Still not enough women and older adults in cholesterol drug trials, study finds

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Although heart disease is the leading cause of death in women, and older adults are more likely to have heart and vascular disease than young people, randomized clinical trials testing medications to lower cholesterol have historically underenrolled both groups. Randomized clinical trials generate the best evidence regarding the benefits or harms

of given drug, and their results are used to shape guidelines for patient management in clinical practice. Due to a push from the U.S. National Institutes of Health and the U.S. Food and Drug Administration, the pharmaceutical industry had begun efforts to enroll more women and seniors into their trials.

However, after analyzing the trends in the types of 485,409 people enrolled in 60 studies from 1990 to 2018, Johns Hopkins Medicine researchers report that ¾ although some progress has been made—women and older adults are still vastly underrepresented in lipid lowering therapy trials compared with their disease burden. The findings, published on May 21, 2020, in the journal *JAMA Network Open*, suggest that trials still aren't reflecting real-world patient populations.

"We want to ensure that the types of patients who will be using these drugs are the ones included in the clinical trials, so that we can determine if these medications are safe and effective for the people who are prescribed them," says senior author Erin Michos, M.D., M.H.S., associate professor of medicine at the Johns Hopkins University School of Medicine. "Although we did see an improvement over the years in representation of women and older adults, that progress was rather modest. Clearly more still needs to be done to shift the balance to represent our patient demographics."

For their study, the researchers reported an increase in the number of women participants from about 20% in the early 1990s to about 33% in the most recent trials analyzed. However, many trials included only women who were past menopause or who were unable to have children, particularly excluding people who were pregnant or breastfeeding. Only slightly more than half of the 60 trials reported results based on effectiveness by gender.

"Heart diseases have been increasingly on the rise among younger women," says lead author Safi U. Khan, M.D., an assistant professor of medicine at West Virginia University. "The exclusion of women of childbearing age into these lipid-lowering trials results in missed opportunities to understand about important cardiovascular disease prevention measures in this group."

In the report on these studies, the percentage of trial participants 65 or older increased from 32% from the early 1990s, compared with 42% in the most recent trials examined. As with gender, only slightly more than half of the 60 studies reported their findings specifically for older adults.

The researchers say older Americans must be included in trials because as people age over time, the way they metabolize drugs may change, or they may develop other health conditions that could alter the effectiveness of the treatment.

More information: Safi U. Khan et al, Participation of Women and Older Participants in Randomized Clinical Trials of Lipid-Lowering Therapies, *JAMA Network Open* (2020). DOI: 10.1001/jamanetworkopen.2020.5202

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