

# **Physician Views: How have cardiologists, internal medicine specialists and general practitioners reacted to the new AHA/ACC cholesterol management guidelines**

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## **Abstracts**

Since being announced last week, new cardiovascular disease treatment guidelines from the American Heart Association (AHA) and the American College of Cardiology (ACC) have been the subject of much debate.

Rather than focus on treating patients towards a target LDL level (as is the case with current recommendations), the guidelines recommend to more broadly assess a patient's risk for cardiovascular diseases and prescribe moderate- or high-intensity statin therapy to patients with either cardiovascular disease, an LDL level of 190 mg/dL or higher, patients with type 2 diabetes who are between 40 and 75 years of age, and patients with an estimated 10-year risk of cardiovascular disease of 7.5 percent or higher who are between 40 and 75 years of age. The new guidelines recommend to remain on statin therapy irrespective of LDL cholesterol levels, eliminating a need for frequent blood testing.

Neil Stone, chair of the expert panel that produced the new recommendations, noted that "although the definition of optimal LDL cholesterol has not changed", the new guidelines "focus on defining groups for whom LDL lowering is proven to be most beneficial." Stone added, "the emphasis is to try to treat more appropriately, we're going to give statins to those who are the most likely to benefit."

Under the new guidelines, which were based on an analysis of the results of randomised controlled trials, doctors may also consider switching some patients to a higher dose of statins to derive greater benefit. Stone noted that the panel chose to

focus on statins "because their use has resulted in the greatest benefit and the lowest rates of safety issues. No other cholesterol-lowering drug is as effective as statins." Stone added that there is a role for other cholesterol-lowering drugs, for example, in patients who suffer side effects from statins.

The new guidelines may lead to increased use of high potency statins, such as AstraZeneca's Crestor (rosuvastatin) and higher doses of Pfizer's Lipitor (atorvastatin), which is now available generically. Meanwhile, use of lower-dose generic statins and non-statin cholesterol medicines, such as Merck & Co.'s Zetia (ezetimibe) and AbbVie's Tricor (fenofibrate), could be reduced. "Non-statins didn't provide enough risk prevention," Stone noted, adding that there has been "over treatment by drugs not proven to add incremental benefit."

Key questions focus on how enthusiastically the guidelines will be embraced by physicians and how rapidly. In a note to investors last week, International Strategy & Investment analyst Mark Schoenebaum suggested that adoption could be relatively slow (and slower than adoption of previous new guidelines). Key to this outlook is that the shift away from target LDL levels may prove controversial, argues Schoenebaum. Many physicians are "strong proponents of low LDL targets and the LDL hypothesis – the simple idea that the lower the LDL the better" added the ISI analyst.

The other much discussed implication is the effect of the guidelines on the uptake of new, non-statin cholesterol-reducing medicines – specifically the PCSK-9 inhibitors.

An FDA official told Bloomberg late last week that outcomes studies would not be required for new drugs in this class to gain approval (although a number of industry commentators pointed out that this is by no means a guarantee on the part of the FDA).

However, assuming approval for such drugs was granted prior to data from outcomes studies, there is some suggestion that the new guidelines could result in slower uptake of new non-statin therapies until these data are made available. Discussing the commercial opportunity for the PCSK9 inhibitors, a number of analysts have pointed out, however, that initial uptake of these new products will occur primarily in patients who cannot be effectively treated with statins or who are intolerant to this drug class. Therefore, if adoption of the guidelines increase the use of statin therapy won't this also highlight an increased number of patients who are eligible for treatment with the PCSK9 inhibitors.

This week's Physician Views poll will ask US-based cardiologists, general practioners

and internal medicine specialists a number of questions in order to gauge their initial reaction to the new guidelines. Specifically the poll will ask:

What their initial reaction is to the new ACC/AHA guidelines

How they expect the guidelines will impact their use of statins

To what extent they expect to conform to the new guidelines

How they perceive the guidelines will impact their use of AstraZeneca's high potency statin Crestor (rosuvastatin)

How they perceive the new guidelines will impact their use of new cholesterol reduction drugs (such as the PCSK9inhibitors) once approved

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