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AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Study Recommends Disclosure of Medical Mistakes That Affect Multiple Patients

Press Release Date: September 1, 2010

Health care organizations should disclose medical mistakes that affect multiple patients even if patients were not harmed by the event, according to an AHRQ-funded research paper published in the September 2 issue of the *New England Journal of Medicine*.

Medical mistakes that affect multiple patients, known as large-scale adverse events (LSAEs) to researchers, are incidents or series of related incidents that harm or could potentially harm multiple patients. These events, which can include incompletely sterilized surgical equipment, poor laboratory quality control and equipment malfunctions, are often identified after care has been provided and can affect thousands of patients.

“It's clear that health care organizations face a dilemma regarding disclosure of large-scale adverse events – whether these events lead to patient harm or not,” said AHRQ Director Carolyn M. Clancy, M.D. “It's not always clear how to do that in a way that minimizes risk to the patient and the organization, but this research can help.”

According to researchers from the University of Washington, Seattle, disclosure policies for adverse events that affect individual patients are becoming more common among health care organizations but often fail to address how to disclose LSAEs that could have affected many patients.

Researchers weighed ethical considerations of whether to disclose such events. For instance, is disclosure ethical if patients were unlikely to have been physically harmed by the event but could be harmed psychologically by the disclosure? The authors reviewed instances in which health care institutions disclosed an LSAE and analyzed the method of disclosure and existing disclosure policies. They concluded that, in most cases, these events should be disclosed and offered these recommendations:

- **Develop an institutional policy**. Organizations should have a clear set of procedures for managing the disclosure process, notifying patients and the public, coordinating follow-up diagnostic testing and treatment and responding to regulatory bodies.
- **Plan for disclosures.** Disclosures should be made proactively, unless a strong, ethically justifiable argument can be made not to do so. The method of disclosure may depend on the event, but patients should be informed personally and all at the same time.
- **Communicate with the public.** Organizations should assume that media coverage of a large-scale adverse event is inevitable. To build public trust, media responses should demonstrate the organization's commitment to honesty and transparency.
- **Plan for patient follow-up.** Organizations should provide follow-up diagnostic testing and treatment to patients affected by the LSAE and address any anxiety caused by the disclosure. Patients who have suffered physical harm due to an event resulting rom a preventable error or system failure should be compensated.

“Disclosing large-scale adverse events is essential if health care organizations are to maintain patients' and the public's trust and ensure that affected patients receive the testing and treatment they need,” said lead author Denise Dudzinski, Ph.D., an associate professor in the Department of Bioethics & Humanities at the University of Washington, Seattle. “These disclosures are never easy, but it is critical that organizations invest the time and resources necessary to learn how to handle these disclosures effectively.”