

More heart attacks and strokes when cholesterol-lowering prescription rejected or unfilled

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Individuals at high risk for cardiovascular events, including those with familial hypercholesterolemia (FH) or atherosclerotic heart disease (ASCVD) experienced more heart attacks, strokes and other cardiovascular events when they were unable to obtain their prescribed LDL-cholesterol lowering medication.

In a new study published today in *Circulation: Cardiovascular Quality and Outcomes*, researchers with the FH Foundation found that individuals with ASCVD or FH whose PCSK9 inhibitors (PCSK9is) were rejected by their insurance plan had an immediate 16 percent increased risk of a cardiovascular event during the 12-month study period.

High cholesterol is a major risk for heart disease, which is the number one killer worldwide. PCSK9is have been shown to lower LDL-cholesterol and improve cardiovascular outcomes in multiple randomized trials, yet many individuals unable to obtain treatment.

"Over eighty thousand individuals at high risk for [cardiovascular events](#) experienced delays in treatment. Unprecedented high insurance denials, high drugs costs and related out-of-pocket costs resulted in individuals not receiving therapy and caused a significant increase in cardiovascular events, including heart attacks and stroke. In other words, real people had real heart attacks and strokes because they could not get the

medicine prescribed by their doctors," said Kelly Myers, FH Foundation [chief technology officer](#) and study author.

To identify whether rejected, unfilled or paid PCSK9i prescriptions had an impact on outcomes, researchers analyzed healthcare encounter data from 139,036 individuals over the age of 18 between August 2015 and December 2017. A status of "paid prescription" was assigned to those who received 338 or more days of therapy within 12 months, "rejected" if the final claims status was rejected, and "unfilled" if the prescription was approved but not filled.

In addition, individuals who did not fill their prescriptions had an immediate 21 percent increased risk of a cardiovascular event during the study period. Approximately 65 percent of unfilled claims were among Medicare patients, likely due to higher co-pay costs.

Myers added, "Higher co-pays led to more individuals giving up their therapy even if they were approved. Unfortunately, we found these treatment delays disproportionately impact the most [vulnerable groups](#), including women, minorities and individuals with lower incomes, who are already undertreated for heart disease."

The study also revealed that individuals with FH, a common genetic condition that causes high LDL-cholesterol from birth, are at an even greater risk than other high-risk groups in the study. All of the individuals in the study had a seven-times higher risk of cardiovascular events than the general population. In addition, individuals with FH had a further three-times increased risk of a cardiovascular event compared to those in the study that did not have FH or ASCVD. In fact, individuals with FH had no difference in risk of a cardiovascular event compared to someone with diagnosed ASCVD. The study's highest risk group was an individual with FH who also had cardiovascular disease. This group had more than five-times the risk of other individuals in the study that did

not have FH or ASCVD. Yet, 63 percent of their prescriptions were rejected.

"While we know that someone who has had a [heart attack](#) or other cardiovascular event is much more likely to have a second event and is at much higher risk than the general population, this new finding underscores that individuals with FH are at as high a risk. It is imperative that we initiate comprehensive treatment early in life, and that individuals receive the medications they have been prescribed," said Daniel J Rader, M.D., chair of the department of Genetics in the Perelman School of Medicine at the University of Pennsylvania, Chief Scientific Advisor of the FH Foundation and senior author of the paper.

"This real-world evidence highlights how much at risk FH individuals are for a heart attack or surgical intervention if their LDL-C is not adequately lowered. Individuals like myself, who have FH and have had a heart attack, are at the highest immediate risk of a life-threatening cardiovascular event, yet over two-thirds of prescriptions for this group are still being rejected," said Katherine Wilemon, Founder and CEO of the FH Foundation.

More information: Kelly D. Myers et al, Effect of Access to Prescribed PCSK9 Inhibitors on Cardiovascular Outcomes, *Circulation: Cardiovascular Quality and Outcomes* (2019). [DOI: 10.1161/CIRCOUTCOMES.118.005404](#)

Provided by The Familial Hypercholesterolemia Foundation

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