

Cardiac clinical trials short on diversity in age, race, gender

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Women, racial minorities, and people over 75 are underrepresented in the clinical trials that help determine the way all cardiac patients are treated, a study from Lankenau Medical Center researchers has found.

This means that the recommendations that doctors use to treat heart problems may not be the best for all groups, said senior author Peter Kowey, head of Cardiology for Main Line Health.

A team at Lankenau Heart Institute and Lankenau Institute for Medical Research laid out the disparities in a research letter published online by the *Journal of the American Medical Association*.

Women, minorities, and the elderly could have different manifestations or severity of a disease, Kowey said, so more of them need to be included in trials to create more personalized guidelines. "We want to make sure that all can benefit without being harmed," Kowey said.

The team looked at 653 studies involving 1.3 million patients. Those studies accounted for 20 percent of citations for acute coronary syndrome guidelines, 25 percent for <u>atrial fibrillation</u>, and 28 percent for heart failure.

The paper found that while women made up 30 percent of study enrollees, they represent 55 percent, 47 percent, and 42 percent of Americans with atrial fibrillation, <u>heart failure</u>, and <u>acute coronary syndrome</u>.



There were also fewer minorities than their percentage of <u>heart disease</u> patients warranted, Kowey said.

And trials often lacked anyone over age 75. By not including patients at "extremes," the guidelines may not reflect what is safe for those groups.

"We have been mostly successful in local studies, mainly because we have the luxury of being" in a diverse area, Kowey said of his own studies. But he reported less success when chairing international studies.

The team found that most trial patients are from North America or Europe, and only 9 percent were from Asia, South America, or Australia.

The authors hope the letter will prompt changes in future trials used to set guidelines for the American Heart Association (AHA) and the American College of Cardiology (ACC).

Jeffrey Anderson, chair of the ACC/AHA Task Force on Practice Guidelines, said the groups are well aware that women, the elderly, and minorities are underrepresented in heart trials. While most care is the same for all groups, he said, some changes may be needed, so researchers must do a better job finding diverse subjects.

Elliot Antman, president of the heart association, agreed. Some people might not find it easy to participate or want to be in trials, he noted.

One option is using <u>electronic medical records</u> to do studies, enabling doctors to find diverse patients at the point of care.

Mobile technologies can also help, he said, as the digital "Health eHeart" study at the University of California shows. Anyone over 18 can sign up for the study online. It also has options to use social media and phone



apps for data.

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