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Large-scale adverse events deserve disclosure, study says

Experts believe patients should be told about mistakes, such as poor infection control, that expose them to potential harm.

By KEVIN B. O'REILLY, amednews staff. *Posted Sept. 23, 2010.*

Hospitals, physician practices and other health care organizations should disclose adverse events that affect numerous patients, even when most patients may not be harmed, a new study shows.

These large-scale adverse events -- usually involving poor infection-control practices or defective equipment -- are ones in which some patients may experience harm while most escape unfavorable consequences, said the study, published Sept. 1 in *The New England Journal of Medicine*.

"We think disclosure should occur in virtually every case," said study lead author Denise M. Dudzinski, PhD, associate professor in the Dept. of Bioethics and Humanities at the University of Washington School of Medicine. "There are some cases in which the risk of harm is higher, and there's a greater obligation to disclose, because of the high likelihood that some patients will need treatment."

There also may be "a higher obligation to disclose if the case involved a breakdown that was a deviation from standards of practice, and we need to make amends for this in some way and make it better," Dudzinski said.

The Joint Commission requires accredited hospitals to disclose adverse events to patients, but that standard applies only in individual cases where the harm is known. The Veterans Health Administration adopted a policy in 2008 recommending disclosure in large-scale events if one in 1,000 patients could face clinically significant short- or long-term health consequences.

The question of how to handle mass events that pose only potential harm has created an ethical dilemma for health care organizations, Dudzinski said. The study examined 20 publicly known events in which hospitals or clinics disclosed these events to patients (**www.ncbi.nlm.nih.gov/pubmed/20818911/**).

Dudzinski's institution, the University of Washington Medical Center in Seattle, was one such organization. A faulty endoscope-disinfection machine exposed about 600 patients to potential infection, though scientists believed the risk was minuscule. Nonetheless, the medical center decided to send letters to all the affected patients, and the news was reported on the front page of *The Seattle Times* in 2004. No cases of infection related to the event were identified, and no patients sued.

Health care organizations that disclose large-scale adverse events should be prepared to handle patients' concerns, Dudzinski said. She suggested that they implement call-in centers, for example, so patients can arrange follow-up information, testing and treatment.

"The disclosure itself is going to stress people out," she said. "From an ethics standpoint, you have to own up to that. If we're going to make patients anxious, we have to figure out what we're going to do to address that anxiety."

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