Treating safety research like other clinical studies slows progress

May 14 2008

Progress in patient safety research could slow to a crawl unless regulators work out a host of ethical issues, Johns Hopkins researchers assert in an upcoming opinion piece.

“We can’t apply a clinical paradigm to patient safety research. It just isn’t the right fit,” says Nancy Kass, Sc.D., deputy director for public health at the Johns Hopkins Berman Institute of Bioethics and an author of the article.

The piece, published in the June issue of The Joint Commission Journal on Quality and Patient Safety, was sparked by a 2006 study led by Peter Pronovost, M.D., Ph.D., professor of anesthesiology, critical care medicine, and surgery at the Johns Hopkins University School of Medicine. In the study, Pronovost, an expert on patient safety, implemented a checklist in intensive care units (ICUs) at 67 Michigan hospitals aimed at preventing bloodstream infections whenever doctors insert catheters.

The results were markedly positive: Bloodstream infections from catheters fell by two-thirds, and on average, infection rates in the ICUs went from 4 percent to zero. Over the course of the study, the program saved more than 1,500 lives and nearly $200 million.

Shortly after the study’s results were published, however, an anonymous complaint led to a federal reexamination of the ethical oversight of the study. As in most human research, Pronovost’s study had been reviewed

by an institutional review board (IRB)—an internal group required at most research institutions to use federal regulations to make sure research studies protect the welfare of human subjects.

Because Pronovost's study enforced safety measures already known to be effective, and because no data were ever collected from patients by name, the Johns Hopkins IRB classified Pronovost's study as "exempt" from further IRB review. This designation meant that informed consent was not necessary from the ICU patients and that IRB review from each of the 67 Michigan hospitals that participated wasn't required. However, after the anonymous complaint, the federal Office for Human Research Protections, a branch of the U.S. Department of Health and Human Services that oversees IRBs, determined that patient consent and Michigan hospital IRB review should have taken place.

According to Kass, who served for more than 10 years on a Johns Hopkins IRB and is an expert in the ethics of human research, such a decision ignores the differences between patient safety research of this sort and other types of research that include riskier and more burdensome interventions and procedures, such as human trials for new drugs.

While well-informed consent is crucial for all patients participating in new drug research, for example, it may not be necessary for studies like Pronovost's research, in which the proposed intervention—a checklist to remember to follow steps, all known to make the ICU safer—is virtually risk-free, where data are lumped together so individual patients' names and information are never collected, and where the consent process may be burdensome to very sick patients. Also, according to Kass, since many small hospitals don't have IRBs, requiring every hospital to get an IRB review for patient safety evaluations would hinder many hospitals from participating in these studies and contributing their experiences to widespread evaluations.

“All of us want to make sure that patients are protected in any type of research,” said Kass, “but it is also critical to recognize which studies are low risk and should easily move through the system, and which ones are high risk and require considerably more scrutiny.”

Kass adds that working through these issues is crucial to advancing patient safety research, a field that has the potential to greatly advance public health.

“When the public thinks about important medical research, they might think about a cure for a horrible disease. I think the average person has heard very little about the fact that many more people die in the hospital of medical errors than they do from lots of diseases,” she says.

“There is an ethical imperative to do patient safety research,” she adds. “We need to find a review system that works so that important research in this field won’t be compromised.”

Source: Johns Hopkins Medical Institutions