The Disclosure Dilemma: When Adverse Events Affect Multiple Patients

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Disclosures

- Nothing to disclose

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Reference

- Dudzinski, DM, PC Hébert, MB Foglia, TH Gallagher. 2010. The Disclosure Dilemma: Large Scale Adverse Events. *New England Journal of Medicine* 36:10, 978-986.
- Available for free at: http://www.nejm.org/doi/full/10.1056/NEJMhle1003134 (September 2, 2010)

Objectives

- Define large-scale adverse events.
- Discern ethically and clinically salient differences between types of large-scale adverse events.
- Identify ethical issues related to disclosure of large-scale adverse events.
- Recognize ethical arguments for and against disclosure of large-scale adverse events.

The Seattle Times

600 UW patients told of cleaning lapse

By Warren King
March 20, 2004
Seattle Times medical reporter

Nearly 600 University of Washington Medical Center patients have been notified that tubular devices used to diagnose diseases of the intestinal tract were not completely cleaned for several months.
UW officials and outside experts said the risk of infection from the incomplete cleaning process, which involves several steps, was very low.
"The risk ... is essentially zero, it is negligible," said Dr. Ed Walker, medical director of the UW Medical Center.
The medical center performed an extensive review of the cleaning lapse and filed reports with the federal Food and Drug Administration (FDA) and the Washington state Department of Health.
Patients who were examined with the devices, called endoscopes, were notified by letter of the problem during the past few weeks.

“The risk is negligible”

- Low increased risk of infection
  - 1 in 1.8 million estimated risk

The Disclosure Dilemma:

- Disclose and risk worrying the well
- Don’t disclose and risk missing an iatrogenic infection or injury

IOM Definitions

- **Medical error:** Failure of a planned action to be completed as intended (execution), or the use of a wrong plan to achieve an aim (planning).
- **Adverse event:** Injury that was caused by medical management and that resulted in measurable disability.
- **Near miss:** an event that could have resulted in an accident, injury or illness but did not, either by chance or through timely intervention

Definition

- **Large Scale Adverse Event**: an individual event or series of related events that increase the risk that multiple patients have been injured due to medical management. The increased risk was unanticipated by health care professionals and often was not recognized at the time of the incident.

Definition

- **Look-back investigations**: Root-cause analyses, tests, and audits that ensue after a LSAE has been identified.
  - These QI procedures almost always occur, but may not include disclosure to patients

Unlike individual adverse event disclosure because:

- Disclose to majority who are not in fact harmed (similar to disclosing near misses)
  - In the individual model, no ethical obligation to disclose unwitnessed near misses
- Public disclosure usually goes with it, media involvement
  - Perception by people who had nothing to do with incident matters – past and future patients are stakeholders

Range of probability & severity of harm

- Incomplete disinfection of endoscopes
- Faulty hormone receptor tests
- Reuse of syringes/vials
- Neurosurgical exposure to prions
- Freak accidents
  - Dirty hydraulic fluid mistaken for sterilization fluid

Factors in reluctance to disclose

- Most pts will not be physically harmed
- No obligation to disclose 'near misses'
- Difficulty predicting likelihood of harm/identifying affected pts
- Legal & reputational risk
- Resources allocated for disclosure, counseling, testing, and f/u treatment
- New infx's may be erroneously ascribed to the LSAE
- Regulatory bodies have not required pt disclosure

Ethical Frameworks

Utilitarian	Best course of action minimizes overall harm and maximizes overall benefit Decision based on predicted consequences
Duty-Based	The right course of action is the one whereby duties are fulfilled appropriately, irrespective of the action's consequences
Communitarian	Individual liberties may be constrained in the interest of society as a whole -- not simply to prevent harm to others but to promote the wellbeing of a community/society

Utilitarian Argument Against Disclosure

- Disclosing events will worry the well and undermine public confidence
  - If no one was physically injured, then anxiety is the only iatrogenic harm (not ameliorated by benefit of treatment)
  - Even if a few were injured, it may be that the collective anxiety of thousands outweighs the benefit of disclosure for a few

Utilitarian Argument supporting disclosure

- Magnitude of harm likely greater in physically harmed minority
- Psychological harm temporary
- Disclosure required for further testing to differentiate harmed from unharmed pts
- Look-backs lengthy – delayed notification increase risk of transmission
- Timely disclosure enhances pt & public trust

Duty-based argument for disclosure

- Duty to inform pts when delivery of hc has put them at risk
- Pts have a right to know
- HCOs obligation to provide care if preventable iatrogenic injury

- Duty to tell the truth/transparency
- Clinicians complicit in institution's decision NOT to disclose may feel they are deceiving their pts

Communitarian Argument for Disclosure

- Allows the few who are harmed to be treated
- Assumes that treating the physically harmed minority is a priority over preventing transient anxiety of majority
- Supports quality improvement in h.c. which benefits the community
- Society has duty to warn of potential hazards in other regards – this is analogous
- Supports HCO's responsibility to care for preventable iatrogenic injury

Facts relevant to ethical analysis

- Probability and severity of harm
- Cause is system breakdowns or deviations from SOP
- Whether testing or treatment is available

Our conclusions

- **HCOs should disclose LSAEs even when the probability of harm is very low.**
- Ethical obligations to disclose are strongest when LSAE was the result of preventable errors or system failures
- Ethical obligations more ambiguous when probability of harm extremely low and no dx tests or effective treatments (e.g. CJD)
- HCOs should have policies to guide disclosure

Examples of LSAEs

1) LSAE due to system failure/error

- Faulty hormone receptor tests in lab in Canada between 1997-2005.
- Estrogen-receptor neg. BRCA pt died, receiving incorrect tx
- Re-tested 1013 people, over 50% converted
  - 383 received incorrect tx
  - 108 pts who died were receiving wrong tx

External Audit Found

- Staff incompetence
- Poor quality control
- Deficient procedures
- Frequent turnover of pathologists

Disclosure Quality

- Attempts to contact women inconsistent, some learned through media reports
- No LSAE policy/procedure to guide disclosure
- Reactive not proactive
- Led to public mistrust

Strong ethical justification for disclosure

- Magnitude of risk of harm
  - Urgency to adjust treatment
- Deviations from standards of practice
  - Pts/colleagues rightly expect compliance with SOP
- Preventable but continued for 8 yrs
- Retributive justice – the right to be compensated for negligence that causes harm.

2) LSAE due to incomplete disinfection of scopes

- Perhaps the most common LSAE

UW Endoscope

- Seattle Times, March 20, 2004
  - "600 patients told of cleaning lapse" (544)
- Endoscope disinfecting machine:
  - One step in 6 stage process failed: soak in glutaraldehyde 2.6% for 20 minutes, device only soaked for 2 minutes
    - "Negligible increase in risk" from standard 1 in 1.8 million endoscope procedures
    - Discovered one new machine was disinfecting faster for 2 months– discovered malfunction
    - Took machine out of service
- Reported to FDA & WA DOH, neither required patient notification
- Root cause analysis done & malfunction corrected

UW Endoscope

- Assure health risk is low (Hep B, C, HIV)
  - Internal and external scientific review
  - Ethics consultation/analysis
- Institution discloses to pts and contacts media
  - Hospital takes & shares responsibility
  - Machine malfunction; manufacturers did not train UW technicians properly
  - Hotline with SW/RNs to answer questions, provide f/u (e.g. testing for bacterial & bloodborne infx)
  - Lab f/u for 1 year
- No new infection, no lawsuits

Empirical Questions: Methods

- Mailed survey (Gallagher et al.)
- Sent to all patients who received original letter
- IRB approved

Prouty CD, Foglia MB, Gallagher TH. Patient's experience with disclosure of LSAE. J Clin Ethics. 2013 Winter;24(4):353-63

Survey Design

- Section 1
  - Remember receiving letter?
  - Satisfaction with letter
- Referred to copy of letter
- Section 2
  - Does letter provide needed info?
  - Impact of letter on impression of UW (honesty/integrity, quality of care),

    overall satisfaction with disclosure
  - How should similar event be handled in future?

Results

- 544 surveys mailed
- 130 non-deliverable
- 11 patients died
- 9 patient refusals
- 127 surveys returned

Recall, Satisfaction with Original Letter

- Did you recall having received letter?
  - 81% yes
- Did the letter provide the information you needed to understand this event?
  - 75% yes
- After reading letter, how concerned were you that the problem with the endoscope cleaning equipment might cause health problems for you?
  - 64% somewhat/very concerned
- At the time, did you think UWMC was right to inform you of this problem?
  - 81% yes

After reading copy of letter

- Does the letter provide you the information you needed to understand this event?
  - 84% yes
- How did this experience affect your impression of UWMC regarding
  - Their honesty and integrity
    - 6% Decreased a lot/decreased a little
    - 35% No change
    - 59% Increased a lot/increased a little
  - The quality of care provided
    - 22% Decreased a lot/decreased a little
    - 48% No change
    - 30% Increased a lot/increased a little
  - Overall satisfaction with how UWCM communicated with you about this event
    - Mean 7.7, 10-point scale

Imagine a similar event happens in the future

- "…where an error occurs that affects many patients but that has very little chance of causing harm to these patients."
  - Medical centers should tell patients about any error in their care, even if the chance of harm is extremely low
    - 94% agree
  - It would make me nervous to be told about an error in my health care, even if the chance of harm is extremely low
    - 28% agree
  - All things considered, if a similar episode happened in the future, would you recommend that organizations like UWMC
    - Inform patients about what happened: 97%
    - Not inform patients about what happened: 7%
    - (4% marked both 'Inform' and 'Not inform')

Preliminary Conclusions

- The majority of patients remembered the disclosure and were satisfied with it.

  1/5 felt worse about the quality of care received

- Nearly all patients want to be informed of any future events.

  Many reasons cited: health, trust, right to know

- Patients want to be told, even if it makes them nervous.

Endoscope Case Overview

- Systematic disclosure process (but no formal policy)
- Utilitarian argument *against* disclosure stronger for low increased risk
- Duty-based argument *for* disclosure remains strong
- Communitarian argument *for* disclosure remains strong
- Disclosure should be the rule for low risk LSAEs

3) The hardest case: surgical exposure to prions

- Pt died of classic sporadic Creutzfeldt-Jakob disease several weeks after nuerosurgery
- Dx not suspected at time of surgery
- Surgical instruments used in 6 other pts

About CJD

- Uniformly fatal, no diagnostic testing or treatment available
- Disease confirmed by brain biopsy or autopsy
- Incubation period of 6 mo – 20+ years
- Low risk of transmission: 1 in 100,000-1 in 1 million/yr
- Est. that Iatrogenic transmission less than 1%
- *Normal disinfection methods ineffective against prions*

2000 WHO disinfection standards

- When pt is *suspected* of having a transmissible spongiform encephalopathy, sequestering, incinerating, or high-intensity sterilization of neurosurgical equipment recommended.

Institutional obligation

- To use best, most current info to prevent transmission
  - See J *Perioper Pract. 2008 Jul;18(7):298-304* for evolution of recs to reduce transmission
- But due to long incubation, hospital may discover long after neurosurgery that other pts were potentially inadvertently exposed or ID a cluster of unrelated pts with ds

Ethical arguments pro/con disclosure

Utilitarian	**Pro**: Could prevent future exposure through neurosurg/devices; Pts can access testing/tx that may be available later
	Con: LT fear outweighs remote chance of transmission; disclosure will not prevent infx of 3rd parties; wouldn't most pts prefer not to know?
Duty based	**Pro**: Duty to tell the truth; pt has right to information
	Con: Duty of non-maleficence (disclosure causes permanent, not transient harm)
Communitarian	**Pro**: Duty to tell the truth, sense of betrayal if pt later learns providers kept terminal, incurable ds a secret
	Con: Why know early if no testing/treatment? Paternalism may be warranted.

- We recommend disclosure, but there's greater justification for non-disclosure in CJD cases.
- Need more research & analysis on this
- Improved disinfection practices priority

Develop LSAE Policy

- VHA has a policy at: http://www1.va.gov/vhapublications/publications.cfm?pub=1, policy 2008-002

Features of VA Policy

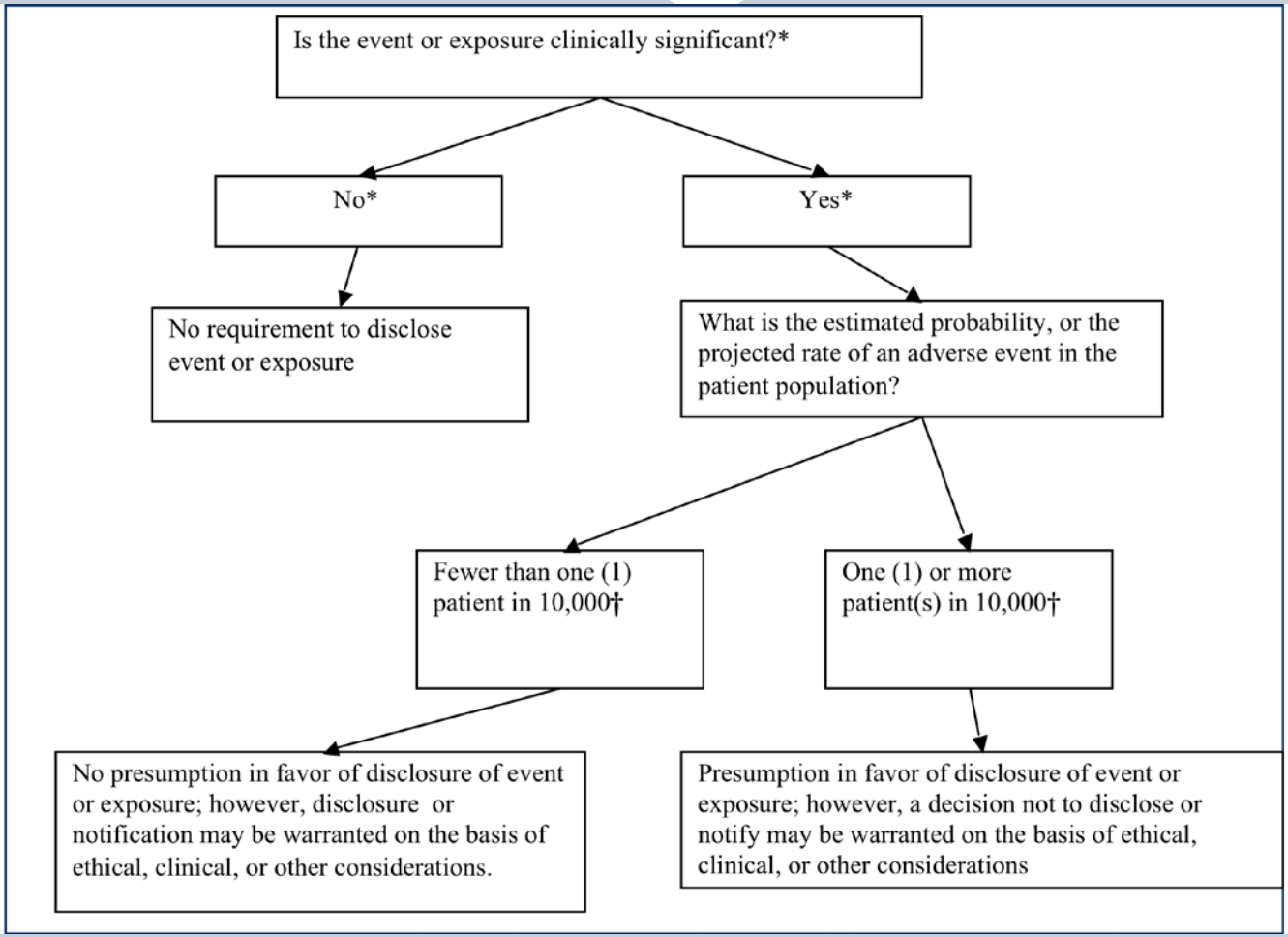
- Preamble asserts that there is “a presumptive obligation to disclose adverse events that cause harm to patients”
- Allows for consideration of factors not directly related to the well being of the affected patient
  - Impact of disclosure on ability to provide care and treatment for all patients
- Convene advisory group of leadership, experts, ethics, to provide recommendations on if and how to disclose

Leadership Decision Process

Core Question Set

- Do we have all the important facts?
- Have we involved everyone who should be part of the decision?
- Does this decision reflect our values?
- Do likely benefits outweigh potential harms?
- Will this decision keep the problem from recurring or establish a good precedent?
- How will it look from outside the organization?

Probability and Severity Matrix



Critique of Matrix

- Threshold for when disclosure is obligated seems arbitrary
- Danger that thresholds can be over privileged in decision making
- Risk assessments can take time – disclosure may be warranted before definitive data available

Our Recommendations

- Clear policies/procedures
  - **Norm is disclosure**
  - Proactive not reactive disclosure

Our Recommendations

- Provide trained personnel for managing disclosure
  - Planning lookback investigation (multidisciplinary)
  - Notifying pts & public
  - Call-in center to address pt concerns
  - Coordinating f/u testing & tx
  - Responding to regulatory bodies

Our recommendations

- Method & components of disclosure
  - Written, oral
  - Greater harm events need oral notification from treating providers
  - Empathic delivery of news
  - Apology
  - Inform pts simultaneously first
  - A few pts will have persistent anxiety despite neg. test results

Our Recommendations

- Assume media coverage is inevitable – show commitment to pt well-being
- HCO's should compensate pts who have been physically harmed by an LSAE resulting from preventable error or system failure

Thank you

- Dudzinski, DM, PC Hébert, MB Foglia, TH Gallagher. 2010. “The Disclosure Dilemma: Large Scale Adverse Events”. *New England Journal of Medicine* 36:10, 978-986.
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History of VHA Directive 2008-002

- Disclosing Adverse Events has been required in VHA going back at least to 1995.
  - Also required by Joint Commission.
- VHA National Center for Ethics in Health Care wrote an White Paper on the Topic in 2003.
- 2005 VHA Directive on Disclosure of Adverse Events to Patients was issued in to make requirements clear.
  - But some details were still arguable and a rewrite was assigned in 2006, especially to accommodate “large scale” disclosures.

Key features

- Convene the Clinical Risk Assessment Advisory Board (CRABB)
  - Recommends to the Secretary whether to disclose and how the disclosure should be conducted
  - Serve in an advisory capacity to those that conduct the actual disclosure
  - Broad participation including ethics
  - Content experts from within and external to VHA participate

CRAAB

- The CRAAB is made up of appropriate representative(s) from:
  - Office of Public Health and Environmental Hazards (Chair),
  - Office of the Deputy Under Secretary for Health for Operations and Management,
  - National Center for Ethics in Health Care,
  - Office of Nursing Services,
  - Office of Quality and Performance,
  - National Center for Patient Safety,
  - Office of Patient Care Services,
  - Subject matter experts from VHA or non-VA experts as needed.

Leadership Decision Process (LDP)

- Preamble asserts that there is “a presumptive obligation to disclose adverse events that cause harm to patients
- Allows for consideration of factors not directly related to the well being of the affected patient
  - Impact of disclosure on ability to provide care and treatment for all patients

Links of Potential Interest

- 2008 Directive: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637
- 2003 White Paper:

  http://www.ethics.va.gov/ETHICS/docs/necrpts/NEC_Report_20030301_Disclosing_Adverse_Events.pdf
- 2005 PowerPoint:

  http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1371_37087_0_0_18/Noel%20Eldridge.ppt