New Cholesterol Guidelines
ACC/AHA 2013

ObamaCare Version

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Disclaimer
- I have no conflict of interest relating in the material covered today.
- I do not serve on any speaker bureau.
- I do not have any personal grants concerning the area of discussion today.

Objectives
1. Discuss the new ACC/AHA cholesterol guidelines
2. List the four groups of patients for whom the benefit of statins clearly outweighs the risk.
3. Discuss treatment options for various groups depending on disease risk.
4. Distinguish between high-dose, moderate-dose and low-dose statin therapy.
5. Apply the “Pooled Cohort Equation” to various patients to assess percent risk of a CV event in 10 years.
6. Discuss the controversies related to the applications of the new guidelines.
2013 ACC/AHA Cholesterol Guidelines

- First major guideline revision of cholesterol since 2002
- These guidelines are already controversial.
- They represent a different way of thinking.
- Panel - Blood Cholesterol Expert Panel
  - ATP IV - Adult Treatment Panel IV – NHLBI panel
  - This has transitioned to ACC/AHA
- 16 members, 13 experts + 3 ex-officio members
  - Primary care, cardiologist, endocrinologist, lipidology, experts in clinical trials, guideline development
  - All 16 members transitioned to the ACC/AHA panel
  - ACC/AHA had a 14 member task force to review the document

Panel

- 9 of 13 had no financial disclosures
- No disclosures from Chair and Co-Chair
  - One of the Co-Chairs is from Tufts University, she is a D. Sc and the Director for Human Nutrition Research Center on Aging – she is a professor of nutrition and family medicine
  - Rest of panel are M.D.’s
  - 3 ex-officio members were two MD’s connected to NHLBI and one Masters of Nursing
- 84 pages, 144 references
- 80 evidence statements generated from research trials (Appendix 4)

Noisy Controversy

- Old guidelines rely on LDL as the goal
- These guidelines rely on RCT’s that largely use a fixed-dose statins as the goal.
- Trying to use proven interventions
- The thought is also that treating to target may result in statin undertreatment if the evidence-based statin dose is not used.

For me there has always been two camps:
- LDL goal vs Statin dose
In most trials, LDL is an association!

It does remind us of the weakness of guidelines and “Process Medicine”

- New York Times editorial told us to ignore them!
- Recent controversies over prostate cancer, mammography
- Some of JNC 8 panel members disagree with their own statements
- We question the legitimacy of the panel members
  - "Too many subspecialist…"
  - "There are no subspecialist…" (as in USPSTF)
  - "Too many conflicts of interest…"
- Guidelines are known to ration care
- Most people believe “more health care is better health care” – so guidelines that recommend NOT doing something are well...

It does remind us of the weakness of guidelines and “Process Medicine”

- The guideline developers have to…
  - Integrate multiple studies
  - Address methodological limitations, conflicting results
  - High quality studies are rare
  - Guidelines are for the masses – they do a poor job at individuality
- Guidelines don’t present recommendations in a benefit/risk/cost format that really guides decision making
- Guidelines have become media events, tied to attention, grants, organizational meetings, blogs
  - There is a risk of over sensationalizing them
Guidelines

- Four groups of patients for whom the benefit of statins clearly outweighs the risk.
- Patients with
  1. Clinically evident CV disease
  2. Primary LDL levels of at least 190
  3. Type 1 or type 2 diabetes with LDL levels of 70 or higher
  4. 10-year risk of CV disease of at least 7.5% and an LDL of at least 70

2013 American College of Cardiology–American Heart Association Guidelines for Use of Statin Therapy in Patients at Increased Cardiovascular Risk.

High-Intensity and Moderate-Intensity Statin Therapy, According to 2013 American College of Cardiology–American Heart Association (ACC-AHA) Cholesterol Guidelines.

<table>
<thead>
<tr>
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<tbody>
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<td><strong>High-Intensity statin therapy</strong></td>
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<tr>
<td>Daily dose lowers LDL cholesterol level by approximately ≥50% on average. Recommended: atorvastatin, 40 to 80 mg; rosuvastatin, 20 to 40 mg.</td>
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<tr>
<td><strong>Moderate-intensity statin therapy</strong></td>
</tr>
<tr>
<td>Daily dose lowers LDL cholesterol level by approximately 30 to &lt;50% on average. Recommended: atorvastatin, 10 to 20 mg; rosuvastatin, 5 to 10 mg; simvastatin, 20 to 40 mg; pravastatin, 40 to 80 mg; lovastatin, 40 mg; extended-release fluvastatin, 80 mg; fluvastatin, 40 mg twice a day; pitavastatin, 2 to 4 mg.</td>
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</tbody>
</table>
What a paradigm shift!

- They also identify patients for whom current data do not support statin therapy and for whom no recommendation is made.
- Age > 75 years unless clinical CV disease is present (PROSPER Trial)
- A need for dialysis (4D Trial)
- NY Heart Association class II, III, IV heart failure
- Panel found no evidence to support the use of non-statin therapy, either combined with a statin or in statin-intolerant patients.
  - No data yet to prove further CV risk reduction
- It is not about treating numbers anymore!

Other Practice Implications

- Elimination of routine LDL assessments in patients on statins – target levels no longer emphasized
- In statin-tolerant patients, avoid non-statin LDL agents
- Conservative therapy in patients older than 75 years who have no evident CV disease
- No use of surrogate markers like C-reactive protein or calcium scores
- Use of a new risk calculator which will target more patients for therapy.
  - This calculator is controversial
  - Based on several large RCT trials
  - It has not been prospectively tested for accuracy
  - It tends to overestimate risk

Calculator can be found on iTunes or Google Play for Android as a App
Internet: Google “Pooled Cohort Equation”
Case 1 – AA Male with low HDL

- 62 year old, AA male
- TC 140; HDL 35; SBP 130
- Not taking antihypertensives
- Not diabetic
- Nonsmoker
- Calculated 10-yr risk of CHD or stroke is 9.1%
- Needs moderate to high-intensity statin therapy
- Key – low total cholesterol, but age > 60 with low HDL

Case 2: White male smoker with high cholesterol

- 42 years of age, white
- TC 250; HDL 40; SBP 130
- Not taking antihypertensives
- Not diabetic
- Smoker
- Calculated 10-yr risk of CHD or stroke is 9.0%
- Needs moderate to high-intensity statin therapy
- Key – high total cholesterol and smokes

Case 3: White female smoker

- 50 years of age, white
- TC 180; HDL 50; SBP 135
- Taking antihypertensives
- Diabetic
- Smoker
- Calculated 10-yr risk of CHD or stroke is 9.8%
- Needs high-intensity statin therapy
- Key – total cholesterol and HDL are OK but patient has diabetes, HTN and smokes.
Case 4: White female with diabetes

- 48 years of age, white
- TC 180; HDL 55; SBP 130
- Not taking antihypertensives
- Diabetic
- Nonsmoker
- Calculated 10-yr risk of CHD or stroke is 1.8%
- Needs moderate intensity statin therapy
- Key – she qualifies because she has diabetes even though she has a low 10-yr risk

Case 5: Healthy, elderly AA male

- 79 years of age, white
- TC 150; HDL 40; SBP 120
- Not taking antihypertensives
- Not diabetic
- Nonsmoker
- Calculated 10-yr risk of CHD or stroke is 13.7%
- Moderate intensity statin therapy???
- Key – he qualifies because of his age and 10-yr risk of 13%
- Do you treat???
- No absolute recommendation made.

Case 6: White Male with high TC

- 57 years of age, white
- TC 250; HDL 45; SBP 110
- Not taking antihypertensives
- Not diabetic
- Nonsmoker
- Calculated 10-yr risk of CHD or stroke is 7.2%
- No therapy recommended besides lifestyle
- Key – high TC, but no risk factors
Case 7: AA female in her 60's
- 64 years of age, white
- TC 190; HDL 45; SBP 125
- Not taking antihypertensives
- Not diabetic
- Nonsmoker
- Calculated 10-yr risk of CHD or stroke is 6.9%
- No therapy recommended besides lifestyle
- Key – low HDL, but no other risk factors

Case 8: AA male, smoker
- 42 years of age, white
- TC 180; HDL 40; SBP 130
- Not taking antihypertensives
- Not diabetic
- Smoker
- Calculated 10-yr risk of CHD or stroke is 6.3%
- No therapy recommended
- Key – smoker, but no other risk factors

For patients without CV disease
- Assess traditional risk factors every 4-6 years in patients 20 to 79 yrs
- Adhere to a heart-healthy diet
  - Vegetables, fruits, whole grain, low-fat dairy, poultry, fish, beans, non-tropical vegetable oils and nuts
  - DASH or Mediterranean diet
  - Limit sugary drinks and sweets
  - Limit saturated and trans fats to 5% of calories
  - Limit sodium to 2400 mg/day
- Exercise regularly
  - At least 40 min 3 to 4 times per week
- Avoid tobacco (nothing about marijuana ☺)
- Maintain a healthy weight
For the clinically suspicious

- If the patient does not fit into one of these options, more information can help a treatment decision
- LDL > 160
- Genetic hyperlipidemia
- CV disease onset on first degree male relative before age 55, or female before age 65
- C-reactive protein >2
- Ankle-brachial index <0.9
- 75% of coronary artery calcium score
- Statin adverse events
- Statin drug interactions
- Patient preferences

High-dose Statin Therapy

- Need for LDL reductions of 50% or higher
- Examples
  - Atorvastatin 80 mg once daily
  - Rosuvastatin 20 to 40 mg once daily
- Use for:
  - Secondary prevention in adults 75 yrs or younger (Level A)
  - Primary prevention in adults with LDL ≥ 190 (Level A)
  - Primary prevention in adults 40 to 75 yrs with LDL > 70 and a 10-yr risk of CV disease of ≥ 7.5% (Level A)
  - For the diabetic it is same (Level C)

Moderate-dose Statin Therapy

- Need for LDL reductions of 30 to 50%
- Examples
  - Atorvastatin 10 mg to 20 mg once daily
  - Pravastatin 40 mg to 80 mg once daily
  - Simvastatin 20 mg to 40 mg once daily
- Use for:
  - Secondary prevention in adults 75 yrs or younger (Level A)
  - Patients who can't tolerate high-dose statin.
  - Primary prevention in adults 40 to 75 yrs with LDL > 70 and a 10-yr risk of CV disease of ≥ 7.5% (Level A)
  - Primary prevention in diabetic adults 40 to 75 yrs with LDL > 70 and a 10-yr risk of CV disease of ≥ 7.5% (Level A)
Low-Dose Statin Therapy

- Need for LDL reduction < 30%
- Examples
  - Pravastatin 10 mg to 20 mg once daily
  - Simvastatin 10 mg once daily
  - Pitavastatin 1 mg once daily
  - Lovastatin 20 mg once daily
- Use for...
  - Those who cannot tolerate high or moderate statin doses

Nonstatin therapy

- Reinforce statin adherence and lifestyle changes
- Do not add gemfibrozil to statin therapy
- No proof adding a nonstatin to statin therapy to further CV risk reduction
- Triglycerides > 500 – use fish oil, niacin, fenofibrate
  - Expert opinion

Monitoring Statin Therapy

- How to monitor statin therapy
  - Baseline ALT, repeat only if symptomatic
  - If severe muscle symptoms
    - Hold statin
    - check CPK
  - Check fasting lipid panel 4 to 12 weeks after statin start, then every 3 to 12 months as clinically indicated
  - If LDL < 40 on two measurements, consider dose reduction of statin
- Monitor for new-onset diabetes
Kelso thoughts and opinions

- Love the fixed-dose strategy and the abandonment of treat-to-target
- Fewer labs
- Primary prevention
  - May lead to overtreatment
  - 10-yr risk calculator in my opinion overestimates the risk or we need to adjust the cut off for therapy to 10 to 15% in the primary prevention patient.
  - In a patient calculated to 7.5% risk, NO efficacy would be realized in AFCAPS study
- More patients, more adverse events and these are undervalued
- No NNT/NNH/Cost analysis to make individual decisions

Insurance companies and government, please drop performance metrics based on LDL targets!!

The guidelines remind us that the recommendations are intended to guide decision making, but not replace clinical judgment.

For those not at high risk, you are encouraged to have “risk discussions” with your patient.

Getting your cholesterol under control does not mean.......