

New guidelines deem 13 million more Americans eligible for statins

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New guidelines for using statins to treat high cholesterol and prevent cardiovascular disease are projected to result in 12.8 million more U.S. adults taking the drugs, according to a research team led by Duke Medicine scientists.

The findings for the first time quantify the impact of the American Heart Association's new [guidelines](#), which were issued in November and generated both controversy and speculation about who should be given a prescription for statins.

In an analysis of health data published online March 19, 2014, in the *New England Journal of Medicine*, a team led by researchers at the Duke Clinical Research Institute found that most of the additional statin users under the new guidelines would be people older than age 60.

"We sought to do a principled, scientific study to try to answer how the new guidelines might affect statin use, particularly as they focused eligibility on patients with an increased risk of developing cardiovascular disease," said lead author Michael J. Pencina, Ph.D., professor of biostatistics at DCRI. "By our estimate, there might be an uptake in usage as a result of the guidelines, from 43.2 million people to 56 million, which is nearly half of the U.S. population between the ages of 40 and 75."

Pencina and colleagues from McGill University and Boston University used the National Health and Nutrition Examination Surveys (NHANES) for their analysis, focusing on 3,773 participants between the ages of 40-75 who had provided detailed medical information, including fasting cholesterol levels from blood tests.

The new guidelines expand the criteria for statin use to include people whose 10-year risk of developing cardiovascular disease, including stroke, is elevated based on a risk-assessment score.

The DCRI-led research team determined that the new guidelines could result in 49 percent of U.S. adults ages 40-75 being recommended for [statin therapy](#), an increase from 38 percent.

The increase is much more pronounced among adults free of cardiovascular disease who are over age 60, with 77 percent recommended for statin use under the new guidelines vs. 48 percent under the previous standards. This contrasts with a modest increase from 27 percent to 30 percent among U.S. adults between the ages of 40 and 60.

Those most affected by the new recommendations are older men who are not on statins and do not have cardiovascular disease. Under the earlier guidelines, about 30.4 percent of this group of men between the ages of 60-75 were recommended for statin use. With the new guidelines, 87.4 percent of these men would be candidates for the therapy. Similarly for healthy women in this age group, those recommended for preventive statin use are projected to rise from 21.2 percent to 53.6 percent.

"The biggest surprise of the research was the age-dependent split for those affected by the new guidelines," Pencina said. "We anticipated that the impact would be age-dependent, but not to the degree observed. The changes for both men and women in the older age groups were huge compared to those between the ages of 40 and 60."

Overall, of the 12.8 million additional U.S. adults recommended for statin use under the new guidelines, 10.4 million are people who would be prescribed the drugs for preventive care. Of those preventive users, 8.3 million would be people over the age of 60.

The analysis also projects that an estimated 1.6 million adults previously eligible for statins under the old guidelines would no longer be candidates under the new standards. This group included primarily younger [adults](#) with elevated cholesterol

but low 10-year risk of [cardiovascular disease](#).

Pencina said an important limitation of the study is the necessary assumption that the new guidelines would be followed to the letter; in real life, people may be recommended for statins but decline to start the therapy.

"Recommendations are just that – recommendations," Pencina said. "These guidelines correctly call for a thorough discussion between the doctor and patient about the risks and benefits of statins. It's not like everybody who meets the guidelines should all of a sudden go on [statins](#)."

Provided by Duke University Medical Center

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