Analysis calls for medical device information to better serve patients and doctors

January 31 2008

The approval process for medical devices does not involve the same rigorous review used for pharmaceuticals, and this needs to change in order to improve health outcomes, say researchers from the University of California, San Francisco.

The UCSF team analyzes the problem and proposes steps toward a solution in a “Perspectives” article in the January 2008 issue of the “Journal of General Internal Medicine” devoted entirely to medical devices. UCSF researchers Mitchell D. Feldman, MD, MPhil, and Jeffrey A. Tice, MD, edited the issue.

The team concludes that after a device achieves Food and Drug Administration (FDA) approval, a technology assessment by an independent organization can help identify medical devices that are truly beneficial and safe. The researchers also suggest that this assessment follow an “evidence-based” approach to information-gathering that includes data on the device’s success in clinical application. This type of data would be valuable for increasing health professionals’ awareness of “the potential promise and pitfalls of new technology,” the team writes.

“These days, patients are asking their doctors for the newest technologies from genetic tests to specific radiation treatments, and many physicians don’t know where to turn for the latest evidence-based information,” said Feldman, professor of medicine at UCSF and corresponding author of the study. “Sometimes, the only information out there is what the manufacturer provides.”

The UCSF analysis evaluated the federal review process, the method by which devices come to market, how the scientific literature reports on clinical trials involving medical devices, and the effectiveness of independent review boards in improving a technology's medical benefit to patients.

Out of the thousands of medical technology applications submitted annually to the FDA, less than 100 undergo the kind of scrutiny required for new drugs, according to information cited in the report. Most new applications are approved through an expedited FDA process that considers new devices similar to those already approved. Plus, the agency relies on manufacturers and clinical investigators to initiate recalls and failure reports when a technology is not beneficial or is potentially harmful to patients, the report states.

"FDA approval should be the start of the process toward clinical application, not the end," Feldman said. "Physicians and patients just aren't aware of the limitations of the FDA process of initial assessment and oversight of new medical technologies. Assessments by objective entities are a necessary addition to FDA approval - so that deficiencies in clinical evidence, and patient safety issues that may arise after approval, are recognized before widespread adoption into clinical practice."

The purpose of independent review organizations is to provide transparent, objective evaluations of new medical devices and to inform the public, physicians and policy makers, Feldman said. Some, like the California Technology Assessment Forum (CTAF), which is profiled in the "Perspectives" article as a case study, have meetings open to the public and populate their review board with experts in medicine, representatives from medical professional societies, technology manufacturers, policy makers and insurance providers, among others. CTAF selects devices for review based on their impact and the availability of relevant clinical data.

The UCSF Division of General Internal Medicine currently subcontracts with CTAF to provide technology assessments.

“In order to be considered in an assessment, CTAF requires that information already be published or accepted by a peer-reviewed journal. This encourages companies to make their trial results available to the public,” said Tice, attending physician in the Division of General Internal Medicine at UCSF and co-author of the study. “CTAF also requires improvements in patient-oriented outcomes, not surrogate markers. For example, we want to see improvements in disease-free survival and patient quality of life, not just a reduction in tumor size.”

Topics can be brought to the board’s attention by all potential stakeholders, including health plans, industry, professional societies and consumer groups. Once findings are presented, the technology’s manufacturer has the opportunity to give testimony, and eventually the board makes recommendations based on the body of information presented.

“We cover it all, from evaluating technologies used in genetic testing, radiation treatment for prostate cancer, digital mammography, computerized prosthetics and pre-natal screening to Positron Emission Tomography scans,” Tice said.

Eventually, the authors suggest, independent review boards should summarize their findings into uncomplicated take-home messages that patients can easily find on their own.

Source: University of California - San Francisco