The Prudent Prescriber

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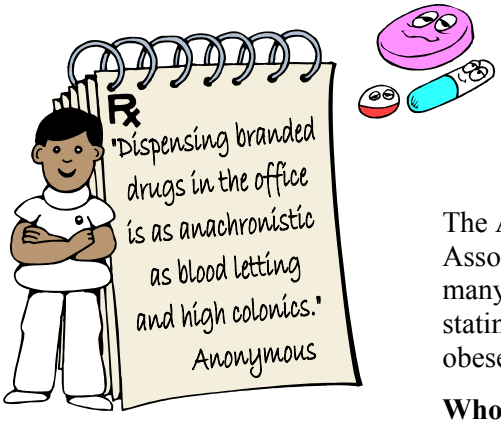

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New Statin Guidelines: Targets Disappear, but Push toward More Statins

Pharm Reps ≠ Rational Prescribing (PR) (RP)

The American College of Cardiology and the American Heart Association just released new guidelines recommending that as many as 70 percent more Americans over age 45 should be taking statins. Whoa! First, do no harm. Last month, I took a look at this obese, complicated document.

Who wrote the guidelines?
It is an impressive group of fifteen academic scientists and physicians. However, seven of the committee members, including a co-chairman of the committee, have extensive ties with the pharmaceutical industry. To their credit, the authors indicate that those members with conflicts of interest were not allowed to vote on the actual guidelines. Further, the vast majority of currently prescribed statins are available as generics. Recall also, however, that both the American Heart Association and the American College of Cardiology have financially incestuous relationships with the pharmaceutical industry.

Healthy Living First
These guidelines provide an ongoing emphasis on eating a healthy diet, exercising regularly, avoiding tobacco products and maintaining a healthy weight. The mindset that taking Lipitor regularly will assuage the damage to one's arteries and guilt for eating French fried onion rings just does not fly.

What's new in these recommendations?
First, the guidelines have moved away from achieving target cholesterol levels. Recall the "know your number" campaigns that created neuroses in both doctors and patients worrying about the fact that the LDL cholesterol was 101, rather than 99. And how many unnecessary drugs got prescribed to get the managed care incentive? For several years, there has been a growing controversy about whether or not statin drugs really worked by reducing cholesterol (cholesterol hypothesis) or by some other mechanism. These guidelines create a chink in the armor of the cholesterol hypotheses.

CHF?
Think:
Ace
Aldactone
B-blocker
Dig
Diuretic

Avoid these expensive "me-too" drugs:
Intermezzo
Vimovo
Livalo
Pristiq
Viibyrd
Edarbi
Daliresp

Treat diabetics BP to 130/80

Antibiotics do NOT help acute bronchitis

ß-blockers in post-MI save lives

Pill splitters save BIG

NOW AVAILABLE ON THE GENERIC MARQUEE

Cymbalta→duloxetine
Avapro→irbesartan
Tricor→fenofibrate micronized
Niaspan→niacin ER
Diovan HCT→valsartan/HCTZ
Atacand HCT→candesartan/HCTZ
Maxalt→rizatriptan

Second, the committee concluded that non-statin drugs do not provide heart attack and stroke risk reduction. So adding Zetia to your patient's statin or prescribing a combination drug, Zetia-simvastatin (Vytorin) may lower cholesterol, but does nothing to protect hearts and brains.

Third, the guidelines are suggesting that we should know our patients' "risk" of heart attack and stroke, rather than their "number." Included with the guidelines is an online calculator, (http://my.americanheart.org/cvriskcalculator) that considers gender, age, race, total cholesterol, HDL (good) cholesterol, blood pressure, treatment or not for blood pressure, diabetes, and smoking. *This is a tool for use by healthy persons who do not have known heart disease or diabetes, are 40-75-years old and whose LDL cholesterol is 70-189.*

Three days after the guidelines were released, two professors from Harvard Medical School, Paul Ridker and Nancy Cook, presented robust data in Lancet that demonstrated that the risk calculator over predicted heart attack and stroke risk by 75% to 150%. Uproar! This guideline tool, as presented, could result in more than 45 million middle aged Americans, who do not have cardiovascular disease, being recommended for statin therapy. Surprisingly, the Heart Association and the cardiologists refused to back down or relook at their calculator.

In three of the four categories where these new guidelines recommend statins, there is total agreement that this class of drugs is helpful. Those are people who have had strokes and heart attacks, those with baseline LDL cholesterols greater than 190, (many of whom have genetic predisposition to very high cholesterols and early heart attacks and strokes) and most patients with diabetes, ages 40-75 years. For these patients, statins are secondary prevention and there are overwhelming data that statins reduce their risk of heart attacks and strokes.

My Take:

1) It is with their fourth category, where the guidelines go awry in recommending treatment of healthy patients with statins. We know that when you treat any chronic illness where the disease is severe, the benefits will mostly outweigh the risks. On the other hand, if you treat a group of patients with mild disease (or no disease at all) the risk will often outweigh the benefits. The guidelines recommend those patients *without* ASCVD or diabetes with a LDL cholesterol of 70-189 mg/dl and an estimated 10 year ASCVD risk **>/= 7.5%** be treated with a statin. This is a step down from the previous 20% or 10% 10 year risk. Suddenly a whole bunch of healthy people become patients.

2) These guidelines comment repeatedly that statins are a well-tolerated, very safe class of drugs. Studies repeatedly suggest otherwise. Eighteen percent or more of statin patients experience side effects, including muscle pain or weakness, decreased cognitive function, increased risk of diabetes (especially for women) cataracts or sexual dysfunction.

3) Playing with their risk calculator is instructive. For example, for a healthy Caucasian patient with ideal everything: total cholesterol (170), HDL (50), systolic blood pressure (110) and nonsmoking with no diabetes, age alone will prompt statin therapy- beginning at 63 years for men and 70 years of age for women.

4) An analysis done by Dr. Abramson in the British Medical Journal in October, 2013, helps with the question that we really want answered.

   For people at low risk of a heart attack or stroke, 140 must take a statin for five years to prevent one heart attack or stroke. So 139 of 140 of these low risk patients, who take a statin for five years, will receive absolutely no benefit, but are subject to the cost and side effects of the medication. And what are the risks? One out of every 5 patients will have some ill effect from taking a statin.

5) In summary, these new guidelines thankfully eliminate cholesterol targets, remind us of the three groups of patients where we should encourage statins, and create increased skepticism of the non-statin cholesterol lowering drugs (read stop Zetia and Vytorin). Unfortunately their on-line CV calculator is defective. This guideline committee persists in the modern guideline writing trend of trying to make the well, ill. This is an ideal clinical situation to engage your patient in shared decision making.

You may access previous issues at http://www.rmhp.org/providers/prudent-prescriber.