

Women get short shrift in many heart device studies, despite requirement

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Despite a long-standing requirement for medical device makers to include women in studies they submit to the Food and Drug Administration for device approval, only a few include enough women or analyze how the devices work specifically in women, according to research reported in *Circulation: Cardiovascular Quality and Outcomes*.

"Women and men differ in their size, bleeding tendencies, and other factors that are directly relevant to how the devices will work," said Rita F. Redberg, M.D., M.Sc., senior author of the study and professor of medicine and director of Women's Cardiovascular Services at the University of California, San Francisco.

"It is likely that the benefits and risks of devices are different in women. Despite the directive to find out, it isn't happening."

In 1994, the Center for Devices and Radiological Health instituted a policy that all FDA submissions seeking new device approval must contain:

- A gender-bias statement explaining whether the proportion of men and women in the study reflects the proportion of men and women who have the condition being treated.
- Differences in the safety and effectiveness of the device in women.

In their analysis, researchers reviewed 123 studies contained in the pre-market approval applications for 78 high-risk cardiovascular devices (the category that includes [heart valves](#) and implanted [defibrillators](#)) that gained [FDA approval](#) between 2000 and 2007.

In 28 percent of the studies, FDA summaries of the evidence didn't report the gender of [study participants](#). In those that did, men made up an average of 67 percent.

The investigators found that the required gender-bias statement was present in only 41 percent of the studies. Of studies that included the statement, 94 percent discussed examining their results by sex, and 26 percent reported differences in device safety or effectiveness between men and women.

In the studies that omitted the gender-bias statement, only 11 percent presented any gender-specific results or discussion. Studies involving fewer than 50 patients were not included in the analysis of sex-specific reporting.

Because non-approved pre-market applications are not publicly available, the researchers could not determine whether these contained a similar percentage of gender-bias statements.

In approved applications, the reviewers found instances in which researchers used inaccurate grounds to exclude women. In some cases, the proportion of women with a heart condition was understated. In others, applicants declared their gender breakdown to be equivalent to previous studies without acknowledging that the previous studies included a disproportionately low number of women.

Between 2000 and 2007, the proportion of women enrolled in studies or the number of successful applications that included the gender-bias statement didn't increase.

"We found no encouraging trends," Redberg said. "Failure to include women in clinical trials has been a big problem for a long time and it isn't improving, so further action is needed."

She suggests strict enforcement of the current requirements, including sending applications back without review until the required statements are submitted.

Women should ask directly about the data if a device is recommended to them, Redberg said. "Ask how many women it was tested in and how the results looked in those women.

Unfortunately, all too often we approve devices based on results in men and assume they will be the same in women. That is not a reasonable assumption, even if a device is being marketed specifically to [women](#)."

Provided by American Heart Association

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