SPEAKER:

In our analysis of Medicare claims, we had very specific definitions of statin muscle intolerance. And we identified 2.3% of the individuals who fulfilled our criteria. These were individuals who changed statins three times within a year, patients who down-titrated or discontinued the statin with a prescription for ezetamibe monotherapy, individuals who had a claim of rhabdomyolysis, or hospitalization for an adverse statin effect.

In clinical practice, we're seeing statin muscle intolerance in more individuals, and this has been a big debate in the field. Why are we seeing more statin muscle intolerance in the clinical trials? First of all, the clinical trials that are cited most often by the Oxford Group use much lower-intensity statins than we use today in our high-risk individuals.

The ASCOT lipid-lowering therapy trial used atorvastatin 20 milligram daily. The Heart Protection Study 2 used simvastatin 40 milligram daily. Currently, we're using rosuvastatin 20 to 40 milligram daily or atorvastatin 40 to 80 milligram daily. And we're using statins in populations that would have been excluded from many of these clinical trials, individuals who are older, people with renal insufficiency, individuals who have multiple drug interactions. And this may be why we're seeing more statin muscle intolerance in clinical practice.

From my perspective, the debate really doesn't have much meaning because individuals who down-titrate or discontinue after a myocardial infarction or other high-risk individuals have more cardiovascular events, more hospitalisations for cardiovascular events, and actually tend to have a higher mortality rate, as shown in a longer-term study from the Partners Health Group.

The health care expenditures for these individuals are substantial, and one needs to be cognizant of our responsibility not only to the patient but our responsibility to society to provide these very high-risk individuals every tool that's available to lower their LDL cholesterol and reduce the likelihood they're going to have a recurrent cardiovascular event that may result in disability and death.