

Admitting clinical errors may not always be the best policy

It may be intuitive that when errors occur, the ethical thing to do is to disclose, but in a paper from the University of Washington, Seattle, reported in the *New England Journal of Medicine*, the authors suggest that disclosure should be decided on a case-by-case rather than a one-size-fits-all basis. The researchers state that this is because there are instances where disclosure itself may cause harm. In these instances, anxiety related to worries about what may be only a minimal risk outweighs the ethical benefit of disclosure. While there is a strong ethical justification to disclose harmful errors to patients, there is no consensus about the need to disclose “near-miss” incidents. In “near-miss” incidents, these patients are often not physically injured; instead they may be psychologically harmed, and thus may not benefit from the disclosure. Yet, by withholding information about the error, institutions could not be sure whether any patient was physically harmed.

Three examples were used to illustrate the disclosure quandary. In the first example, a laboratory in Canada misdiagnosed the estrogen receptor (ER) status of several hundred women with breast cancer. Women who were ER positive received different chemotherapy regimens than women who were ER negative. The misdiagnosis was disclosed, but patients faced long delays due to inconsistent attempts at contacting women at risk for incorrect results. In this example, the researchers said the need to disclose was “unambiguous”. This was because the risk of harm was due to deviations from standards of practice, and because the harm was preventable.

In the second example, the University of Washington Medical Center

realised that some endoscopes were not cleaned completely. Any risk from this was remote, but the hospital disclosed the finding to all potentially affected patients. Considerable time and resources were used to develop and implement a process for follow-up on the disclosure. In the end, there was no infection with blood-borne pathogens and there were no lawsuits.

In the third example, a neurosurgery patient was found (after death) to have Creutzfeldt-Jakob disease (CJD). The center realised that instruments used in the patient’s surgery had been used in surgeries of six other patients. However, the incubation period of CJD ranged from 6 months to 20 years, and may never develop. Thus, it would be difficult to know whether harm has occurred until years or decades after exposure. The researchers said that in instance, the duty to tell the truth might be outweighed by the duty of non-maleficence. Non-disclosure was as justified as disclosure.

The authors state that the ethical obligation to disclose is greatest when an adverse event results from a preventable error or system failure. But the duty to disclose is more ambiguous when the probability of harm is extremely low but the severity of harm is great, and there is no definitive diagnostic test or effective treatment.

The authors state that institutional policies are usually not helpful, because while they may help guide ethical deliberations, but usually do not cover large-scale adverse events. However, the authors state that an exception is the Veterans Health Administration Directive on Disclosure of Adverse Events to Patients. They state that this Directive outlines a clear and systematic process for disclosure decisions regarding large-scale adverse events. For example, the Directive defines a threshold parameter – disclosure is not obligatory when <1 in 10,000 patients is expected to be affected; or when an event is not clinically significant regardless of the number of patients exposed.

The authors recommend that institutions should develop a clear set of procedures for managing the disclosure process; for notifying patients; for coordinating follow-up testing and treatment; and for conveying truthful and accurate information to the press. **SMA**

Source: Dudzinski DM, et al. The disclosure dilemma – large-scale adverse events. N Engl J Med 2010; 363(10): 978-986.