

## Some doctors challenge new statin guidelines

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Photo: CDC/Amanda Mills

They say too many people would get the cholesterol-lowering drugs; heart groups defend the recommendations.

(HealthDay)—A new online cholesterol risk calculator produced by two leading U.S. heart organizations is flawed and overstates a person's risk of heart disease, a pair of Harvard Medical School professors say.

The professors contend that this flaw could lead the calculator to mistakenly suggest that millions of people should be taking cholesterol-lowering statin drugs, *The New York Times* reported Monday.

Key officials with the American Heart Association (AHA) and the American College of Cardiology (ACC) stood by the calculator during a hastily gathered news conference Monday morning at the heart association's annual meeting in Dallas.

Harvard professors Dr. Paul Ridker and Dr. Nancy Cook reportedly pointed out problems with the calculator a year ago, saying that it did not seem to work accurately when they tested it using patient data, the *Times* reported.

When the online calculator went live last week, Ridker and Cook again tested it and reported serious flaws that could overestimate a person's risk of [heart disease](#) by 75 percent to 150 percent, the newspaper reported. Their findings are to be published Tuesday in the medical journal *The Lancet*, according to the *Times'* report.

AHA and ACC officials said Monday that the Harvard professors' analysis of the calculator relied on patient data from three heart studies involving people both younger and healthier than the average American.

"These people exist in the U.S. population, but it's a very healthy, skewed group," said Dr. Donald Lloyd-Jones, chair of the department of preventive medicine at Northwestern University's Feinberg School of Medicine.

Lloyd-Jones said he and others met with Ridker on Saturday, as the AHA meeting got under way, and reviewed a limited amount of the Harvard doctors' data. He said he's still waiting to see the full report.

"I think all of us would like to see Dr. Ridker's data, and see that play out in scientific discussion rather than in the media," Lloyd-Jones said.

The two heart health groups said they created the calculator—as well as a set of aggressive new cholesterol-lowering guidelines—using a broad range of [patient data](#) that allowed them to incorporate factors that hadn't been included in previous risk assessments. For example, prior attempts did not include calculations for African-American populations, and did not attempt to include stroke risk.

"The truth is, the risk equations work exactly the way we asked them to," Lloyd-Jones said.

Officials from both heart groups added that just because the calculator suggests some people would benefit from statins doesn't mean they absolutely have to take them.

Instead, the calculator should prompt a conversation with their doctor about whether they need to take statins or undertake other lifestyle changes to lower their cholesterol.

"We're acknowledging the unique judgment of a physician when he looks at the patient's specific condition," said Dr. Neil Stone, chair of the AHA's cholesterol guideline committee and a professor of preventive cardiology at Northwestern's Feinberg School of Medicine.

Cardiologists are concerned that the confusion surrounding the calculator and new cholesterol treatment guidelines could cause patients to refuse to take statins.

"I fear that the confusion is going to shake the public's confidence in these lifesaving drugs," said Dr. Kevin Marzo, chief of cardiology at Winthrop-University Hospital in Mineola, N.Y. "It is my hope that the guideline writers will revise the online calculator so that any deficiencies created will be quickly corrected."

The two heart groups unveiled the calculator last week in connection with aggressive new guidelines for combating high cholesterol. Those guidelines call for the use of statins to treat more people.

Previously, doctors adhered to rigid clinical guidelines to prescribe a statin when cholesterol levels reached a certain threshold.

Under the new guidelines, people will be advised to take statins based on a number of different health risk factors. These risk factors include if they already have heart disease, if their bad (LDL) cholesterol is extremely high (190 milligrams per deciliter of blood or more) or if they're middle-aged with type 2 diabetes.

In addition, people between 40 and 75 years of age with an estimated 10-year risk of heart disease of 7.5 percent or more are advised to take a statin. Experts say this new rule could greatly alter the number of patients who will now be advised to take such a drug.

"We've come up with an approach that calls for treating about a third of adults between 40 and 75 years of age with statins for primary prevention," said Dr. David Goff, co-chair of the risk assessment working group for the guidelines and dean of the Colorado School of Public Health at the University of Colorado-Denver.

"I think it sounds about right," given that one out of three adults in America die from heart disease and stroke, Goff said.

The alleged problems with the calculator prompted at least one prominent cardiologist to tell the *Times* that implementation of the new cholesterol treatment guidelines should be delayed.

"It's stunning," Dr. Steven Nissen, chief of cardiovascular medicine at the Cleveland Clinic, told the newspaper. "We need a pause to further evaluate this approach before it is implemented on a widespread basis."

Dr. Sidney Smith, a cardiologist at the University of North Carolina at Chapel Hill and a past AHA president, said that would not happen.

"We intend to move forward with these guidelines and develop effective strategies to implement them," Smith said.

**More information:** For more on [statins](#) visit the U.S. National Library of Medicine.

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