30,000 maximum allowed
Operational Costs	$975,899	Two FTE administrators; 1 P/T physician, 1 secretary, managerial consulting
Total Program Cost	$3,884,036	All costs (reimbursement $, time loss $, & Administrative $) over 63 months

Role of Compensation in Disclosure Process

Australia: Open Disclosure

- Open Disclosure Standard adopted 2003
- Focus on adverse event
- High, low level events
- Expression of regret, but no apology
- Extensive educational resources developed

Open Disclosure Pilot

- Individual states draft policy consistent with Open Disclosure
- Pilot projects ongoing
- Tension between transparency and medico-legal concerns
  - Results of root cause analyses protected, not disclosed
- Pilot results highlight challenges of implementation
  - Balancing timely disclosure with thorough RCA
  - Evaluation of policy's impact on patients limited

UK: Being Open

- Being Open policy published in 2006
- Used Australia Open Disclosure model as starting point
- Apology plays central role
  - "Patients should receive an apology after the patient safety incident has occurred and staff should feel able to apologize on the spot. Saying sorry is not an admission of liability and it is the right thing to do."
- Extensive educational effort underway
- Little systematic evaluation of impact

Canadian Disclosure Guidelines

- Formal guidelines released in 2008
- Incorporate features from many countries
- Reflect ongoing tension between open disclosure and acknowledgement of error
  - Encourage open disclosure, but “these guidelines purposely avoid use of the term ‘error’”
- Apology allowed in some circumstances but language of apology ambiguous

New Zealand

- Highlights disconnect between medico-legal climate and disclosure
- Developed a nearly no-fault system for compensating medical injuries
- New Zealand disclosure programs early in their development
  - Principle of disclosure endorsed
  - District health boards need disclosure policy by 2010

Looking Forward

- Support for concept of disclosure is high, but implementation uneven
- Little is know about how disclosure is currently taking place
  - Even less known about disclosure-and-offer programs
- Malpractice environment is an obstacle to disclosure, but not the most important obstacle
- Some of the legal barriers to disclosure emanate from within healthcare
- We are at the beginning of the beginning