Safety of medical devices not often evaluated by sex, age, or race

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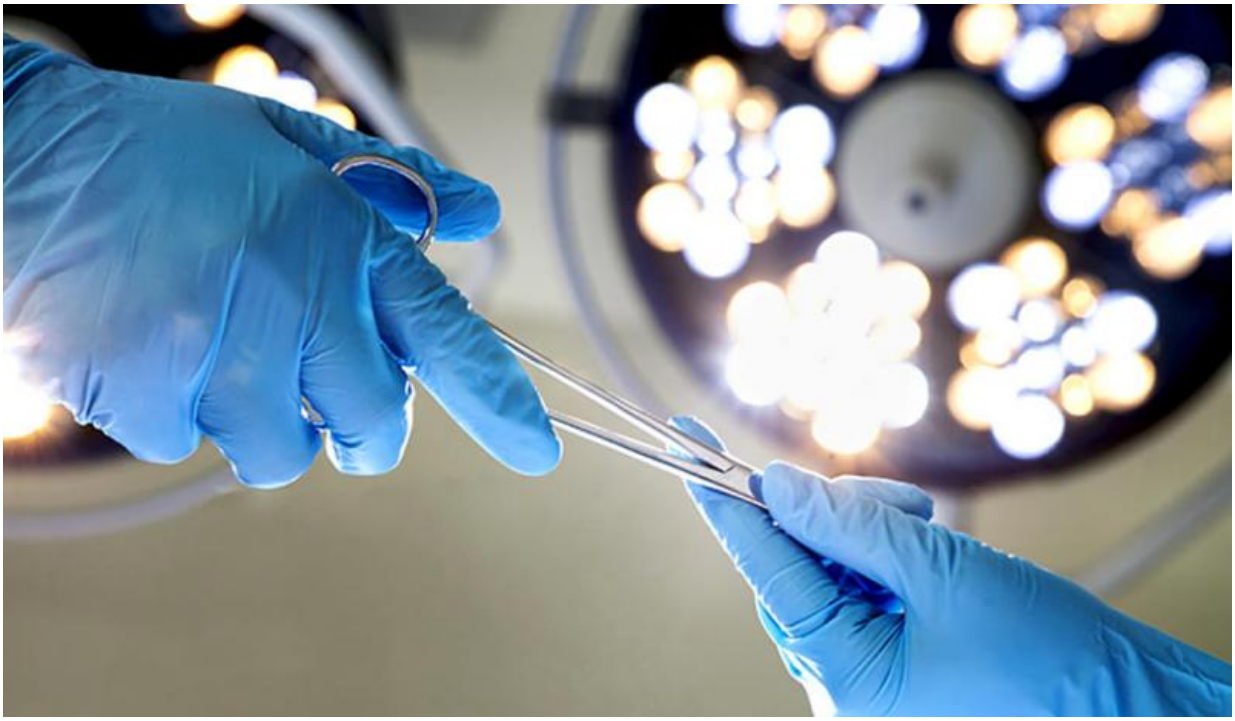

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Researchers at Yale and the University of California-San Francisco have found that few medical devices are analyzed to consider the influence of their users' sex, age, or race on safety and effectiveness.

The findings are published in *JAMA Internal Medicine*.

"We know that women, the elderly, and minorities have been underrepresented in clinical trials for drugs and treatments of many diseases and conditions," said lead author Sanket S. Dhruva, M.D., a postdoctoral fellow at Yale School of Medicine. "Our new study shows how these important patient groups are also being overlooked in the evaluation of medical devices."

The researchers examined 82 studies filed in 2015 with the U.S. Food and Drug Administration (FDA) in support of premarket approval for original medical devices. Only 9 percent were analyzed by age and 4 percent by race. Of the 77 studies that included both men and women, only 17 percent were analyzed by sex.

The researchers found infrequent analyses despite an action plan implemented by the FDA in 2014 calling for examination of results by age, race, and/or ethnicity.

"Moreover, when such data were reported, we often could not determine if statistical tests or analyses were employed," Dhruva said. "This makes it difficult to evaluate the clinical significance of the findings."

The age and sex of study participants were reported in only about two-thirds of all studies supporting agency premarket approval for medical devices in 2015. Race and/or ethnicity was reported in about half.

The study arrives in advance of Congress' consideration to reauthorize the Medical Device User Fee Amendments by Sept. 30. Reauthorization of the amendments, first established by a law in 2002, provides the opportunity for Congress to require the clinical trial enrollment of women, minorities, and the elderly in the proportions used by device's target population.

More information: Sanket S. Dhruva et al. Inclusion of Demographic-

Specific Information in Studies Supporting US Food & Drug Administration Approval of High-Risk Medical Devices, *JAMA Internal Medicine* (2017). DOI: 10.1001/jamainternmed.2017.3148