HEALTH LAW, ETHICS, AND HUMAN RIGHTS

The Disclosure Dilemma — Large-Scale Adverse Events

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In 2003, the infection-control staff of a Toronto teaching hospital realized that the sterility of prostate-biopsy equipment had been inadvertently compromised by incomplete cleaning.[1] Although the risk of infectious transmission was considered very low, hospital officials could not be certain that hundreds of men had not been exposed to harmful pathogens. The hospital faced a dilemma: should they disclose this adverse event that may have harmed many patients (a large-scale adverse event)? Or should they not disclose the event if the risk of harm was remote and if the disclosure would primarily cause anxiety to patients who would ultimately not be physically harmed by the event?

The hospital decided it had a duty to inform more than 900 men and offer them pathogen testing. Infection linked to the biopsy was not detected in any of the notified patients. Nevertheless, a $100 million (Canadian) class-action suit with punitive damages of $50 million (Canadian) was filed on behalf of the notified patients.[2,3] This suit claimed that the disclosure and subsequent period of waiting for test results had caused psychological harm. The hospital settled the suit without admitting liability and offered a total of $1.2 million (Canadian) to 748 class-action members.[4]

Such large-scale adverse events are not uncommon.[5-45] (Table 1). Yet, whether and how to disclose such events to patients pose substantial challenges,[47,48] especially when the majority are more likely to be harmed by the disclosure itself than by the event. In this article, we define large-scale adverse events, describe several representative cases, and recommend key elements of a policy concerning these events.

LARGE-SCALE ADVERSE EVENTS DEFINED

Large-scale adverse events are individual events or a series of related events that injured or increased the risk that many patients would be injured because of health care management. The increased risk was not anticipated by health care professionals, and often was not recognized at the time of the incident. Without further testing, the subgroup of patients who have been injured generally cannot be distinguished from the group of patients who have not been harmed. Look-back investigations are the root-cause analyses, tests, and audits that ensue after such an event has been identified.

RELUCTANCE TO DISCLOSE

There are ethical reasons why institutions may hesitate to disclose large-scale adverse events to patients. As in the Toronto case, in many such events there is good reason to believe at the outset that the majority of patients have escaped physical harm and had a "near miss."[49] Although the ethical justification for disclosing harmful errors to patients is strong,[50] there is no consensus about the need to disclose near-miss incidents.[51-53] Because patients involved in a near-miss incident are not physically injured, they may not benefit from the disclosure and may in fact be psychologically harmed. However, without disclosing the event and conducting look-back investigations, institutions cannot be sure whether any patient was physically harmed by the event.

Practical, legal, and financial considerations, such as the difficulty in predicting the likelihood of harm and identifying the injured patients, may also lead well-meaning institutions to consider not disclosing large-scale adverse events. In addition, for many such events, the disclosure leads to media coverage, with potential legal risk and injury to the institution's reputation. Finally, conducting the disclosure and providing follow-up counseling, testing, and treatment require considerable resources. Especially with look-back investigations involving thousands of persons, testing will inevitably identify patients with hep-

atitis or human immunodeficiency virus infection for whom a link between the infection and the large-scale adverse event is extremely unlikely but cannot be disproved.[3,4]

These barriers have led to instances in which these events were not disclosed. Published reports of 21 cases of endoscope contamination in England showed that although corrective actions were undertaken, in most cases patients were not notified.[8] A subsequent task force concluded that the risk of infection associated with such incidents was "too low" to warrant notification of involved patients.[8,13]

DISCLOSURE WHEN THE RISK OF PHYSICAL HARM IS LOW

Two ethical frameworks are often used in determining whether to disclose large-scale adverse events: utilitarian and duty-based. In a utilitarian framework, the best course of action minimizes overall harm and maximizes overall benefit. In those events in which the chance of physical harm is low, a utilitarian analysis might appear to support the decision not to disclose. Institutions may have concern that disclosing these low-risk events would simply worry the well and undermine public confidence. For those patients who end up being in the near-miss group (usually the majority), the psychological harm of disclosure is not ameliorated by the potential benefit of treatment. In the end, if no one was physically hurt, then anxiety from the disclosure was the only iatrogenic harm.

However, the utilitarian arguments favoring disclosure are compelling. Further testing is often required to differentiate harmed from unharmed patients; this testing requires disclosure to patients. Look-back investigations can be lengthy, potentially delaying notification until physically harmed persons can be identified, and such delays increase the risk of the transmission of possible infectious diseases to third parties. In addition, preventing psychological harm to persons who were not physically injured usually does not, on balance, minimize overall harm, since the magnitude of harm is probably greater in the injured minority. Finally, timely and effective disclosure can enhance patient and public trust.[2,4] Thus, from a purely utilitarian perspective, disclosure of large-scale adverse events is ethically appropriate even when the chance that any patients have been physically harmed is extremely low.

A utilitarian analysis should be complemented by alternative ethical frameworks. In duty-based frameworks, the right course of action is the one whereby duties are fulfilled appropriately, irrespective of the action's consequences. Patients rightly expect individual practitioners to disclose iatrogenic injury. Similarly, health care institutions have a duty to inform patients when the delivery of health care has put them at risk. This duty to tell the truth translates to an obligation of transparency at the institutional level. Clinicians who are complicit in the institution's decision to withhold information may feel they are deceiving their patients, paternalistically protecting autonomous patients who have a right to know.

In summary, both utilitarian and duty-based frameworks provide support for the disclosure of large-scale adverse events, even when the probability of physical harm to patients is very low. However, these events occur along a spectrum of probability, severity, and treatability. Below we describe three examples of large-scale adverse events and discuss their distinguishing features. As these cases illustrate, the ethical obligations to disclose are greatest when the events resulted from preventable errors or system failures, whereas duties to disclose are more ambiguous when the probability of harm is extremely low but the severity of harm is great and there are no definitive diagnostic tests or effective treatments.

ERRORS IN BREAST HORMONE-RECEPTOR TESTING

Some large-scale adverse events, such as the errors in breast hormone–receptor testing in Canada, are associated with a considerably higher probability and severity of harm than the Toronto prostate-biopsy case.[7,46] In early 2005, aggressive metastatic disease had developed in a patient in Newfoundland who had a diagnosis of estrogen-receptor–negative breast cancer. After the patient's husband received advice from another oncologist, the patient's hormone-receptor test was repeated. She was found to be hormone-receptor–positive; these results called the initial test result into question. Despite starting antiestrogen therapy, the patient died of advanced disease.[7]

The incorrect test result led to retesting of other receptor-negative patients in Newfoundland and Labrador. Of the first 25 patients who

Table 1. Large-Scale Adverse Events.*

Event and Location	Description and Outcome	No. of Patients Affected	Physical Harm	Disclosure	Reference
Contaminated medical equipment					
Endoscopy Center of South Nevada, Las Vegas	Reuse of soiled endoscope cleaning solution, syringes, and vials; personnel performed two procedures at a time, March 2004 through Jan. 2008; hotline set up by Southern Nevada Health District; lawsuit filed	40,000	At least seven cases of acute HCV infection	Yes	MMWR,[29] Wells,[31] Wells and Harasim,[32] Manning,[33] Allen[43]
Fremont Cancer Center, Fremont, CA	Reuse of syringes in infected patients; breach of infection-control practices; lawsuit filed in 2001	600	A total of 99 patients tested positive for HCV in 2001	Yes	Wells[45]
Veterans Health Administration (VHA), TN, GA, and FL	Improper setup and reprocessing of flexible endoscope tubing and accessories from 2003 through 2009	10,555	A total of 6 patients tested positive for HIV, 34 for HCV, and 13 for HBV as of Oct. 2009; no. of infections due to improper setup and reprocessing unknown	Yes	Dept. of Veterans Affairs[34]
West Allegheny Health System, Pittsburgh	Two colonoscopes inadequately cleaned	200	Unknown	Yes	Bails[24]
University of Washington Medical Center, Seattle	Malfunctioning machine led to incomplete disinfection of endoscope	600	None reported	Yes	King[11]
Allegheny General Hospital, Pittsburgh	Malfunctioning machine led to incomplete disinfection of bronchoscopes and pseudomonas outbreak	≥16	A total of 16 patients became ill, and 1 died	Yes	Appelby[35]
North Shore University Hospital, Manhasset, NY	Improperly disinfected endoscopes because of two employees who neglected quality-control procedures	177	Unknown	Yes	Healy[19]
Toronto Prostate Biopsy, Toronto	Improperly cleaned prostate-biopsy equipment from 1997 through 2003; class-action lawsuit filed, $1.2 million (Canadian) settlement	>900	None, according to final settlement papers	Yes	George Farkas v. Sunnybrook and Women's College Health Sciences Centre[2,4]
Outpatient clinic, GA	Outbreak of *Pseudomonas aeruginosa* infections after transrectal ultrasound-guided prostate biopsies performed	4	A total of 4 patients hospitalized and recovered	Unknown	Gillespie et al.,[21] MMWR[37]
Iatrogenic transmission of Creutzfeldt–Jakob disease					
McKay-Dee Hospital, Ogden, UT	CJD diagnosed in patient after neurosurgery; normal sterilization procedures not effective against prions, so potential exposure occurred through surgical instruments; both CDC and state health department told hospital it was not required to notify patients	155	Unknown	Yes	Collins[26]
Exempla Saint Joseph Hospital, Denver	CJD diagnosed in patient after neurosurgery; potential exposure through surgical instruments	6	Unknown	Yes	Joint Commission International Center for Patient Safety,[17] Klein[27]
Tulane University Hospital and Clinic, New Orleans	CJD diagnosed in patient after neurosurgery; potential exposure through surgical instruments	8	Unknown	Yes	Hwang and Hamilton,[25] Klein[27]

Other event					
Eastern Regional Integrated Health Authority, Newfoundland, Canada	Hormone-receptor tests incorrect because of laboratory errors between May 1997 and August 2005; lawsuit filed; some patients learned about error through media reports rather than letters; apology to patients delayed	1,013	A total of 383 women received incorrect treatment; 108 patients who died received incorrect treatment	Yes	Cameron,[7] CBC News,[38] CBC News[46]
Portlaoise Hospital, Portlaoise, Ireland	Suboptimal reading of approximately 2900 mammograms, Nov. 2003 through Aug. 2007	Not known	On re-review, breast cancer detected in 7 women	Yes	Donnellan,[39] Hunter[40]
Miramichi Regional Health Authority, Miramichi, New Brunswick, Canada	Poor quality of a pathologist's work on breast- and prostate-cancer biopsy specimens; audit of his cases from 1995 through Feb. 2007; lawsuit filed	23,700	Incomplete results in 18% of 227 initial cases; 3% of cases misdiagnosed	Yes	CBC News,[41] Miramichi Regional Health Authority[44]
Veterans Affairs Medical Center, Philadelphia	Suboptimal quality standards, especially by one physician, and poor radiation safeguards led to improperly placed radioactive seeds for brachytherapy for ≥6 yr; brachytherapy program suspended in 2008	92	Yes	Yes	Bogdanich[36]
Duke University Health System, Durham, NC	Dirty hydraulic fluid drained from elevators placed in drum labeled as sterilization fluid and thought to be trash; drum picked up by manufacturer as surplus and redistributed to hospital; hydraulic fluid used to sterilize surgical equipment in Nov. and Dec., 2007; lawsuit filed and settled for "great worry, anxiety, apprehension, and emotional distress"; CDC determined hospital officials did not heed complaints of surgical employees, thereby delaying discovery of mistake	≥3,500	Unknown physical harm	Yes	Goldsmith[42]
VHA medical centers throughout the United States	Laboratory values, vital signs, and medical data sometimes appeared under the wrong patient's name in electronic medical records in 51 medical centers	Not known	Potential harm, but none documented	Yes	Yen[30]
Electroencephalography clinics, Toronto	HBV outbreak from 1990 through 1996 associated with reusable subdermal electroencephalographic electrodes; transmission from technician who was HBeAg carrier and did not wear gloves	18,567	HBV infection developed in 75 patients; 4 patients admitted to hospital	Yes	Hepatitis B Outbreak Investigation Team[10]
Unnamed teaching hospital, United States	Contaminated oxygen in wall; residual cleaning solvent, carbon tetrachloride, in hose from delivery truck to hospital; two patients reported malodorous gas; emergency response activated and patients switched to tank oxygen; all patients who received oxygen affected	Not known	"No patients suffered any apparent ill effects"[22]	Yes	Gilmour et al.[22]
Broward General Medical Center, Fort Lauderdale, FL	Nurse reused single-use saline bags and tubing during cardiac stress tests between 2004 and 2009	1,851	Unknown	Yes	Nolin and Giovis[20]

* CDC denotes Centers for Disease Control and Prevention, CJD Creutzfeldt–Jakob disease, HBeAG hepatitis B e antigen, HBV hepatitis B virus, HCV hepatitis C virus, and HIV human immunodeficiency virus.

were retested, more than half "converted." Authorities at the Eastern Regional Integrated Health Authority retested approximately 1,000 patients who were initially tested between May 1997 and August 2005. A total of 383 of these patients had not received the recommended treatment, and 108 of these patients had died.[48] Fifty women, some of whom had undergone mastectomies, had been told they had advanced breast cancer when they did not.[7,48]

External audits of the laboratory noted staff incompetence, poor quality control, deficient procedures, and frequent turnover of the staff of pathologists.[48] There were long delays and inconsistent attempts at contacting women who were at risk for having incorrect results. Some women only learned of their risk through the media. The initial attempts by the Eastern Regional Integrated Health Authority to keep its audits away from public scrutiny led to community mistrust of the health care system.[7]

In the Newfoundland case, the ethical analysis regarding disclosure is unambiguous. The magnitude of the risk of harm, as well as the fact that the harm was preventable and involved deviations from standards of practice, clearly warranted disclosure. Although the organization may have been harmed by the disclosure, the obligations to patient care, transparency, and retributive justice (the right to be compensated for negligence that causes harm) far outweighed the risks to the institution. This case also illustrates how the lack of effective disclosure policies regarding large-scale adverse events can compound harm. Delayed disclosures hindered a switch to appropriate therapies, causing dissatisfaction and reducing patients' and the public's faith in their health care institutions.

INSUFFICIENT DISINFECTION OF ENDOSCOPES

Some large-scale adverse events are caused by deviations from standards of practice,[31] but often they are not. Perhaps the most common large-scale adverse events involve insufficient disinfection of equipment. At the University of Washington Medical Center, one step in a six-step endoscope disinfection process failed. The faulty machine was running several minutes too fast. Two months later, when the malfunction was detected, the hospital corrected the flaw and identified approximately 600 patients who were exposed to incompletely cleaned endoscopes.[11] Scientists could not calculate the increased risk posed by omitting one cleaning step, but they thought it was remote and indistinguishable from the baseline risk of contracting bloodborne pathogens from an endoscope (estimated to be 1 in 1.8 million).[54,55] Despite the extremely low risk of infection, the hospital considered the rationale for disclosure to be compelling and sent letters to all affected patients. The event was reported in a front-page story in the *Seattle Times*.[11]

The hospital devoted considerable time and resources to developing and implementing a process for following up on the disclosure. It enlisted its organizational ethics consultants and patient relations department, set up a hotline to answer concerned patients' questions, referred interested patients to physicians, and provided free follow-up testing. No cases of infection with bloodborne pathogens were identified and no lawsuits were filed.

NEUROSURGERY AND CREUTZFELDT–JAKOB DISEASE

The most vexing large-scale adverse events involve potential injuries that cannot be definitively diagnosed and have no treatment. A patient who underwent neurosurgery in Denver was found several weeks later at autopsy to have died of classic sporadic Creutzfeldt–Jakob disease. This diagnosis was not suspected at the time of surgery. Instruments used in this patient's surgery were later used in surgery involving six other patients.[17]

Creutzfeldt–Jakob disease is a transmissible spongiform encephalopathy, a rare prion disease that causes rapid, fatal progression of neurologic symptoms. Iatrogenic transmission of Creutzfeldt–Jakob disease has been associated with neurosurgical procedures and corneal transplantation.[18,56] The incubation period for surgical exposure to Creutzfeldt–Jakob disease ranges from 6 months to 20 years or more.[17,57] Once symptoms appear, patients die within about 1 year.[58] Creutzfeldt–Jakob disease is diagnosed by postmortem examination of the brain. Estimates of risk range from 1 in 100,000 to 1 in 1 million.[58] Iatrogenic transmission is estimated to account for less than 1% of cases of transmissible spongiform encephalopathy.[12] Prevention of surgical transmission of Creutzfeldt–Jakob disease is possible but cumbersome and costly. Although

normal disinfection methods are ineffective against prions, available guidelines for infection control involve the sequestering, incinerating, or high-intensity sterilizing of neurosurgical instruments if transmissible spongiform encephalopathy is suspected.[18,59]

This event is among the most rare and challenging type of large-scale adverse event, since it is difficult to know whether any harm has occurred until decades after the exposure. Thus, a duty to tell the truth might be outweighed by a duty of nonmaleficence. The fear and worry that could accompany disclosure may constitute a greater and more permanent harm in the case of Creutzfeldt–Jakob disease than in other large-scale adverse events without any corresponding benefit, given the remote chance of transmission of this disease and the lack of diagnostic and treatment options.

The rationale for disclosure is also compelling. There is a professional duty to disclose because contracting the disease, even decades later, is a severe, deadly harm. Arguably, a patient has a right to this information. Should Creutzfeldt–Jakob disease develop in the patient, the harm is intensified by the sense of betrayal if the patient learns that providers have kept the risk of the development of a terminal, incurable disease a secret. If a potentially infected patient has subsequent neurosurgery, additional patients may be at risk for exposure, thereby amplifying harm. Disclosure would also allow patients to access testing and treatment that become available in the future,[16] and it would demonstrate to the community that the hospital puts the interests of its patients first, even if the benefits to the patient are small and there is a risk of litigation.

Thus, when the institution has no testing or treatment to offer patients and the disclosure is associated with a risk of creating clinically significant long-term harm, a true ethical dilemma exists. Although, on balance, we believe that disclosure is often warranted, there is also greater ethical justification for nondisclosure in this case than in the other types of large-scale adverse events. The challenge of disclosing large-scale adverse events related to prion diseases is an important topic for further analysis.

INSTITUTIONAL POLICIES

Although many health care organizations have adopted policies encouraging disclosure of adverse events to individual patients, these policies seldom address large-scale adverse events. Lacking guidance on how best to manage the disclosure process and fearing that inappropriate disclosure will only make a bad situation worse, the institutional responses to such events can be slow and haphazard.

The Veterans Health Administration (VHA) Directive 2008-002 on Disclosure of Adverse Events to Patients is a notable exception. This policy, which outlines a clear and systematic process for disclosure decisions regarding large-scale adverse events, includes convening a multidisciplinary advisory board with representation from diverse stakeholder groups and experts, including ethicists.[60] The role of the advisory board is to recommend whether or not to disclose and to provide guidance on the manner of disclosure.

The policy endorses transparency and expresses a "presumptive obligation to disclose adverse events that cause harm to patients,"[60] but it adds that other factors (not directly related to the well-being of exposed or affected patients) must be weighed when making disclosure decisions (e.g., the effect of disclosure on perceived institutional integrity or on the capacity of the VHA to provide care and treatment for all veterans). The board is influenced by a core set of ethically salient questions such as "Would the decision indicate that we are taking responsibility for our collective action?"[60]

The board is also guided by a probability and severity matrix that favors disclosure when 1 patient or more of 10,000 patients is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated. Disclosure is not obligatory when an adverse event is clinically significant but less than 1 of 10,000 patients is expected to be affected, or when an event is not clinically significant regardless of the number of patients exposed to the event. However, the policy notes that disclosure may still be warranted on the basis of ethical or other considerations.

Although this matrix reflects important utilitarian considerations, there is a danger that the 1 in 10,000 "threshold" can be unduly emphasized in decision making to the exclusion of other important institutional and professional commitments. In addition, because definitive evidence of harm can usually be established only after a look-back investigation is well under way,

disclosure of large-scale adverse events may be warranted before conclusive determination of the magnitude and scope of harm. Nonetheless, the VHA policy represents a valuable resource for all health care institutions.

RECOMMENDATIONS

INSTITUTIONAL POLICIES FOR LARGE-SCALE ADVERSE EVENTS

Although large-scale adverse events are less common than adverse events affecting individual patients, they occur frequently enough to warrant thoughtful policies and procedures. Institutions should have a clear set of procedures (and should provide accountable, trained personnel) for managing the disclosure process, notifying patients and the public, coordinating follow-up diagnostic testing and treatment, and responding to regulatory bodies. The policy should advocate prompt initiation of a look-back investigation to identify and rectify root causes. Although rapid look-back investigations may require the diversion of safety experts from their regular tasks, timely and accurate information about the cause of and health risks associated with large-scale adverse events is essential to the disclosure and follow-up process.

PLANS FOR DISCLOSURE

Institutions should proactively (rather than reactively) disclose all large-scale adverse events to affected patients unless a strong, ethically justifiable case can be made not to disclose. Temporary anxiety in patients involved in near-miss incidents is not a sufficient argument against disclosure. The method of disclosure may depend on the event. Initially, written notification regarding low-risk, low-harm, large-scale adverse events may be appropriate, whereas oral notification by treating physicians regarding events involving greater harm may be indicated. Considerable planning is required to ensure empathic delivery of the essential information, including an apology, to patients. Clinicians caring for affected patients, designees from the ethics committee, and patient representatives should be involved in developing disclosure and follow-up plans. Broad input is critical to ensure that institutional self-interest does not inadvertently trump the needs of affected patients. All affected patients should be first informed simultaneously and personally, rather than through the media.

COMMUNICATION WITH THE PUBLIC

Institutions should assume that media coverage of large-scale adverse events is inevitable. Responses to the media should demonstrate the institution's commitment to honesty and transparency to build public trust.

PLANS FOR PATIENT FOLLOW-UP

Institutions should provide follow-up diagnostic testing and treatment to patients affected by the large-scale adverse event and address anxiety produced by the disclosure. For example, a call-in center staffed by qualified health care professionals to address patient concerns and coordinate testing and treatment should be available as soon as patients receive notification. Institutions should anticipate that for a small number of patients, anxiety may persist despite negative results of repeated tests to detect infection. Institutions should compensate patients who have been physically harmed by a large-scale adverse event resulting from a preventable error or system failure.[61]

CONCLUSIONS

The disclosure of large-scale adverse events is a challenging dilemma. Not all such events are alike, and these differences have important implications for disclosure. Disclosure should be the norm, even when the probability of harm is extremely low. Although risks to the institution are associated with disclosure, they are outweighed by the institution's obligation to be transparent and to rectify unanticipated patient harm. Faithful adherence to these duties may increase the public's positive perception of the institution and its integrity.

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1. Infection control: Ontario. Infectious Diseases News Brief. Ottawa: Public Health Agency of Canada, 2003. (Available at http://www.phac-aspc.gc.ca/bid-bmi/dsd-dsm/nb-ab/2003/nb4703_eng.php.)
2. George Farkas v. Sunnybrook and Women's College Health Sciences Centre. 03002596655CD. Ontario Superior Court of Justice, February 4, 2005.
3. Trus Biopsy class actions: settlement agreement — George Farkas v. Sunnybrook Health Sciences Centre. Ontario Superior Court, July 13, 2009. (Accessed July 15, 2010, at http://www.reolaw.ca/pdf/sunnybrook_settlement_agreement.pdf.)
4. George Farkas v. Sunnybrook and Women's College Health Sciences Centre. 03-CV-259655CP. Ontario Superior Court of Justice, 2009.
5. Caulfield T, Dossetor J, Boshkov L, Hannon J, Sawyer D, Robertson G. Notifying patients exposed to blood products associated with Creutzfeldt-Jakob disease: integrating science, legal duties and ethical mandates. CMAJ 1997;157:1389-92.
6. Report of an independent review of endoscope decontamination in Northern Ireland. Belfast: Department of Health, Social Services and Public Safety, March, 2005.
7. Cameron MA. Report of the Commission of Inquiry on Hormone Receptor Testing to the Minister of Health and Community Services. St. John's, NL, Canada: Newfoundland Commission of Inquiry on Hormone Receptor Testing, 2009.
8. Gamble HP, Duckworth GJ, Ridgway GL. Endoscope decontamination incidents in England 2003-2004. J Hosp Infect 2007; 67:350-4.
9. Harpaz R, Von Seidlein L, Averhoff FM, et al. Transmission of hepatitis B virus to multiple patients from a surgeon without evidence of inadequate infection control. N Engl J Med 1996; 334:549-54.
10. Hepatitis B Outbreak Investigation Team. An outbreak of hepatitis B associated with reusable subdermal electroencephalogram electrodes. CMAJ 2000;162:1127-31.
11. King W. 600 UW patients told of cleaning lapse. Seattle Times. March 20, 2004.
12. Lewis V, Boyd A, Masters C, Collins S. Apparently sporadic CJD and covert health-care transmissions. Lancet Neurol 2002;1:470-1.
13. Morris J, Duckworth GJ, Ridgway GL. Gastrointestinal endoscopy decontamination failure and the risk of transmission of blood-borne viruses: a review. J Hosp Infect 2006;63:1-13.
14. Muscarella LF. MyEndosite home page. (Accessed July 15, 2010, at http://www.myendosite.com.)
15. Department of Veterans Affairs, Office of Inspector General. Healthcare inspection: follow-up colonoscope reprocessing at VA medical facilities. Washington, DC: VA Office of Inspector General, September 17, 2009. (Accessed July 15, 2010, at http://www4.va.gov/oig/54/reports/VAOIG-09-02848-218.pdf.)
16. Potash J. Intra-operative exposure to sporadic Creutzfeld-Jakob disease: to disclose or not to disclose? In: Ford PJ, Dudzinski DM, eds. Complex ethics consultations: cases that haunt us. New York: Cambridge University Press, 2008:205-11.
17. Sentinel event alerts: exposure to Creutzfeldt-Jakob disease. Oakbrook Terrace, IL: The Joint Commission International Center for Patient Safety, June 2001.
18. Sutton JM, Dickinson J, Walker JT, Raven ND. Methods to minimize the risks of Creutzfeldt-Jakob disease transmission by surgical procedures: where to set the standard? Clin Infect Dis 2006;43:757-64.
19. Healy P. Hospital on Long Island may have exposed 177 to viruses. New York Times. June 16, 2004.
20. Nolin R, Giovis J. Nurse endangered 1,851 patients, hospital says. South Florida Sun-Sentinel. October 6, 2009. (Accessed August 10, 2010, at http://articles.sun-sentinel.com/2009-10-06/news/0910050417_1_stress-tests-nurse-heart-stress.)
21. Gillespie JL, Arnold KE, Noble-Wang J, et al. Outbreak of Pseudomonas aeruginosa infections after transrectal ultrasound-guided prostate biopsy. Urology 2007;69:912-4.
22. Gilmour IJ, McComb RC, Palahniuk RJ. Contamination of a hospital oxygen supply. Anesth Analg 1990;71:302-4.
23. Davies P. Germ watch: clinic infections put a sterilizer of lab devices under microscope; maker of widely used system defends its effectiveness after bacterial outbreaks: word of probe by FDA. Wall Street Journal. December 24, 2004. (Accessed July 15, 2010, at http://www.myendosite.com/articles/wsj122404.pdf.)
24. Bails J. Candor praised in scope problems. Pittsburgh Tribune-Review. April 1, 2005. (Accessed July 15, 2010, at http://www.pittsburghlive.com/x/pittsburghtrib/trib/tribeast/s_319469.html.)
25. Hwang S, Hamilton D. 8 Patients may have CJD from re-used 'sterile' surgical instruments. Wall Street Journal. October 27, 2000.
26. Collins LM. McKay-Dee patients told of rare risk: man who had surgery died of Creutzfeldt-Jakob disease. Deseret Morning News. January 20, 2006.
27. Klein A. Reused devices: surgery's deadly suspects. Washington Post. December 30, 2005:A03.
28. Idaho investigates brain-wasting disease. Casper Star Tribune. May 15, 2008. (Accessed August 10, 2010, at http://trib.com/news/state-and-regional/article_c953bd33-6d55-5591-965a-198f7cd1c33e.html.)
29. Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic — Nevada, 2007. MMWR Morb Mortal Wkly Rep 2008;57:513-7.
30. Yen H. Veterans exposed to incorrect drug doses. Associated Press. January 14, 2009.
31. Wells A. Public health crisis: new hepatitis case surfaces. Las Vegas Review-Journal. March 19, 2008. (Accessed July 15, 2010, at http://www.lvrj.com/news/16810116.html.)
32. Wells A, Harasim P. Exposure feared: 40,000 LV clinic patients urged to be tested for viruses. Las Vegas Review-Journal. February 28, 2008. (Accessed July 15, 2010, at http://www.lvrj.com/news/16067972.html.)
33. Manning M. Large-scale hepatitis alert has no precedent. Las Vegas Sun. February 29, 2008. (Accessed July 15, 2010, at http://www.lasvegassun.com/news/2008/feb/29/large-scale-hepatitis-alert-has-no-precedent/.)
34. VA continues notification process for veterans affected by reprocessing issues. Washington, DC: Department of Veterans Affairs, April 3, 2009.
35. Appelby J. Widely used sterilizer under attack: hospital blames it for outbreak. USA Today. January 2, 2003.
36. Bogdanich W. At V.A. hospital, a rogue cancer unit. New York Times. June 20, 2009. (Accessed July 15, 2010, at http://www.nytimes.com/2009/06/21/health/21radiation.html.)
37. Pseudomonas aeruginosa infections associated with transrectal ultrasound-guided prostate biopsies — Georgia, 2005. MMWR Morb Mortal Wkly Rep 2006;55:776-7.
38. Eastern Health sends written apology to breast cancer patients. CBC News. May 14, 2008. (Accessed July 15, 2010, at http://www.cbc.ca/canada/newfoundland-labrador/story/2008/05/14/cancer-apology.html.)
39. Donnellan E. Hospital sharing unit chief resigns. Irish Times. November 2, 2009. Accessed August 10, 2010, at http://www.irishtimes.com/newspaper/ireland/2009/1102/1224257900953.html.)
40. Hunter N. Shock at more breast test errors. Irishhealth.com. May 11, 2007. (Accessed August 10, 2010, at http://www.irishhealth.com/article.html?id-12476.)
41. Miramichi pathology class-action lawsuit filed. CBC News. July 22, 2008. (Accessed July 15, 2010, at http://www.cbc.ca/canada/new-brunswick/story/2008/07/22/nb-lawsuit.html?ref=rss.)
42. Goldsmith T. Duke patients settle hydraulic fluid claims. The News & Observer. June 19, 2008. (Accessed August 10, 2010, at http:www.lawnmed.com/pdf/www.newsobserver.com_news_v-print_story:1113155.html.pdf.)
43. Allen M. How hepatitis probe led to clinic: old-fashioned

legwork yielded clues that came together. Las Vegas Sun. March 2, 2008. (Accessed July 15, 2010, at http://www.lasvegassun.com/news/2008/mar/02/probe-led-quickly-quickly-clinic/.)
44. Miramichi Regional Health Authority releases results of pathology review and will conduct an external review of pathology specimens. Press release of the Miramichi Regional Health Authority, February 11, 2008. (Accessed July 15, 2010, at http://rha7.ca/media_releases_en/2008_02_11_miramichi_regional_health_authority_releases_results_of_pathology_review_and_will_conduct_an_additional_external_review_of_pathology_specimens.pdf.)
45. Wells A. Public health crisis: 'message of hope' on hepatitis. Las Vegas Review-Journal. March 23, 2008. (Accessed July 15, 2010, at http://www.lvrj.com/news/16936876.html.)
46. Hormone testing: judicial inquiry probes faulty breast cancer tests. CBC News, March 18, 2008. (Accessed July 15, 2010, at http://www.cbc.ca/news/background/cancer/inquiry.html.)
47. Chafe R, Levinson W, Sullivan T. Disclosing errors that affect multiple patients. CMAJ 2009;180:1125-7.
48. Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. Infect Control Hosp Epidemiol 2007;28:146-55.
49. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health system. Washington, DC: National Academies Press, 2000.
50. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. N Engl J Med 2007;356:2713-9.
51. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA 2003;289:1001-7.
52. Wu A. Is there an obligation to disclose near-misses in medical care? In: Sharpe VA, ed. Accountability: patient safety and policy reform. Washington, DC: Georgetown University Press, 2004:135-42.
53. Disclosure Working Group. Canadian disclosure guidelines. Edmonton, AB: Canadian Patient Safety Institute, 2008.
54. Kimmey M, Burnett D, Carr-Locke D. Transmission of infection by gastrointestinal endoscopy. Gastrointest Endosc 1993;36:885-8.
55. American Society for Gastrointestinal Endoscopy. Infection control during GI endoscopy. Gastrointest Endosc 2008;67:780.
56. Lumley JS. The impact of Creutzfeldt-Jakob disease on surgical practice. Ann R Coll Surg Engl 2008;90:91-4.
57. Johnson RT, Gibbs CJ Jr. Creutzfeldt–Jakob disease and related transmissible spongiform encephalopathies. N Engl J Med 1998;339:1994-2004.
58. CJD (Creutzfeld-Jakob disease, classic). Atlanta: Centers for Disease Control and Prevention. (Accessed July 15, 2010, at http://www.cdc.gov/ncidod/dvrd/cjd/index.htm.)
59. WHO infection control guidelines for transmissible spongiform encephalopathies: report of a WHO consultation, Geneva: World Health Organization, 1999.
60. Veterans Health Administration. Disclosure of adverse events to patients. VHA directive 2008-002. Washington, DC: Department of Veterans Affairs, January 18, 2008. (Accessed July 15, 2010, at http://www1.va.gov/vhapublications/viewpublication.asp?pub_id=1637.)
61. Mello MM, Gallagher TH. Malpractice reform — opportunities for leadership by health care institutions and liability insurers. N Engl J Med 2010;362:1353-6.
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