



Help with the Headlines

HEALTH NEWS IN PERSPECTIVE

Topic: Understanding Wider Use of Statins

Two studies published in July offer support for guidelines encouraging doctors to prescribe cholesterol-reducing drugs far more widely than the current standard of care.

The studies, published in The Journal of the American Medical Association on July 14, 2015, conclude that the drugs, called statins, are both effective and cost effective for reducing the incidents of heart attacks and strokes even in low-risk individuals. The studies were publicized in the New York Times on July 14, 2015.

What are “Bad and “Good” Cholesterol?

According to the Centers for Disease Control and Prevention:

“Molecules called lipoproteins carry cholesterol in the blood. Two important kinds of lipoproteins are low-density lipoprotein (LDL) and high-density lipoprotein (HDL). When checking LDL and HDL, doctors often include another type of fat called triglycerides.

Total cholesterol is a measure of the total amount of cholesterol in your blood and is based on the HDL, LDL, and triglycerides numbers.

LDL cholesterol makes up the majority of the body's cholesterol. LDL is known as ‘bad’ cholesterol because having high levels can lead to plaque buildup in your arteries and result in heart disease and stroke.

HDL cholesterol absorbs cholesterol and carries it back to the liver, which flushes it from the body. HDL is known as ‘good’ cholesterol because having high levels can reduce the risk for heart disease and stroke.

Triglycerides are a type of fat found in your blood that your body uses for energy. The combination of high levels of triglycerides with low HDL cholesterol or high LDL cholesterol can increase your risk for heart attack and stroke.”

According to the Mayo Clinic:

“Non-high-density lipoprotein cholesterol (non-HDL-C) is the difference between the total cholesterol concentration and the HDL cholesterol concentration.”

How do statins work? What are the most common names?

Statins are a commonly used type of cholesterol lowering drug. These medicines work by blocking a step in cholesterol production in the liver.

The most widely used statins are atorvastatin (Lipitor), pravastatin (Pravachol), simvastatin (Zocor), rosuvastatin (Crestor), and lovastatin (Mevacor).



TALK WITH YOUR DOCTOR TO UNDERSTAND IF STATIN USE IS RIGHT FOR YOU.

What steps did the American College of Cardiology and the American Heart Association take in 2013 to define new eligibility criteria for statin therapy?

In 2013 the American College of Cardiology and the American Heart Association (ACC/AHA) updated their guidelines for the management of cholesterol. The expert panel was charged with evaluating scientific studies to support cholesterol-lowering treatments for reducing cardiovascular disease risk. Accordingly, the expert panel focused on three critical questions that served as the foundation for the evidence upon which the new guidelines were developed. These questions resulted in four patient groups who benefit from statin therapy.

The three critical questions raised by the expert panel were:

1. What is the evidence for low-density lipoprotein cholesterol (LDL-C) and non-high-density lipoprotein cholesterol (non-HDL-C) goals for the secondary prevention of cardiovascular disease (after you have been diagnosed with cardiovascular disease)?
2. What is the evidence for LDL-C and non-HDL-C goals for the prevention of developing (primary prevention) cardiovascular disease?
3. For primary and secondary prevention, what is the impact on cholesterol levels, effectiveness, and safety of specific cholesterol-modifying drugs used for cholesterol management in general and in selected subgroups of patients?

The panel identified four major benefit groups in whom the cardiovascular disease risk reduction of statin therapy clearly outweighs the risk of serious side effects from the medications:

1. Patients with clinical cardiovascular disease (previous heart attack, cardiac-related chest pain, previous coronary stents or coronary artery by-pass surgery, or stroke)
2. LDL-C level of 190 mg/dl or higher
3. Diabetic patients without clinical cardiovascular disease, from 40 to 75 years of age and LDL-C levels from 70 to 189 mg/dl
4. Patients with no diabetes or clinical cardiovascular disease, from 40 to 75 years of age, LDL-C from 70 to 189 mg/dl and an estimated 10-year coronary heart disease risk (fatal or non-fatal heart attack or stroke) of 7.5% or higher

What did they recommend?

The new guidelines recommended using the new Pooled Cohort Equations Calculator to estimate the 10-year coronary heart disease risk in both white and black men and women who do not have clinical coronary heart disease.

The new changes are intended to provide strong supporting scientific evidence for the treatment of cholesterol in women and men with and without clinical coronary heart disease.

What is the Pooled Cohort Equations Calculator?

Prior to the development of the new guidelines, medical health professionals used the Framingham risk score to assess an individual's chances of having a cardiovascular event within 10 years. However, the Framingham calculator used older data and did not include stroke as an outcome.

The ACC/AHA Pooled Cohort Equations Risk Calculator uses the latest data to predict nonfatal heart attack, fatal coronary heart disease, and nonfatal or fatal stroke.

In addition, the calculator includes race as a characteristic and lifetime atherosclerotic cardiovascular disease risk estimates for adults aged 20-59 years. It does not include notable risk factors from chronic kidney disease and any measure of social deprivation.



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Why were these new guidelines controversial?

Many concerns were immediately raised after release of the new guidelines, mainly related to the fourth major statin benefit group. Reports have argued that the new Pooled Cohort Equations risk calculator could overestimate cardiovascular disease risk and thereby increase adult eligibility to statin therapy in up to 12.8 million people compared to the old guidelines. Consequently, critics claim that new guidelines can lead to an unnecessary increase of statin use and expose people to unjustified drug side effects while increasing costs to the health care system.

How did the authors of the recently published eligibility study seek to determine whether the new guidelines improve the identification of adults at higher risk for cardiovascular events?

The new eligibility study looked at 2,435 individuals who were not on statin therapy and compared the effectiveness and accuracy between the new 2013 ACC/AHA guidelines and the 2004 guidelines to identify individuals at higher risk for incidents of cardiovascular disease (defined as first occurrence of a heart attack or stroke), evidence of coronary artery calcium, or both. Participants in this study were drawn from the large prospective Framingham Heart Study who underwent a computed tomography scan of the coronary arteries between 2002 and 2005.

What did they find?

They found that among 2,435 patients who had never used a statin medication, the new ACC/AHA risk calculator led to a significant increase in statin-eligible individuals compared to the old guidelines (39% vs. 14%). Interestingly, participants who were statin-eligible by the new guidelines had an increased risk for experiencing heart attacks or strokes and had elevated levels of calcium in the coronary arteries compared to statin-eligible individuals by old guidelines. The results of the study suggest that the new guidelines may properly identify people at higher risk for developing cardiovascular disease and not lead to unjustified overtreatment of statins in millions of individuals.

What were the eligibility study's limitations?

The study limitations were the small number of patients and cardiovascular events. Additionally, the Pooled Cohort

Equation risk calculator distinguishes between ethnic groups to estimate the 10-year cardiovascular risk, yet nearly every study participant was white, and results may not be generalizable to other ethnic groups. Also, it is important to understand that the study did not specifically test if statin therapy had an overall health benefit in primary prevention of heart attacks and strokes. Therefore, future studies should analyze the risks and benefits of long-term statin therapy in low-to-intermediate risk individuals to further our knowledge in new statin-eligible individuals identified by new guidelines.

How did the researchers design the cost-effectiveness study?

The cost-effectiveness study was also performed based on the criticism that expansion of statin treatment eligibility by the new guideline's risk estimator would expose millions of people to unnecessary treatment costs and risks. The authors developed a cardiovascular disease computer-simulation model to project the lifetime health outcomes and cardiovascular-related costs of 1 million hypothetical individuals in the United States. The hypothetical patients received statin therapy, had cardiovascular events and died from cardiovascular or other causes based on the natural history of cardiovascular disease and different statin treatment parameters.

What did they conclude?

Using the current 10-year cardiovascular disease risk threshold of 7.5% or higher used in the revised ACC/AHA cholesterol treatment guidelines, it was estimated that 48% of adults were treated with statins. This resulted in an acceptable cost-effectiveness profile as calculated by an incremental cost-effectiveness ratio of \$37,000 quality-adjusted life year (quality-adjusted life year is a generic measure used to assess the value for money of a medical intervention), compared with a threshold of 10% or higher. Interestingly, when the 10-year cardiovascular disease risk threshold was lowered to 3% or higher the simulation model estimated an additional increase in cardiovascular events prevented with statin therapy, suggesting that more lenient cardiovascular disease thresholds might also be cost effective.

Why is this important?

The results of the study are important because it suggest that the new ACC/AHA guideline's risk estimator should prevent a large number of cardiovascular events by increasing statin eligibility

in patients (without clinical cardiovascular disease and with a 10-year risk of 7.5% or higher for such events) in a cost-effective and justified manner.

What should consumers do with this new information?

It is important for consumers to understand that statins are overall safe and inexpensive drugs and should be used as the drug of choice to lower LDL-C. New ACC/AHA guidelines recommend the use of statin therapy for primary prevention in patients with a 7.5% or higher 10-year cardiovascular disease risk. There is sufficient data from randomized control trials to support its use and safety profile. The two new studies discussed above add to the body of evidence and support the use of statins for primary prevention based on the individual's level of risk without concerns for inappropriate overtreatment. The 2013 Pooled Cohort Equation risk calculator is preferred and should be used over the Framingham Risk Score to estimate the 10-year cardiovascular disease risk as it may identify more patients at high risk of heart attacks and strokes who could benefit from statins. Finally, the risks and benefits of statin therapy should be carefully discussed between patients and clinicians before initiating therapy, especially in primary prevention, to identify each individual's risk and reach a shared decision.

Help with the Headlines is a collaboration of Women's Health Research at Yale and the OhioHealth Healthcare System, a nationally recognized not-for-profit organization with providers across 46 counties, offering a holistic approach to prevention, treatment and rehabilitation of heart disease.

OhioHealth is staffed by physicians, psychologists, nutritionists and nurses who answer the questions of the moment on heart and vascular health.

The information provided here may help you make more informed choices. However, it is not a substitute for an individualized medical opinion or diagnosis, and everyone should always consult with their personal physicians to make decisions about their condition or treatment.