The Disclosure Dilemma — Large-Scale Adverse Events

Denise M. Dudzinski, Ph.D., Philip C. Hébert, M.D., Ph.D., Mary Beth Foglia, R.N., Ph.D., and Thomas H. Gallagher, M.D.

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. 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. 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.

Such large-scale adverse events are not uncommon. (Table 1). Yet, whether and how to disclose such events to patients pose substantial challenges, 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 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.

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.” Although the ethical justification for disclosing harmful errors to patients is strong, there is no consensus about the need to disclose near-miss incidents. 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.34

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

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.24

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 anti-estrogen 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>
<thead>
<tr>
<th>Event and Location</th>
<th>Description and Outcome</th>
<th>No. of Patients Affected</th>
<th>Physical Harm</th>
<th>Disclosure</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contaminated medical equipment</strong></td>
<td></td>
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<tr>
<td>Endoscopy Center of South Nevada, Las Vegas</td>
<td>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</td>
<td>40,000</td>
<td>At least seven cases of acute HCV infection</td>
<td>Yes</td>
<td>MMWR, Wells, Wells and Harasim, Manning, Allen</td>
</tr>
<tr>
<td>Fremont Cancer Center, Fremont, NE</td>
<td>Reuse of syringes in infected patients; breach of infection-control practices; lawsuit filed in 2001</td>
<td>600</td>
<td>A total of 99 patients tested positive for HCV in 2001</td>
<td>Yes</td>
<td>Wells</td>
</tr>
<tr>
<td>Veterans Health Administration (VHA), TN, GA, and FL</td>
<td>Improper setup and reprocessing of flexible endoscope tubing and accessories from 2003 through 2009</td>
<td>10,555</td>
<td>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</td>
<td>Yes</td>
<td>Dept. of Veterans Affairs</td>
</tr>
<tr>
<td><strong>West Allegheny Health System, Pittsburgh</strong></td>
<td>Two colonoscopes inadequately cleaned</td>
<td>200</td>
<td>Unknown</td>
<td>Yes</td>
<td>Bails</td>
</tr>
<tr>
<td>University of Washington Medical Center, Seattle</td>
<td>Malfunctioning machine led to incomplete disinfection of endoscope</td>
<td>600</td>
<td>None reported</td>
<td>Yes</td>
<td>King</td>
</tr>
<tr>
<td>Allegheny General Hospital, Pittsburgh</td>
<td>Malfunctioning machine led to incomplete disinfection of bronchoscopes and pseudomonas outbreak</td>
<td>≥16</td>
<td>A total of 16 patients became ill, and 1 died</td>
<td>Yes</td>
<td>Appelby</td>
</tr>
<tr>
<td>North Shore University Hospital, Manhasset, NY</td>
<td>Improperly disinfected endoscopes because of two employees who neglected quality-control procedures</td>
<td>177</td>
<td>Unknown</td>
<td>Yes</td>
<td>Healy</td>
</tr>
<tr>
<td>Toronto Prostate Biopsy, Toronto</td>
<td>Improperly cleaned prostate-biopsy equipment from 1997 through 2003; class-action lawsuit filed, $1.2 million (Canadian) settlement</td>
<td>&gt;900</td>
<td>None, according to final settlement papers</td>
<td>Yes</td>
<td>George Farkas v. Sunnybrook and Women's College Health Sciences Centre</td>
</tr>
<tr>
<td>Outpatient clinic, GA</td>
<td>Outbreak of <em>Pseudomonas aeruginosa</em> infections after transrectal ultrasound-guided prostate biopsies performed</td>
<td>4</td>
<td>A total of 4 patients hospitalized and recovered</td>
<td>Unknown</td>
<td>Gillespie et al., MMWR</td>
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<tr>
<td><strong>Iatrogenic transmission of Creutzfeldt-Jakob disease</strong></td>
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<tr>
<td>McKay-Dee Hospital, Ogden, UT</td>
<td>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</td>
<td>155</td>
<td>Unknown</td>
<td>Yes</td>
<td>Collins</td>
</tr>
<tr>
<td>Exempla Saint Joseph Hospital, Denver</td>
<td>CJD diagnosed in patient after neurosurgery; potential exposure through surgical instruments</td>
<td>6</td>
<td>Unknown</td>
<td>Yes</td>
<td>Joint Commission International Center for Patient Safety</td>
</tr>
<tr>
<td>Tulane University Hospital and Clinic, New Orleans</td>
<td>CJD diagnosed in patient after neurosurgery; potential exposure through surgical instruments</td>
<td>8</td>
<td>Unknown</td>
<td>Yes</td>
<td>Hwang and Hamilton, Klein</td>
</tr>
<tr>
<td>Other event</td>
<td>Description</td>
<td>Number</td>
<td>Result</td>
<td>Reference</td>
<td></td>
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<td>---------------------------------------------------------------------------</td>
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<tr>
<td>Eastern Regional Integrated Health Authority, Newfoundland, Canada</td>
<td>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</td>
<td>1,013</td>
<td>Yes</td>
<td>Cameron,7 CBC News,38 CBC News46</td>
<td></td>
</tr>
<tr>
<td>Portlaoise Hospital, Portlaoise, Ireland</td>
<td>Suboptimal reading of approximately 2900 mammograms, Nov. 2003 through Aug. 2007</td>
<td>Not known</td>
<td>Yes</td>
<td>Donnellan,39 Hunter40</td>
<td></td>
</tr>
<tr>
<td>Miramichi Regional Health Authority, Miramichi, New Brunswick, Canada</td>
<td>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</td>
<td>23,700</td>
<td>Yes</td>
<td>CBC News,41 Miramichi Regional Health Authority44</td>
<td></td>
</tr>
<tr>
<td>Veterans Affairs Medical Center, Philadelphia</td>
<td>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</td>
<td>92</td>
<td>Yes</td>
<td>Yes Bogdanich36</td>
<td></td>
</tr>
<tr>
<td>Duke University Health System, Durham, NC</td>
<td>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</td>
<td>≥3,500</td>
<td>Unknown physical harm</td>
<td>Yes Goldsmith42</td>
<td></td>
</tr>
<tr>
<td>VHA medical centers throughout the United States</td>
<td>Laboratory values, vital signs, and medical data sometimes appeared under the wrong patient’s name in electronic medical records in 51 medical centers</td>
<td>Not known</td>
<td>Potential harm, but none documented</td>
<td>Yes Yen30</td>
<td></td>
</tr>
<tr>
<td>Electroencephalography clinics, Toronto</td>
<td>HBV outbreak from 1990 through 1996 associated with reusable subdermal electroencephalographic electrodes; transmission from technician who was HBeAg carrier and did not wear gloves</td>
<td>18,567</td>
<td>Yes</td>
<td>Hepatitis B Outbreak Investigation Team10</td>
<td></td>
</tr>
<tr>
<td>Unnamed teaching hospital, United States</td>
<td>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</td>
<td>Not known</td>
<td>“No patients suffered any apparent ill effects”22</td>
<td>Yes Gilmour et al.22</td>
<td></td>
</tr>
<tr>
<td>Broward General Medical Center, Fort Lauderdale, FL</td>
<td>Nurse reused single-use saline bags and tubing during cardiac stress tests between 2004 and 2009</td>
<td>1,851</td>
<td>Unknown</td>
<td>Yes Nolin and Giovis20</td>
<td></td>
</tr>
</tbody>
</table>

* 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. Fifty women, some of whom had undergone mastectomies, had been told they had advanced breast cancer when they did not.

External audits of the laboratory noted staff incompetence, poor quality control, deficient procedures, and frequent turnover of the staff of pathologists. 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.

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.

**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.

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. The incubation period for surgical exposure to Creutzfeldt–Jakob disease ranges from 6 months to 20 years or more. Once symptoms appear, patients die within about 1 year. 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. Iatrogenic transmission is estimated to account for less than 1% of cases of transmissible spongiform encephalopathy. Prevention of surgical transmission of Creutzfeldt–Jakob disease is possible but cumbersome and costly. Although...

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**INSUFFICIENT DISINFECTION OF ENDOSCOPIES**

Some large-scale adverse events are caused by deviations from standards of practice, 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. 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). 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.

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.
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?”

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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From the Department of Bioethics and Humanities (D.M.D., M.B.F., T.H.G.), Department of Health Services (M.B.F.), and Department of Internal Medicine (T.H.G.), University of Washington; and the Ethics Consultation Service, University of Washington Medical Center (D.M.D.) — both in Seattle; and Department of Family and Community Medicine and Joint Centre for Bioethics, Sunnybrook Health Sciences Centre, University of Toronto, Toronto (P.C.H.). Address reprint requests to Dr. Dudzinski at the Department of Bioethics and Humanities, University of Washington School of Medicine, Box 357120, Seattle, WA 98195-7120, or at dudzin@uw.edu.
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