A call to prevent unsafe high-risk medical devices from reaching the marketplace

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This is Rita F. Redberg, M.D., M.Sc., professor of medicine and director of the UCSF Women's Cardiovascular Services. Credit: Susan Merrell/UCSF

Technological advancements in medicine have allowed patients suffering from musculoskeletal conditions such as hip and knee pain to regain mobility and live relatively pain-free. But some "high risk" surgical devices that have been approved by the U.S. Food and Drug Administration (FDA) are not required to go through clinical trials, where a product is tested to determine its safety and effectiveness.

"This could be potentially very dangerous. Many Americans – patients and even physicians - are not aware of how many devices in this country are on the market without having clinical data of safety and effectiveness," said Rita F Redberg, MD, MSc, professor of medicine and director of the UCSF Women's Cardiovascular Services.

UCSF and the Australian Joint Registry published this month a perspective in the New England Journal of Medicine that reveals the complex history of how metal-on-metal hip implants reached the marketplace. The implants are categorized by the FDA as high-risk devices, yet have been allowed into the marketplace without first testing them. They failed at a dangerously high rate, often requiring reparative surgery at least four times as often as traditional hip replacement surgery .

The perspective's authors are calling for changes in how the FDA approves metal-on-metal hip replacement devices and other high-risk devices for the marketplace.

"If those hip implants are recalled, besides the problem of having to remove them because they're very painful, they can release chromium ions into the blood stream which pose an unknown risk," Redberg said. "Patients would also undergo significant disability having a second, third or fourth hip operation."

U.S. hospitals perform 48 million medical procedures each year, according to the U.S. Centers for Disease Control and Prevention. Of that number, roughly 676,000 patients undergo total knee replacement surgeries and 327,000 undergo total hip replacement surgeries.

"Some patients' mobility will decline to the point of needing walkers or wheelchairs to get around and other serious events up to and including death can occur from subsequent operations," Redberg said. "And that's

just for the metal-on-metal implants."

An Obscure Loophole

These high-risk metal-on-metal devices avoid going through clinical trials because of FDA loopholes in the 510(k) clearance, which allow them into the marketplace by claiming "substantial equivalence," which means they are similar to already approved devices or "predicate devices."

"All you have to do is show that your device is substantially similar to a number of other devices," Redberg said. "And some of those devices which were originally approved have been recalled or pulled off the market, but their original approval was still allowed for those 'predicate devices' that claimed 'substantial equivalence.'"

Even voluntarily recalled devices can serve as predicates under the 510(k) clearance as long as the FDA did not require their removal from the market or a court did not find they were misbranded or misrepresented in any way.

"High-risk medical devices should go through randomized clinical trials done in people so we can assure patients they are safe and effective," Redberg said. "Even the more stringent pre-market approval (PMA) process doesn't always mean that you actually have gone through randomized clinical trials, so we have to make sure these devices not only go through pre-market approval but randomized clinical trials as well."

Questions to Ask

For patients who are in the process of undergoing a medical procedure,

Redberg suggests they stay informed and ask many questions.

"Just like for any kind of procedure, I would ask, 'Are there scientific data that show this procedure or device is going to help me?'" Redberg said. "'Has it been studied in clinical trials? Has it been studied in patients like me? What are the risks? What are the alternatives?' Those are the questions patients should be asking before every procedure."

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