

New cholesterol-lowering guidelines would increase cost of treatment

February 19 2020



Peter Ueda, intern physician and postdoctoral researcher at the Department of Medicine in Solna at Karolinska Institutet. Credit: Stefan Zimmerman

The financial burden on health systems would drastically increase if new

European expert guidelines for cholesterol-lowering treatment were implemented, according to a new simulation study by researchers at Karolinska Institutet in Sweden, published in the *European Heart Journal*. The findings highlight an urgent need for cost-effectiveness analysis given the current cost of the proposed treatment for very high-risk patients, the researchers say.

In August 2019, the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) recommended that low-density lipoprotein cholesterol levels (LDL-C), often described as the "bad" cholesterol, should be substantially lowered to prevent [cardiovascular disease](#), especially in very [high-risk patients](#). The guidelines carry significant weight for clinicians and authorities and are often used as a reference point for treatments in Europe and elsewhere.

For patients with a very high risk of cardiovascular disease, such as those with a recent heart attack, the new guidelines recommend both lowering the LDL-C level by at least 50 percent and having a LDL-C level of less than 1.4 millimoles per liter of blood (mmol/L). This is a sharp reduction compared to previous guidelines presented three years earlier. To reach these targets, the organizations recommend combining lifestyle modifications with the low-cost, cholesterol-lowering statins and ezetimibe. If the LDL-C goal isn't reached despite the use of these therapies, adding a new type of high-cost cholesterol-lowering drug known as a PCSK9 inhibitor is recommended.

In this study, the researchers predicted the implications of the new guidelines by calculating how many patients would be eligible for expanded therapy. Using Sweden's national registry for heart disease patients, SWEDEHEART, the researchers studied more than 25,000 people who suffered heart attacks between 2013 to 2017 and whose cholesterol levels were measured during follow-up visits after six to 10 weeks.

The researchers found that more than 50 percent of the patients would be eligible for PCSK9 inhibitors as they would not have reached the LDL-C targets with only high-intensity statins and ezetimibe. When use of two currently approved PCSK9 inhibitor drugs (alirocumab or evolocumab) was simulated in those patients, around 90 percent of all patients attained the LDL-C target. The annual cost of treating a patient in Sweden with PCSK9 inhibitors is more than 4,500 euros compared to only around 30 euros with statins or ezetimibe.

"PCSK9 inhibitors are clearly effective cholesterol-lowering drugs that may reduce the risk of cardiovascular events, but they come at a substantial cost," says Ali Allahyari, [resident physician](#) in cardiology and doctoral student at the Department of Clinical Sciences, Danderyd Hospital, Karolinska Institutet, and first author of the study. "If half of the patients with heart attacks were eligible for this drug, the [financial burden](#) on [health systems](#) throughout Europe and other countries using the ESC/EAS guidelines could be substantial unless the cost of treatment is reduced."

Using previous analyses, the researchers explored to what degree lowering bad cholesterol can reduce the risk of another severe cardiovascular episode. They estimated that using the PCSK9 inhibitor drug alicumab to prevent one major adverse cardiovascular event, such as another heart attack, would cost around €846,000 in Sweden (8.9 million Swedish kronor).

"Many new therapies are being tested and introduced in cardiovascular medicine today," says Peter Ueda, intern physician and postdoctoral researcher at the Department of Medicine in Solna who led the study. "Our analyses highlight yet another situation for which we need to consider what we deem reasonable in terms of the number of patients being treated, the expected health gains and cost."

More information: Ali Allahyari et al, Application of the 2019 ESC/EAS dyslipidaemia guidelines to nationwide data of patients with a recent myocardial infarction: a simulation study, *European Heart Journal* (2020). [DOI: 10.1093/eurheartj/ehaa034](https://doi.org/10.1093/eurheartj/ehaa034)

Provided by Karolinska Institutet

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