The Prudent Prescriber

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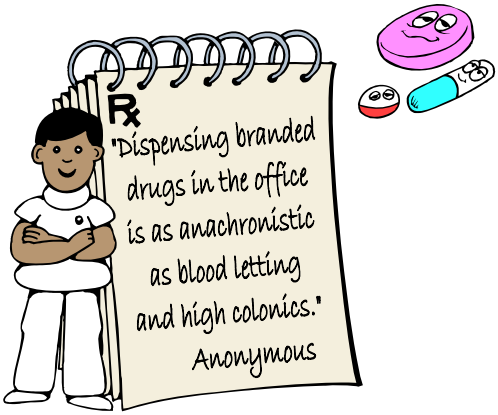


September 2017

"Free" Statins for the Well?

The American College of Cardiologists, The United States Preventive Services Task Force (USPSTF)

Is this Prudent Prescribing?

Has common sense been dealt another blow?

I worship the USPSTF. I also understand the high prevalence of CV disease and death in our country. Nonetheless, I was aghast at the ACC/AHA guidelines in 2013 and blamed their cavalier recommendation to "statin-ize" our population, particularly those over age 60. I wrote it off on the biases and conflicts of interest of the ACC/AHA guideline committee. Now the beloved USPSTF, thought free of conflict of interest, is beating the same illogical drum.

The New Guideline

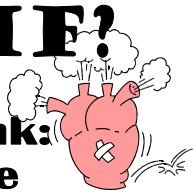
The USPSTF has released a "**B**" recommendation for adults aged 40 to 75 years who meet all of the following criteria: (1) no history of CVD, (2) one or more CVD risk factors (dyslipidemia, diabetes, smoking or hypertension) and (3) a calculated 10 years CVD event rate of 10% or greater… be treated with a low-moderate dose of a statin.

"B" *The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.*

Pharm Reps ≠ Rational Prescribing
(PR) **(RP)**

Antibiotics do NOT help acute bronchitis

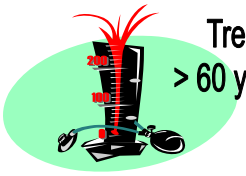
CHF?
Think:
Ace
Aldactone
B-blocker
Dig
Diuretic



Avoid these expensive "me-too" drugs:

Intermezzo
Vimovo
Livalo
Pristiq
Viibyrd
Edarbi
Daliresp

ß-blockers in post-MI save lives



Treat patients > 60 years to 150/90

Pill splitters save BIG

NOW AVAILABLE ON THE GENERIC MARQUEE

Frova→frovatriptan
Voltaren gel→diclofenac Na 1% gel
Crestor→rosuvastatin
Nuvigil→armodafinil
Jalyn→dutasteride/tamsulosin
Ortho Tri-Cyclen Lo→Tri-Lo-Marzia, Tri-Lo-Sprintec, & others

Adults in the same age range with no known cardiovascular disease and one or more CV risk factors and the risk of a CV event over the next 10 years of 7.5% to 10% earn a "**C**" recommendation for low-moderate dose statins. "C" *The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.*

The USPSTF indicates that there is insufficient evidence "**I**" for statins in those individuals over 75 years with similar characteristics. Approximately 35% of patients without CV disease over 75 years now take statins. A new analysis of the ALLHAT study suggests possible harm of statin therapy in this age group (increased mortality, no decrease in cardiovascular risk). (Han, JAMA Int Med , 2017, May 22)

The USPSTF recommends using the ACA/AHA calculator (cvriskcalculator.com).

What would implementation of this recommendation mean?

Pagidipati *et al* (JAMA, 2017:317(15); 1563-67 April 18, 2017) found that implementation of the USPSTF recommendations would be associated with **an incremental increase of 15.8% of US adults receiving statin treatment.** Full implementation of the ACC/AHA guidelines would be associated with an incremental increase of 24.3%.

As this guideline "gives" a "**B**" recommendation, managed care companies are required to buy this service for their insured without copays or deductibles.

Low-moderate dose statins include:

- Atorvastatin 10-20 mg
- Pravastatin 10-80 mg
- Simvastatin 10-40mg
- Lovastatin 20-40mg
- Rosuvastatin 5-10 mg
- Fluvastatin 20-40mg
- Fluvastatin ER 80mg
- Pitavastatin 1-4 mg

Rocky Mountain Health Plans data for 2016 reveal that over 90% of these low-moderate dose statins prescribed were from the first four drugs on the above list and were not a significant blip in terms of costs.

The science

The USPSTF based this recommendation on a Cochrane Review that looked at 19 randomized controlled trials conducted during 1994-2008, one to 6 years in duration, 56,934 patients, 85.9% Caucasian, 60% men, mean age 57 years that compared statins versus placebo or "no statin" as primary prevention for CV events. The results:

- For all-cause mortality, the absolute risk difference was – 0.40% or a Number Needed to Treat (NNT) with a statin was 250 for one year.
- For CV mortality, the absolute risk difference was – 0.43% or a NNT for one year with a statin to prevent one CV death was 233.
- Stroke, NNT = 263.
- MI, NNT=123.
- Composite CV outcomes, NNT = 72.

Why you should think thrice before recommending this guideline

This study that demonstrates a decrease in all-cause mortality and modest improvements in CV outcomes is **not** a credible recommendation for statins as a primary prevention intervention. Here's why.

- ❖ A relook at these studies revealed that ~10% of these patients had underlying CV disease. This creates bias in favor of statins.

- There was a failure to report adverse events in many of these studies; the USPSTF minimizes the side–effects of statins comparing them to placebo. That benign characterization belies most physicians' experiences with prescribing statins.
- There was selective reporting of outcomes in many of the studies and it will not surprise you that all but one of the original studies was paid for by Big Pharma.
- The risk calculator that drives this guideline has been shown to overestimate actual risk in multiple external validation cohorts (*J Am Coll Cardiol*. 2016;67(18):2118–2130, *JAMA Intern Med*. 2014;174(12):1964–1971, *Ann Intern Med*. 2015;162(4):266–275).
- These studies carried out decades ago may not be generalizable to our current population that is now more ethnically diverse.

My Take

I have always wanted to be a public-health guru when I grow up. Statins for primary prevention seem like a great, inexpensive population based intervention, like B vitamins in your bread*. Alas, our currently available data, when looked at carefully, do not support "statins for the well."*

Beware the risk calculator whether are you are following the ACC/AHA statin guidelines or those of the Preventive Services Task Force. As outlined above, there are convincing data that demonstrate that this calculator over estimates the risks of a cardiovascular event. If you must use this calculator, then follow the guidelines from the UK National Institute for Clinical Excellence (NICE). The Brit guideline, "Do not use statins in people with a 10 year cardiovascular risk below 20%."

Finally, it is disappointing that both the USPSTF and the American Family Physician (January 2017) in reporting on this guideline continue to present outcomes as "relative risks" rather than NNT or NNH. I would expect this from Big Pharma, but not the USPSTF in 2017. **Relative risk reductions are meaningless** and physicians and patients, alike, can certainly get our heads around number needed to treat and to harm.

The views expressed here are my own and may not reflect those of my employers, Rocky Mountain Health Plans and the Mesa County Health Department.

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