Points of Interest

2013 ACC/AHA Blood Cholesterol Guideline
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The Expert Panel acknowledges that the process does not provide for a comprehensive approach to the detection, evaluation, and treatment of lipid disorders as was done in the prior ATP III Report. However, the guidelines are not intended to be a comprehensive approach to lipid management for purposes other than ASCVD risk reduction. It is a systematic evidence review indicated a consistent reduction in ASCVD events from statin therapy in secondary and primary prevention populations, with the exception of no ASCVD event reduction in those with New York Heart Association (NYHA) class II-IV heart failure or receiving maintenance hemodialysis. In the clinical trials reviewed that specifically addressed statin treatment in these groups, there were individuals with and without heart disease; although statin therapy did not reduce ASCVD events in 2 RCTs for each condition there was insufficient information on which to base recommendations for or against statin treatment. In individuals with these conditions, the potential benefit, adverse effects, and drug-drug interactions along with other cautions and contraindications to statin therapy and choice of statin dose must also be considered by the treating clinician. The random clinical trial (RCTs) either compared fixed doses of statins with placebo or untreated controls, or compared fixed doses of higher-intensity statins with moderate-intensity statins.

4 major statin benefit groups were identified for whom the ASCVD risk reduction clearly outweighs the risk of adverse events. Individuals 1) with clinical ASCVD, 2) primary elevations of LDL–C >190 mg/dL, 3) diabetes aged 40 to 75 years with LDL–C 70 to 189 mg/dL and without clinical ASCVD, or 4) without clinical ASCVD or diabetes with LDL–C 70 to 189 mg/dL and estimated 10-year ASCVD risk >7.5%.

Clinical ASCVD is defined by the inclusion criteria for the secondary prevention statin RCTs (acute coronary syndromes, or a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin).

10-year risk of ASCVD (defined as nonfatal MI, CHD death, nonfatal and fatal stroke)

The basis for differentiation among specific statins and doses arose from the RCTs, where there was a high level of evidence that high-intensity statin therapy reduced ASCVD risk more than moderate-intensity statin therapy. Classifying specific statins and doses by the percent reduction in LDL–C level is based on evidence that the relative reduction in ASCVD risk from statin therapy is related to the degree by which LDL–C is lowered. Conclusion re: target goals/dosing of therapy-- Expert Panel did not find evidence to support titrating cholesterol-lowering drug therapy to achieve optimal LDL–C or non-HDL–C levels because the clinical trials were essentially fixed dose trials & given the absence of data on titration of drug therapy to specific goals, no recommendations are made for or against specific LDL–C or non-HDL–C goals for the primary or secondary prevention of ASCVD.

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In the relatively few individuals >75 years of age who were included in RCTs of high versus moderate-intensity statin therapy there was not clear evidence of an additional reduction in ASCVD events from high-intensity statin therapy. In contrast, individuals >75 years of age did experience a reduction in ASCVD events in the trials of mostly moderate-intensity statin therapy, compared with control. Therefore, moderate-intensity statin therapy should be considered for individuals >75 years of age with clinical ASCVD.

However, acknowledging that older participants in RCTs were likely to be healthier than many older individuals in the general population, the use of statin therapy should be individualized in persons >75 years of age with clinical ASCVD, and there was no significant difference between placebo groups and statin treatment groups in the rates of ALT elevations. In addition, the FDA has indicated that if the baseline hepatic transaminases are normal, further hepatic monitoring is not needed. During statin therapy, it is reasonable to measure hepatic function if symptoms suggesting hepatotoxicity.

Statins modestly increase the excess risk of type-2 diabetes in individuals with risk factors for diabetes. The potential for an ASCVD risk reduction benefit outweighs the excess risk of diabetes in all but the lowest risk individuals. Individuals receiving statin therapy should be evaluated for new-onset diabetes according to the current diabetes screening guidelines.

REFERENCES
Accessed 1/3/14
http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437741.48606.98
2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk

It is reasonable to assess 10-year ASCVD risk every 4 to 6 years in adults 40-79 who are free from ASCVD. The current tool used to calculate cardiovascular risk in the clinical setting is the Framingham Risk Score. The Framingham Risk Score and the ACC/AHA Cardiovascular Risk calculator use age, gender, systolic blood pressure, treatment for blood pressure, total cholesterol levels, high density lipid levels, and current smoking status as factors in their assessment. The ACC/AHA calculator also includes race (African American versus other) and diabetes status as factors in their assessment. The calculator can be downloaded/found at: http://my.americanheart.org/professional/Statements Guidelines/PreventionGuidelines/Prevention-Guidelines_UCM_457698_SubHomePage.jsp

REFERENCES

Medication Pass Observation Protocol for Long Term Care

Revisions to Appendix P of the State Operations Manual (SOM): Changes have been made to the Sub-Task 5E - Medication Pass Observation Task in the Traditional Survey.

- The number of observations required to calculate the facility medication error rate is revised to a minimum of 25 medication administration opportunities. A minimum number is specified because it is acceptable to include more than 25 observations in a medication observation to capture multiple routes, times, and caregivers.
- This revision eliminates the current requirement to extend the medication pass for another 20-25 opportunities if errors are detected in the first 20-25 observations.

- Form CMS–20056 (2/2013), Medication Administration Observation will be used; this form replaces Form CMS-677, Medication Pass Worksheet.

The medication error rate calculation for both the Traditional and QIS surveys.

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Invokana (Canagliflozin)- Antidiabetic Agent, SGLT2 Inhibitor (sodium-glucose co-transporter 2)–Janseen

Indication- Type II diabetes mellitus as an adjunct to diet & exercise, as monotherapy or in combination with other antidiabetic agents to improve glycemic control

Dosing- 100mg once daily prior to first meal of the day, max dose 300mg once daily

Renal dosing- eGFR 45-60ml/min max dose 100mg; eGFR 30-45ml/min use not recommended; eGFR<30ml/min use contraindicated

Drug Interactions- Phenytoin, Rifampin, Phenobarbital, Rifamptin, Ritonavir may decrease serum concentrations of Invokana; LEVEL D severity (renal function dependant)

Monitoring- Blood glucose, HbA1c, potassium levels baseline and after initiation, renal function—frequent if eGFR <60ml/min (quarterly), LDL—baseline and 6months later (possible increase in LDL), blood pressure, infections

Adverse Effects- Increased potassium (more likely if predisposed), genitourinary infections, renal insufficiency, orthostatic hypotension

Namenda XR (Memantine) – NMDA receptor antagonist – Forest lab

Indication -- for the treatment of moderate to severe dementia of the Alzheimer’s type

Dosing- Initial Dose 7 mg NAMENDA XR once daily; Maintenance Dose 28 mg NAMENDA XR once daily; A minimum of 1 week of treatment with the previous dose should be observed before increasing the dose; strengths 7mg, 14mg, 21mg and 28mg

Conversion: Patients treated with NAMENDA tablets may be switched to NAMENDA XR capsules as follows: It is recommended that a patient who is on a regimen of 10 mg twice daily of NAMENDA tablets be switched to NAMENDA XR 28 mg once daily capsules the day following the last dose of a 10 mg NAMENDA tablet. There is no study addressing the comparative efficacy of these 2 regimens.

Renal dosing---In a patient with severe renal impairment, it is recommended that a patient who is on a regimen of 5 mg twice daily of NAMENDA tablets be switched to NAMENDA XR 14 mg once daily capsules the day following the last dose of a 5 mg NAMENDA tablet

Administration pearls - NAMENDA XR can be taken with or without food. NAMENDA XR capsules can be taken intact or may be opened, sprinkled on applesauce, and thereby swallowed. The entire contents of each NAMENDA XR capsule should be consumed; the dose should not be divided. Except when opened and sprinkled on applesauce, as described above, NAMENDA XR should be swallowed whole

Drug Interactions— Use with other NMDA antagonists (amantadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution

Adverse effects --- most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo with administration of NAMENDA XR 28 mg/day were headache, diarrhea and dizziness