EDITORIAL

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You'll Have a Dickens of a Time

Most of you are no doubt familiar with the opening of Charles Dickens' classic novel *A Tale of Two Cities*: "It was the best of times, it was the worst of times." In many ways Dickens has presaged my current thinking about the new lipid guidelines that were recently issued. On the one hand, they are truly the very best guidelines that could possibly be produced at the present time; on the other hand, they may also be the worst set of guidelines that could possibly be promulgated on the practice community at the present moment.

Let's first take a good look at what the new guidelines actually recommend. First, it's important to understand that the parentage of the new guidelines has changed in a very important way from that of earlier recommendations. The previous lipid guidelines—the National Cholesterol Education Panel (NCEP) recommendations—were issued in 2001 and were sponsored and endorsed by the National Institutes of Health (NIH) as the federal government's best effort at lipid recommendations for the general practice community. An update in 2004 further advised that a low-density lipoprotein cholesterol (LDL-C) goal of < 70 mg/dL is appropriate for many patients with preexisting vascular disease.

New guidelines were clearly overdue. Indeed, an expert panel had already been convened and was hard at work. However, a year or so ago the NIH made a critical strategic decision that it no longer wanted to be in the guideline business. The NIH rather abruptly decided that there would be no further iterations of the NCEP guidelines.

Fortunately the NIH did not simply drop the ball. Rather, it decided to pass the baton (mixed metaphor—sorry!) to a joint task force of the American Heart Association (AHA) and the American College of Cardiology (ACC). After all, who better to ponder lipid goals than the vascular experts who populate these 2 august societies? These 2 groups took a good look at the work that had been done by the expert panel, and decided that they would bless the new recommendations.

The fruit of the years of labor were finally presented at the annual meeting of the AHA held in Dallas in 2013. I didn't make it to all of the heart sessions during that meeting. (I was distracted to a considerable extent by the 50th anniversary commemoration of President John F. Kennedy's assassination going on just a few blocks away from the convention center at the Texas School Book Depository site.) But I can tell you I was definitely at the AHA session where the guidelines were formally presented, and it was indeed a lively and controversial session.

By far the biggest change in the new guidelines, representing both its greatest strength and its greatest weakness, is the new emphasis on overall cardiovascular risk assessment rather than on the attainment of a certain defined LDL-C goal. Indeed, a feature of the new guidelines, which many find disconcerting, is that there is no longer any mention whatsoever of LDL-C goals or targets!

The guidelines are also heavily statin-centric; other classes of lipid-lowering agents, such as fibrates or niacin, receive short shrift indeed. The recommendations are that statins should be prescribed routinely for each of the following "statin benefit groups":

1. Patients who have clinical atherosclerotic cardiovascular disease and thus fall into the "secondary prevention" category.
2. Those with LDL-C levels of ≥ 190 mg/dL and who have no secondary cause, such as certain medications or diseases such as hypothyroidism or nephrotic syndrome.
3. Patients with diabetes without established cardiovascular disease aged 40 to 75 years with LDL-C levels between 70 mg/dL and 189 mg/dL.
4. Patients without diabetes with established atherosclerotic cardiovascular disease aged 40 to 75 years with LDL-C levels from 70 mg/dL to 189 mg/dL and a calculated cardiovascular risk of at least 7.5% over the next 10 years.

The fourth category is potentially the most confusing for conscientious providers. The risk calculator that determines whether or not someone has a risk of > 7.5% over the next year is not the traditional Framingham risk calculator, with which many providers are familiar. Rather, it is a brand-new, improved risk calculator devised by the panel. The calculator can be found on both the AHA and ACC websites and in iOS and Android apps (See App Corner, p.38).

To make things even more confusing, once it has been determined that a statin is indicated, the dosing of the

statin, either low, moderate, or high intensity, must be selected on the basis of determined risk level. Fortunately, the panel has given us a nice table defining which statins qualify for inclusion in each of these 3 intensity categories. As a general rule, the low-intensity statins should almost always be avoided. But the determination of whether moderate or high-intensity statins are indicated gets somewhat murky. The first two aforementioned classes both deserve high-intensity statins. However, patients with diabetes who haven't had an event could go with either moderate- or high-intensity statins, and those patients without diabetes or LDL-C levels ≥ 190, but with a 10-year risk of at least 7.5%, can also receive either moderate- or high-intensity statins.

So there it is, and it all does make a certain amount of sense. You first determine the patient's risk category, which determines whether or not statins are indicated. If they are, you then decide what level of potency your prescribed statin should possess. There is no need to go checking LDL-C levels later, because your therapy is not targeted at any particular LDL-C level. You might want to check occasionally, though, just as a way of assessing patient compliance.

So what should we make of all of this? From a purely scientific point of view, it seems abundantly clear that these are the most scientifically valid set of guidelines that have ever been produced, generated by genuine experts who bent over backward to examine every possible relevant study. The new risk calculator is clearly a broader-based tool than the Framingham calculator, which was based on now-dated data from a very narrow heavily-white population basis. Although the new risk calculator has been criticized by some as a very imperfect tool that overestimates risk in some subpopulations, I firmly believe it is considerably less imperfect than the Framingham tool. It is, quite frankly, the best risk calculator anyone could come up with at this time, and the cutoff for treatment at a risk of 7.5% or higher over 10 years seems eminently reasonable to me.

So what's the problem with the new guidelines? I think you astute readers already know what the problem is: These guidelines simply represent way too radical a change for the huge bulk of busy, harried providers out there. The average primary care provider is currently struggling to complete a multifaceted patient encounter in 15 minutes or less and then document it in excruciating detail. He or she is going to be extremely hard-pressed to master and implement the new guidelines. The guidelines are indeed the most scientifically accurate and thorough guidelines that could be humanly produced, but they represent such a radical change from previous guidelines that a huge number of providers are going to be playing catch-up for a long time. I hope that their learning curve can be a very rapid one, but I worry that these scientifically pristine guidelines will be slow to find their way into general practice. ●

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