

## **New analysis estimates numbers of older US adults who may benefit from statin therapy**

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Researchers estimate more than 11 million older Americans may be newly eligible for statin therapy if findings from a recently published large clinical trial are adopted into clinical practice guidelines, according to a new analysis of the trial data. The analysis is published online in *Circulation: Cardiovascular Quality and Outcomes*.

Using data from the 1999 National Health and Nutrition Examination Survey, researchers found that 33.5 million older Americans (men age 50 years and older and women age 60 years and older) are currently taking a statin (24.4 percent) or have risks that would indicate a need for statin therapy based on current guidelines but do not take a statin (33.5 percent).

They estimated that an additional 19.2 percent of older adults could be considered eligible for statin therapy based on their matching the inclusion criteria used in a recently published clinical trial, Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER), presented in November at the American Heart Association's Scientific Sessions 2008 in New Orleans, La.

"Based on our analysis, more than 44.7 million older Americans might have an indication for statin therapy when you consider those who already meet current guidelines for statin therapy and those who might be eligible based on the criteria proposed in JUPITER," said the study's lead author Erica S. Spatz, M.D., an internist and fellow in the Robert

Wood Johnson Clinical Scholars Program at Yale University, New Haven, Conn. "That's nearly 80 percent of this segment of the population who could potentially be recommended a statin therapy if those criteria were adopted into guidelines."

The study is a numerical analysis rather than an endorsement of using statins to aggressively lower cholesterol and high sensitivity C-reactive protein (hsCRP) in people not currently considered candidates for that therapy, as was done in JUPITER. Additionally, the exclusion criteria for study participants in the JUPITER trial may make it difficult to generalize those findings.


"Certainly the JUPITER findings were intriguing and they will be evaluated as any future revisions are considered for treatment guidelines for reducing cardiovascular risk," said American Heart Association president Timothy Gardner, M.D. "This additional analysis of that data provides useful information about how many individuals would meet the JUPITER inclusion criteria. A more in-depth study of further implications, including cost-analysis, will be critical in future decision-making processes about preventive measures for the population as a whole. All of this will need to be carefully considered in the context of available resources and the most effective ways to make the most positive impact possible in reducing heart disease and stroke."

Spatz, who was not involved in the JUPITER trial, said her analysis does highlight an important challenge for healthcare providers and systems: Even under current treatment guidelines, fewer than half (42 percent) of older Americans who qualify for statin therapy actually get it. Although there are many possible reasons for this lack of treatment, many patients who could benefit are being missed - and this problem is likely to increase if the size of the population eligible for statins increases, she said.

"We must reduce risk, both with lifestyle changes and when indicated, with medications," said Gardner. "Clearly, as a nation, we are not adequately reducing the risk of those who, even under current guidelines, already need statin treatment but are not receiving it. Determining the most effective ways to do that is paramount."

In JUPITER, researchers explored whether statin use reduced heart attacks, strokes and death in patients who did not have cholesterol levels that would dictate cholesterol-lowering treatment, but had elevated levels of hsCRP, an inflammatory marker. Elevated levels of hsCRP have been associated with the development of coronary artery disease.

"That trial was terminated early after an interim analysis showed greater benefits in people taking statins than in those taking a placebo," Spatz said. "Our suspicion was that the findings from JUPITER might potentially impact a sizeable number of older adults in the United States; the question for us was how many more people might now have an indication to take a statin medication under these criteria."

Spatz used information from the 1999  National Health and Nutrition Examination Survey (NHANES), a periodic survey conducted by the federal government that is statistically representative of the U.S. population. Her study examined data from a subset of 2,322 older men and women who answered the NHANES survey questionnaires and also allowed researchers to take a fasting blood sample to test for a variety of cardiovascular risk factors, including cholesterol level and level of hsCRP.

Using those data, Spatz and her co-authors estimate that another 13.9 percent (8 million) of the older population would be candidates for statin therapy under the strictest JUPITER trial criteria - hsCRP at or above 2 milligrams per liter (mg/L) and low-density lipoprotein cholesterol (LDL) under 130 milligrams per deciliter (mg/dL), Spatz said.

She estimated that another 3 million people, or 5.3 percent of the older population, would qualify for statins under an expanded, but still plausible, treatment criteria of hsCRP at or above 2 mg/L and LDL cholesterol between 130 and 160 mg/dL.

Overall, the people who may now qualify for a statin based on JUPITER's findings share many characteristics with those who already qualify for a statin medication. The two groups were similar in age, race and socioeconomic status and had equal degrees of high blood pressure and abdominal obesity, both of which are risk factors for heart disease. Compared to people who have no indication for a statin medication, the JUPITER group was distinguishable in that they were more likely to be female and older, and to have obesity, high blood pressure and the metabolic syndrome.

"This further suggests we may be missing a group of people who in addition to having an elevated hsCRP, have other features that put them at risk for heart disease, and for whom a statin medication may be beneficial," Spatz said.

Spatz hopes her study will help provide important information for the development of future guidelines about using statin medications to reduce cardiovascular disease by providing some of the information necessary to determine whether the number of people who would get statin therapy under JUPITER criteria would be cost-effective from a public health standpoint.

Source: American Heart Association

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