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Lipid Management in 2019: Putting Evidence-Base Guidelines into Practice

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Disclosures

No RWI

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Objectives

- Review current evidence-based guidelines for the management of dyslipidemia.
- Outline non-pharmacologic strategies for management of elevated LDL-C and triglycerides.
- Identify guideline based pharmacotherapy for the management of dyslipidemia and use case examples to discuss their clinical application.

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2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA

Guideline on the Management of Blood Cholesterol

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American Heart Association.

Comparison of 2013 and 2018 Cholesterol Guidelines

Topic	2013 Guideline	2018 Guideline
Lifestyle	Cornerstone of ASCVD prevention	Cornerstone of ASCVD prevention
First-line drugs for ASCVD risk reduction	Statins	Statins
Nonstatin agents in secondary prevention	Not recommended due to insufficient evidence	Includes recs for nonstatin agents
Risk assessment in primary prevention	Starts with PCE risk estimation	Starts with PCE risk estimation
Clinician-pt risk discussion	Introduced	Emphasized before beginning statin
Tailoring treatment	Biomarkers and noninvasive tests	Extensive list of risk enhancers
Intermediate risk pts	No rec for additional testing	Consider CAC scoring

Top 10 Take Home Messages

1. In all individuals, emphasize a heart-healthy lifestyle across the life course.

    - Healthy lifestyle reduces ASCVD risk at all ages.
    - Foundation of ASCVD risk reduction
    - Re-emphasis on the 2013 Lifestyle Guideline
    - Recently released Primary Prevention Guideline

Eckel RH et al. *Circulation* 2013;129:S76–S99
Arnett DK, Blumenthal RS et al., *Circulation* 2019; DOI: 10.1161/CIR.0000000000000678

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2019 Prevention Guideline: Nutrition and Diet

- A diet emphasizing intake of vegetables, fruits, legumes, nuts, whole grains, and fish is recommended to decrease ASCVD risk factors (I, B-R)
- Replacement of saturated fat with dietary monounsaturated and polyunsaturated fats can be beneficial to reduce ASCVD risk (IIa, B-NR)
- A diet containing reduced amounts of cholesterol and sodium can be beneficial to decrease ASCVD risk (IIa, B-NR)

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2019 Prevention Guideline: Nutrition and Diet

- As a part of a healthy diet, it is reasonable to minimize the intake of processed meats, refined carbohydrates, and sweetened beverages to reduce ASCVD risk (II, B-NR)
- As a part of a healthy diet, the intake of *trans* fats should be avoided to reduce ASCVD risk (III – Harm B-NR)

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2019 Prevention Guideline: Exercise and Physical Activity

- Adults should be routinely counseled in healthcare visits to optimize a physically active lifestyle (I, B-R)
- Adults should engage in at least 150 minutes per week of accumulated moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity (or an equivalent combination of moderate and vigorous activity) to reduce ASCVD risk I, B-NR)

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2019 Prevention Guideline: Exercise and Physical Activity

- For adults unable to meet the minimum physical activity recommendations, engaging in some moderate- or vigorous-intensity physical activity, even if less than this recommended amount, can be beneficial to reduce ASCVD risk (IIa, B-NR)

- Decreasing sedentary behavior in adults may be reasonable to reduce ASCVD (IIb, C-LD)

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Lifestyle Counseling Tools

Exercise Prescription

Exercise Really *is* Medicine

My Exercise Prescription

Type of Physical Activity	Aerobic	Strength	Flexibility
Frequency (days per week)			
Time (minutes per day)			
Intensity (how hard)	Target HR (pulse rate): _____ Perceived Exertion: _____		

Rated Perceived Exertion Scale

This scale of numbers is used as a rating system for exercise intensity. A rating of 0 would be nothing at all (sitting in a chair) and a 10 would be very, very heavy (how you feel at the end of an exercise stress test). In most cases, you should exercise at a level of 3-4 , which is safe and improves your health.

0	0.5	1	2	3	4	5	6	7	8	9	10
Nothing at All	Just Noticeable	Very Light	Light	Moderate	Somewhat Heavy	Heavy		Very Heavy			Very, Very Heavy

Target Heart Rate (Pulse)

- Your nurse or doctor can help you find a target heart rate zone for your needs, goals and physical condition.
- You gain the most benefits and lower the risks when you exercise in your target heart rate zone.
- You can find your target heart rate zone like this:
  - Your maximum heart rate is approximately 220 minus your age.
  - So if you are 40 years old, 220 - 40 = 180.
  - When you exercise, your target heart rate should be 60-80% of 180, or between 108 and 144 beats per minute.

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A Heart Healthy TOOLBOX LIFESTYLE CHANGE TOOLS FOR

Specific, Measurable, Adjustable, Realistic, and Time-Based Goals

SMART Goals for Lasting Change

SMART = Specific, Measurable, Adjustable, Realistic, & Time-Based

Setting goals can help you make lasting lifestyle changes to improve your health. Goals help you see what is important as well as stick to your plan. As you get into the habit of setting and meeting goals, you may find you are more able to believe in yourself and your ability to make changes. The tips below will help you set clear and effective goals.

1 Specific

Be as clear as possible regarding what you will do. Make sure the goal is your goal and not meant to please someone else. Write your goal down and put it in a place you will see each day.

Example: "I want to complete the 5K (3 mile) Heart Walk in October."

2 Measurable

Spell out exactly what you will do, how long, and how often.

Example: "Over the next two weeks I will walk 30 minutes over my lunch hour, on Mondays, Wednesdays, and Fridays."

3 Adjustable

Keep a good attitude when working on your goal. Don't get too upset if you miss a target. If you have a setback, just reset your goal to take this into account. Being too hard on yourself can get in the way of long-term success.

Example: An illness prevents you from doing the Heart Walk in October, so adjust your goal to find another 5K walk to register for in November or December.

4 Realistic

Be realistic about the goals you set. You should feel at least 70% confident you will be successful in meeting the goal. Sometimes it helps to break your goal down into smaller steps. Start with 1 or 2 goals—not a whole list.

Example: Perhaps you want to run a marathon someday. If you have not been a regular exerciser, it would not be realistic to run a marathon in 3 months. Instead, try for a 5K (about 3 miles) in 3 months, and then a 10K (about 6 miles) run and so on.

5 Time-based

Goals that reach out beyond six months are too long to keep you interested and motivated. Set and re-evaluate goals every 2-3 months. Success in meeting small goals helps to build confidence for continued success.

Example: A goal of running a 5K race in 3 months is a time-based goal. Another example would be "My smoking quit date will be my birthday, October 1st this year."

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A Heart Healthy TOOLBOX LIFESTYLE CHANGE TOOLS FOR HEALTH CARE PROFESSIONALS & THEIR PATIENTS

Clinical Tools

For you and your patients!

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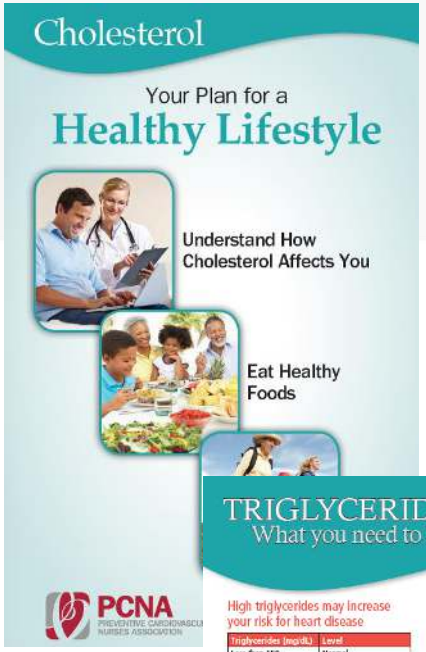

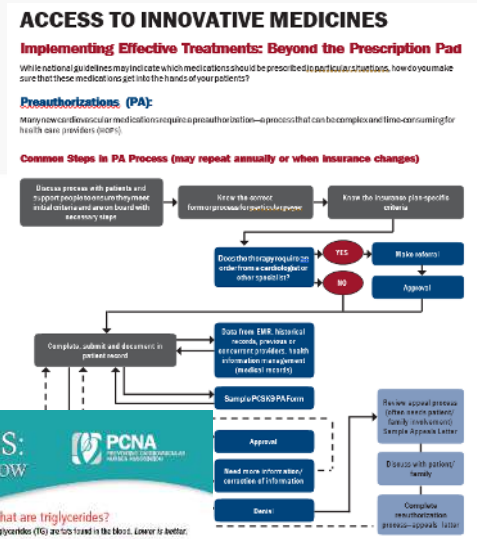

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Lifetime Risk in Young Adults

- In young adults 20 to 39 years of age, an assessment of lifetime risk facilitates the clinician–patient risk discussion.

- ASCVD Risk Estimator can be used to estimate lifetime risk in young adults.
  - Search ASCVD Risk Estimator Plus

- Emphasize intensive lifestyle efforts.

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Top Ten Take Home Messages

2. In patients with clinical ASCVD, reduce low-density lipoprotein cholesterol (LDL-C) with high-intensity statin therapy or maximally tolerated statin therapy (I, A).

- The more LDL-C is reduced on statin therapy, the greater will be subsequent risk reduction.
- Use a maximally tolerated statin to lower LDL-C levels by ≥50%.

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Definition of Clinical ASCVD

- Acute coronary syndrome including those with history of myocardial infarction or unstable angina
- Stable angina
- Coronary or other arterial revascularization
- Stroke or transient ischemic attack
- Peripheral artery disease including aortic aneurysm of atherosclerotic origin.

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Table 3. High-, Moderate-, and Low-Intensity Statin Therapy*

	High Intensity	Moderate Intensity	Low Intensity
LDL-C lowering†	≥50%	30%–49%	<30%
Statins	**Atorvastatin (40 mg‡) 80 mg** **Rosuvastatin 20 mg (*40 mg***	**Atorvastatin 10 mg** (20 mg) **Rosuvastatin** (5 mg) **10 mg** **Simvastatin 20–40 mg§**	Simvastatin 10 mg
	…	**Pravastatin 40 mg** (80 mg) **Lovastatin 40 mg** (80 mg) Fluvastatin XL 80 mg **Fluvastatin 40 mg BID** Pitavastatin 1–4 mg	**Pravastatin 10–20 mg** **Lovastatin 20 mg** Fluvastatin 20–40 mg

*Percent reductions are estimates from data across large populations. Individual responses to statin therapy varied in the RCTs and should be expected to vary in clinical practice (S3.2.1-2).

Top Ten Take Home Messages

3. In very high-risk ASCVD, use a LDL-C threshold of 70 mg/dL to consider addition of nonstatins to statin therapy.

- Very high-risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.
- If LDL-C level remains ≥70 mg/dL on maximally tolerated statin, reasonable to add ezetimibe (I, B-NR).
- If LDL-C level remains ≥70 mg/dL on maximally tolerated statin + ezetimibe, reasonable to add PCSK9 inhibitor (IIa, A).

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High-Risk Conditions

High-Risk Conditions
Age ≥65 y
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
Diabetes mellitus
Hypertension
CKD (eGFR 15-59 mL/min/1.73 m^2)
Current smoking
Persistently elevated LDL-C (LDL-C ≥100 mg/dL despite maximally tolerated statin therapy and ezetimibe
History of congestive HF

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Case Presentation

- 62 year old female patient had a MI with stent placement in the LAD and Cx 2 months ago. She has diabetes, HTN, and CKD.
- Meds include atorvastatin 80 mg, lisinopril 20 mg, metoprolol XL 25 mg.
- She reports fatigue and no other symptoms.
- LDL-C is 120 mg/dL

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According to the 2018 multisociety cholesterol guideline, what is the first management change you would consider for this patient?

A. **Add ezetimibe 10 mg daily**
B. Encourage a vegan diet
C. Add a PCSK9 inhibitor
D. Switch to a different statin

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Case continued

- The patient returns to clinic 2 months later . Cardiac rehab is going well. Her LDL-C is now 99 mg/dL on atorvastatin 80 mg and ezetimibe 10 mg daily.
- You note a carotid ultrasound report that shows right and left proximal ICA stenosis > 50%.

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According to the 2018 multisociety cholesterol guideline, what is the next consideration for management of this patient?

A. Switch to a different statin
B. Encourage a vegan diet
C. **Add a PCSK9 inhibitor**
D. No change in management since the LDL-C is < 100 mg/dL

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Case Continued

- Following the addition of evolocumab 140 mg every 2 weeks to statin and ezetimibe, LDL-C is 32 mg/dL. Your patient is concerned her LDL-C is so low.
- What is the most appropriate intervention?

A. At this time, continue current management strategies.
B. Reduce rosuvastatin dose.
C. Stop ezetimibe.
D. Encourage patient to start a keto diet.

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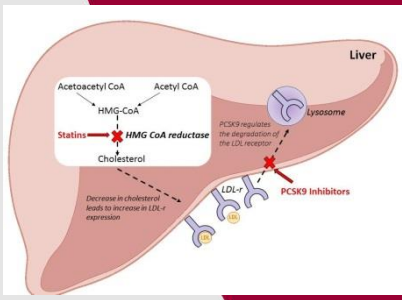
Drugs that ↓Cholesterol and ↓ ASCVD Risk in Secondary Prevention

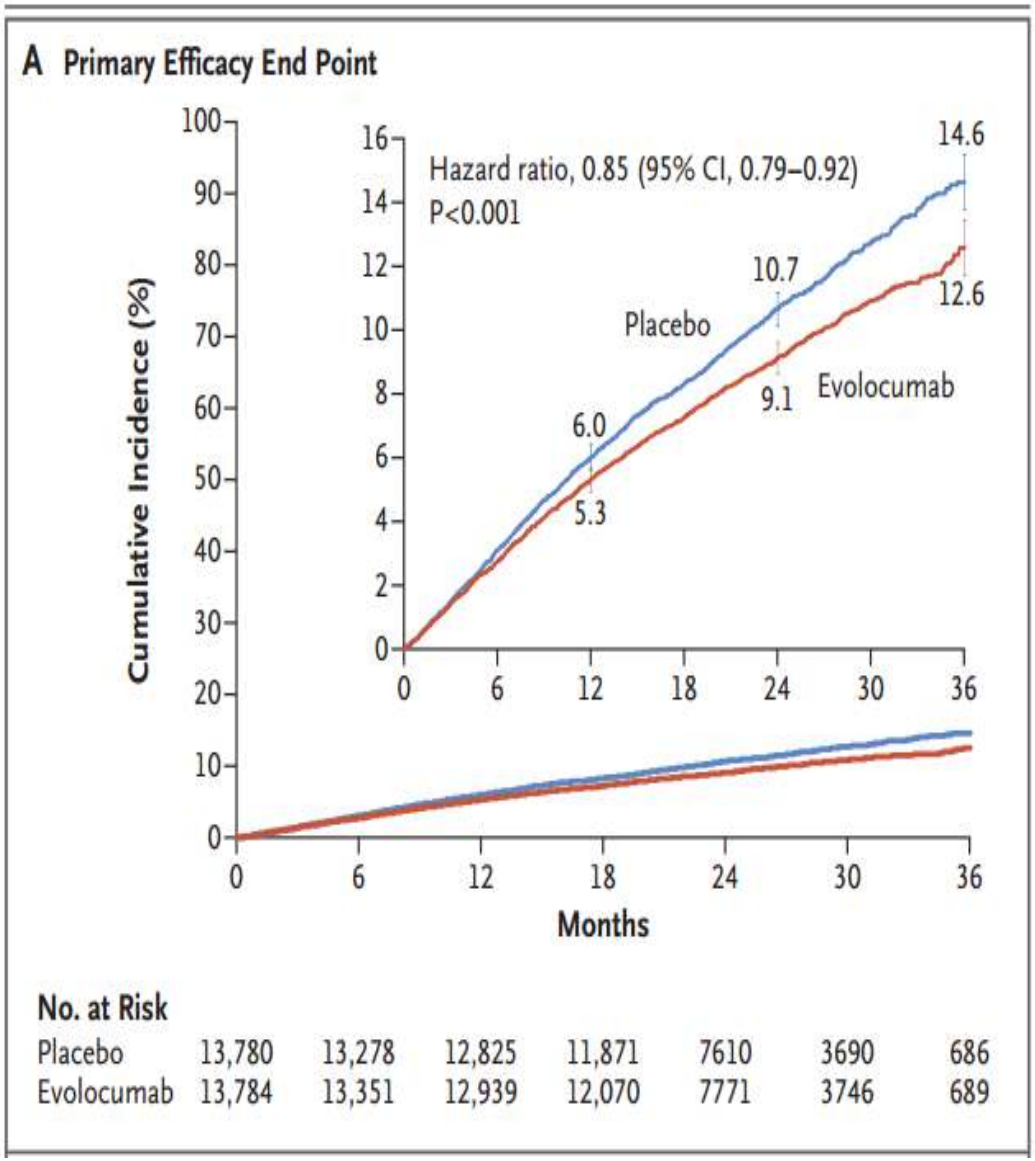
- Statins (high intensity): inhibit HMG CoA reductase in liver and upregulate LDL receptors on hepatocyte surface



- Ezetimibe: inhibits cholesterol absorption in the brush border of the small intestine; target is the Niemann-Pick sterol transporter

- PCSK9 inhibitors (alirocumab, evolocumab): inhibit LDL receptor destruction by PCSK9

- LDL-C 92 → 30 (↓59%)
- Primary efficacy end point = composite of CVD death, MI, CVA, hospitalization for unstable angina, or coronary revascularization.
- Median follow-up: 2.2 yrs.



Sabatine MS et al. *N Engl J Med* 2017;376:1713-1722.

EBBINGHAUS: Neurocognitive Substudy of FOURIER

- Concern over very low LDL-C levels with PCSK9 inhibitor therapy
- In subgroup of patients from FOURIER, prospectively assessed cognitive function using the Cambridge Neuropsychological Test Automated Battery
- 1204 patients were followed for a median of 19 months
- No significant between-group difference in cognitive function

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Top Ten Take Home Messages

4. In patients with severe primary hypercholesterolemia (LDL-C ≥ 190 mg/dL), begin high-intensity statin therapy (I, B-R).
   - No need to calculate 10-year ASCVD risk
   - If the LDL-C level remains ≥100 mg/dL, adding ezetimibe is reasonable (IIa, B-R).
   - If the LDL-C level remains ≥100 mg/dL & the patient has multiple risk factors, a PCSK9 inhibitor may be considered (IIb, B-R).

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Top Ten Take Home Messages

5. In patients 40 to 75 years of age with diabetes and LDL-C ≥70 mg/dL, start moderate-intensity statin therapy without calculating 10-year ASCVD risk (I, A).

    - In patients with DM at higher risk (multiple risk factors or 50 to 75 years of age), it is reasonable to use a high-intensity statin to reduce the LDL-C level by ≥50% (IIa, B-R).

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Top Ten Take Home Messages

6. In adults 40 to 75 years of age evaluated for primary ASCVD prevention, have a clinician–patient risk discussion before starting statin therapy (I, B-NR).

Risk discussion should include:

- Presence of major risk factors
- 10-year ASCVD risk estimation
- Presence of risk enhancing factors
- Potential benefits of lifestyle and statin therapies
- Potential for adverse effects and drug–drug interactions; consideration of costs of statin therapy
- Patient preferences & values in shared decision-making

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Primary Prevention

- Emphasize a heart-healthy lifestyle
- Assess ASCVD risk (pooled cohort equations, sex- and race-specific):
  - -20-39 years: Lifetime risk estimation
  - -40-75 years: 10 year ASCVD risk

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ASCVD Risk Estimator Plus

Estimate Risk | Therapy Impact | Advice

15.8% Current 10-Year ASCVD Risk

Lifetime ASCVD Risk: **50%** Optimal ASCVD Risk: **1.8%**

Current Age * 55
Age must be between 20-79

Sex * Male | ✔ Female

Race * White | ✔ African American | Other

Systolic Blood Pressure (mm Hg) * 155
Value must be between 90-200

Diastolic Blood Pressure (mm Hg) 82
Value must be between 60-130

Total Cholesterol (mg/dL) * 260
Value must be between 130 - 320

HDL Cholesterol (mg/dL) * 40
Value must be between 20 - 100

LDL Cholesterol (mg/dL) 150
Value must be between 30-300

History of Diabetes? * Yes | ✔ No

Smoker: * Yes | ✔ Former | No

How long ago did patient quit smoking? * Less than 6 months ago

On Hypertension Treatment? * ✔ Yes | No

On a Statin? ✔ Yes | No

On Aspirin Therapy? ✔ Yes | No

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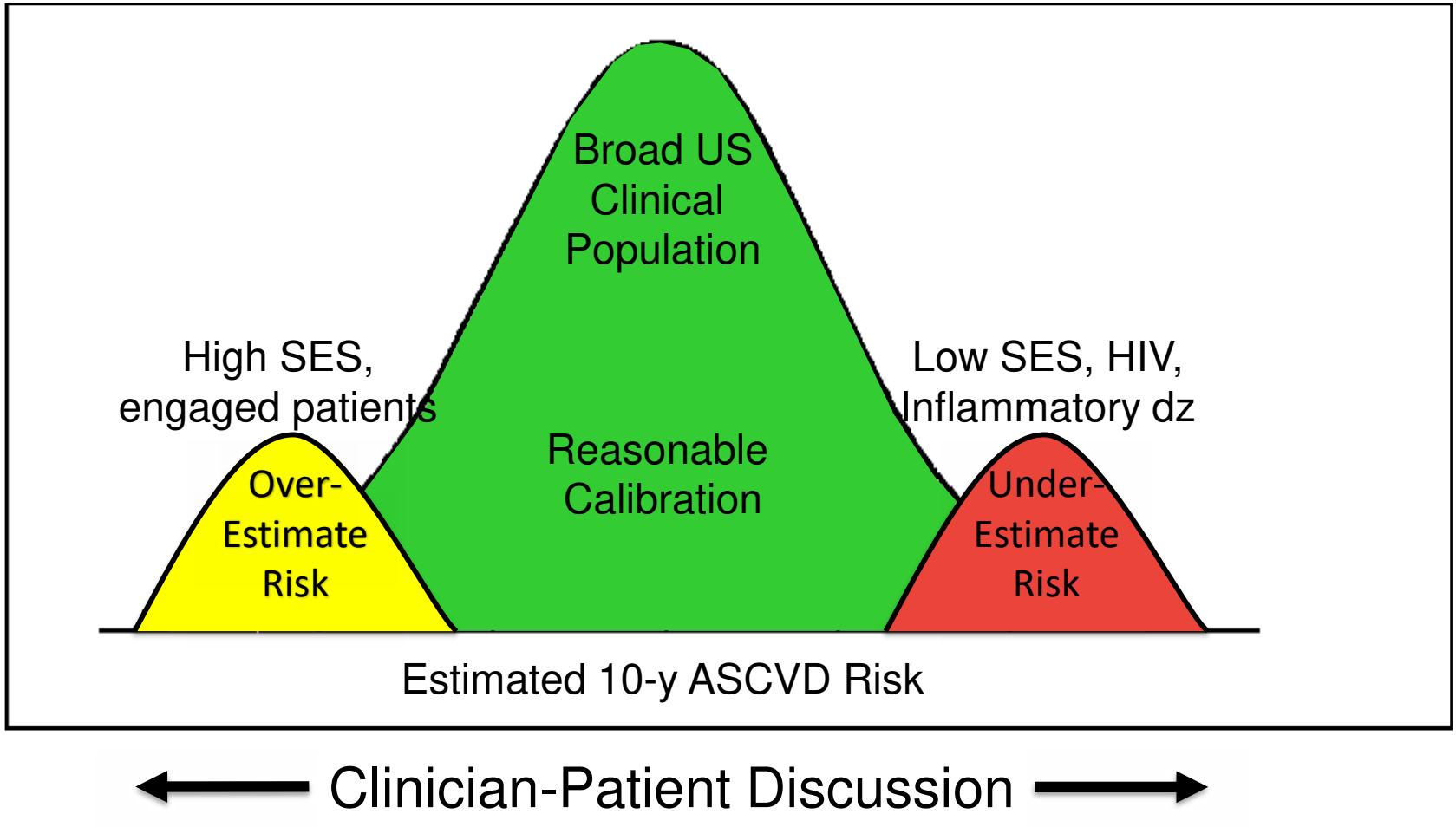
Performance of Pooled Cohort Equations in Diverse Population Samples: Predictable



Top Ten Take Home Messages

7. In adults 40 to 75 years of age without diabetes and with LDL-C levels ≥70 mg/dL, at 10-year ASCVD risk of ≥7.5%, start a moderate-intensity statin if a discussion of treatment options favors statin therapy (I, A).

    - Risk-enhancing factors favor statin therapy
    - If risk status is uncertain, consider using coronary artery calcium (CAC) to improve specificity.

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Top Ten Take Home Messages

8. **In adults 40 to 75 years of age without diabetes and 10-year risk of 7.5% to 19.9% (intermediate risk), risk-enhancing factors favor initiation of statin therapy (IIa, B-R).**

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Risk Enhancing Factors

- Family history of premature ASCVD;
- Persistently elevated LDL-C levels ≥160 mg/dL:
- Metabolic syndrome;
- Chronic kidney disease;
- History of preeclampsia or premature menopause (age <40 yrs)
- Chronic inflammatory disorders (e.g., rheumatoid arthritis, psoriasis, or chronic HIV);
- High-risk ethnic groups (e.g., South Asian);
- Persistent elevations of triglycerides ≥ 175 mg/dL.

<u>If measured in selected individuals:</u>

- Apolipoprotein B ≥130 mg/dL;
- High-sensitivity C-reactive protein ≥2.0 mg/L;
- Ankle-brachial index <0.9;
- Lipoprotein (a) ≥50 mg/dL or 125 nmol/L, especially at higher values of lipoprotein (a).

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Top Ten Take Home Messages

9. In adults 40 to 75 years of age without diabetes and with LDL-C levels ≥70 mg/dL- 189 mg/dL, at a 10-year ASCVD risk of ≥7.5% to 19.9%, if a decision about statin therapy is uncertain, consider measuring coronary artery calcium (CAC) (IIa, B-NR).

   - If CAC is zero, treatment with statin therapy may be withheld or delayed, except in cigarette smokers, those with diabetes mellitus, and those with a strong family history of premature ASCVD.
   - A CAC score above 0 favors statin therapy.

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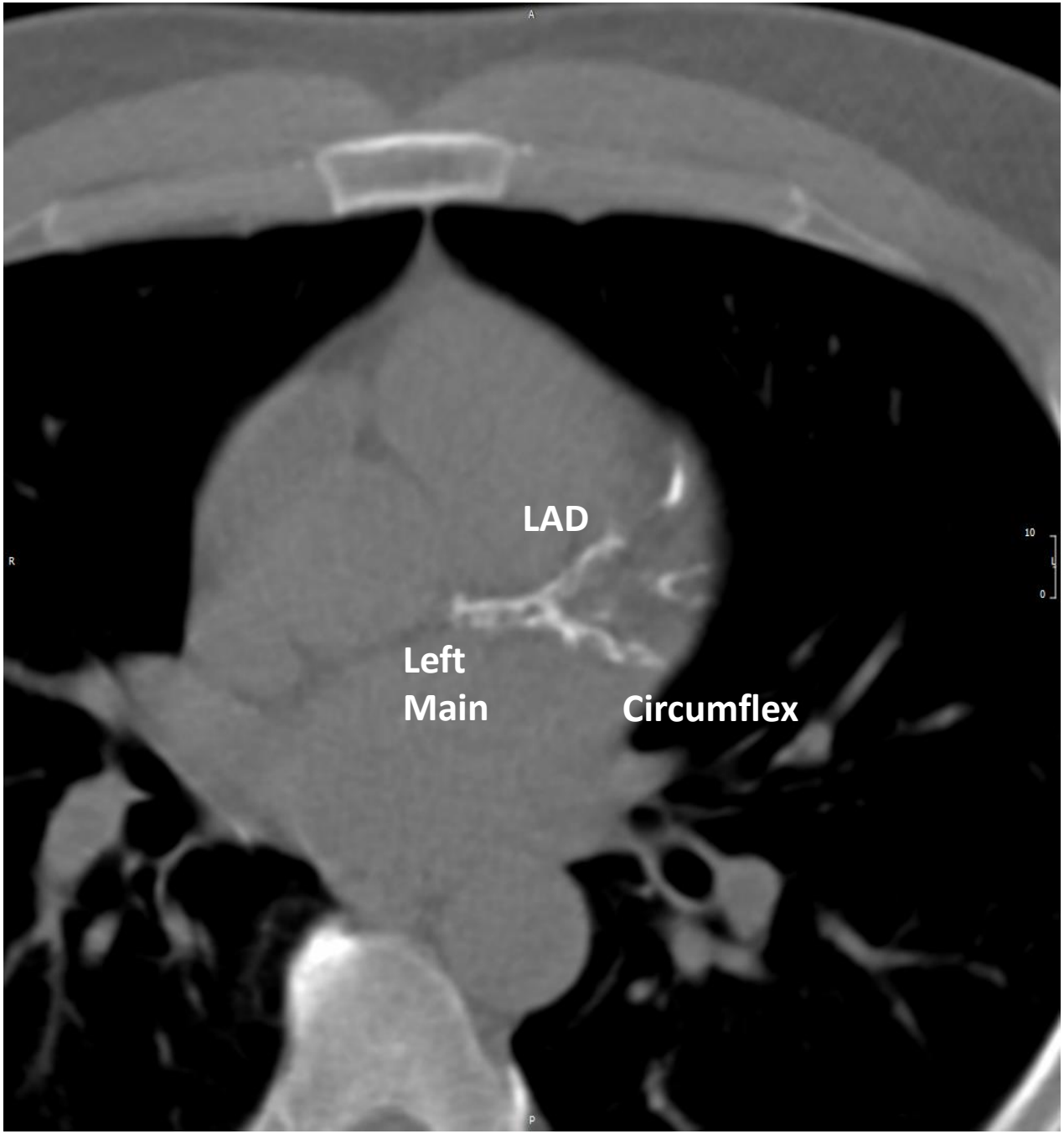
A
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CAC Categories and CVD Events: MESA

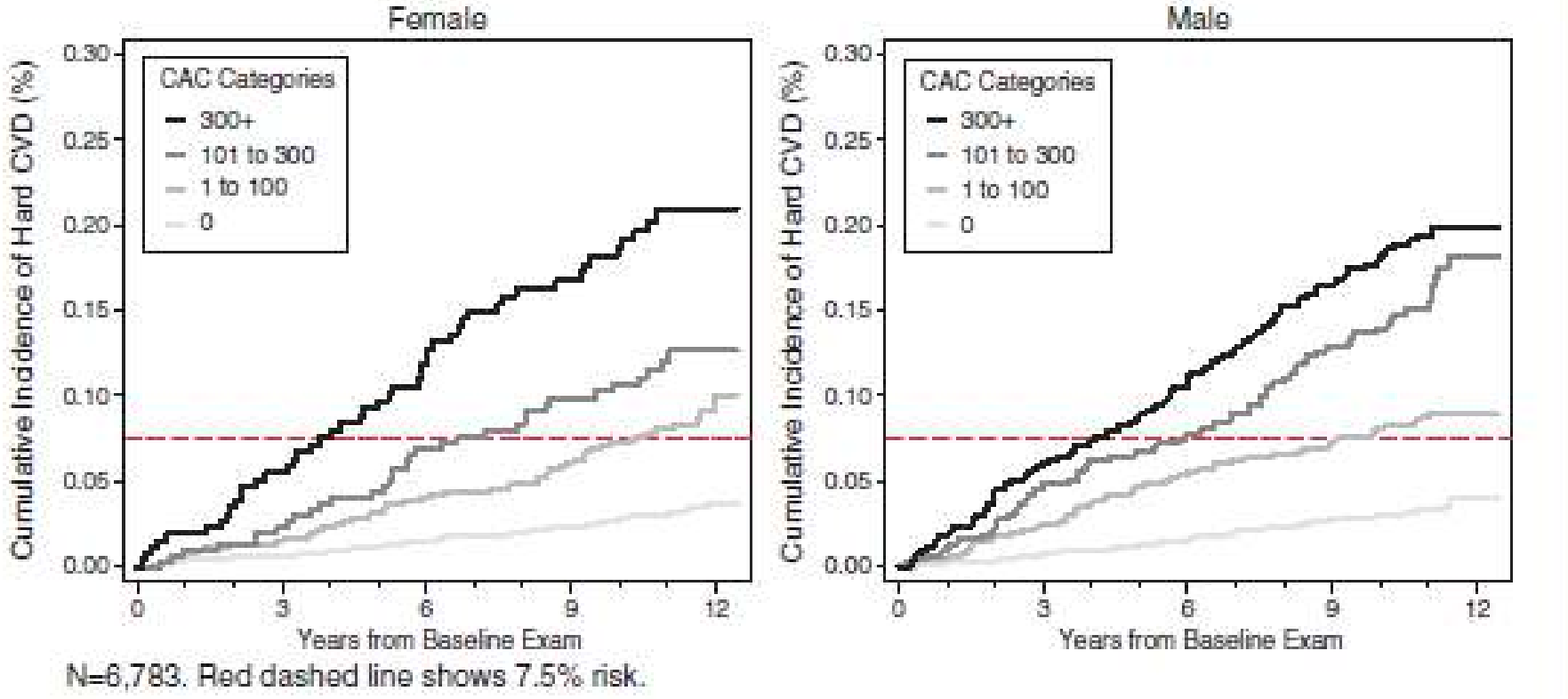
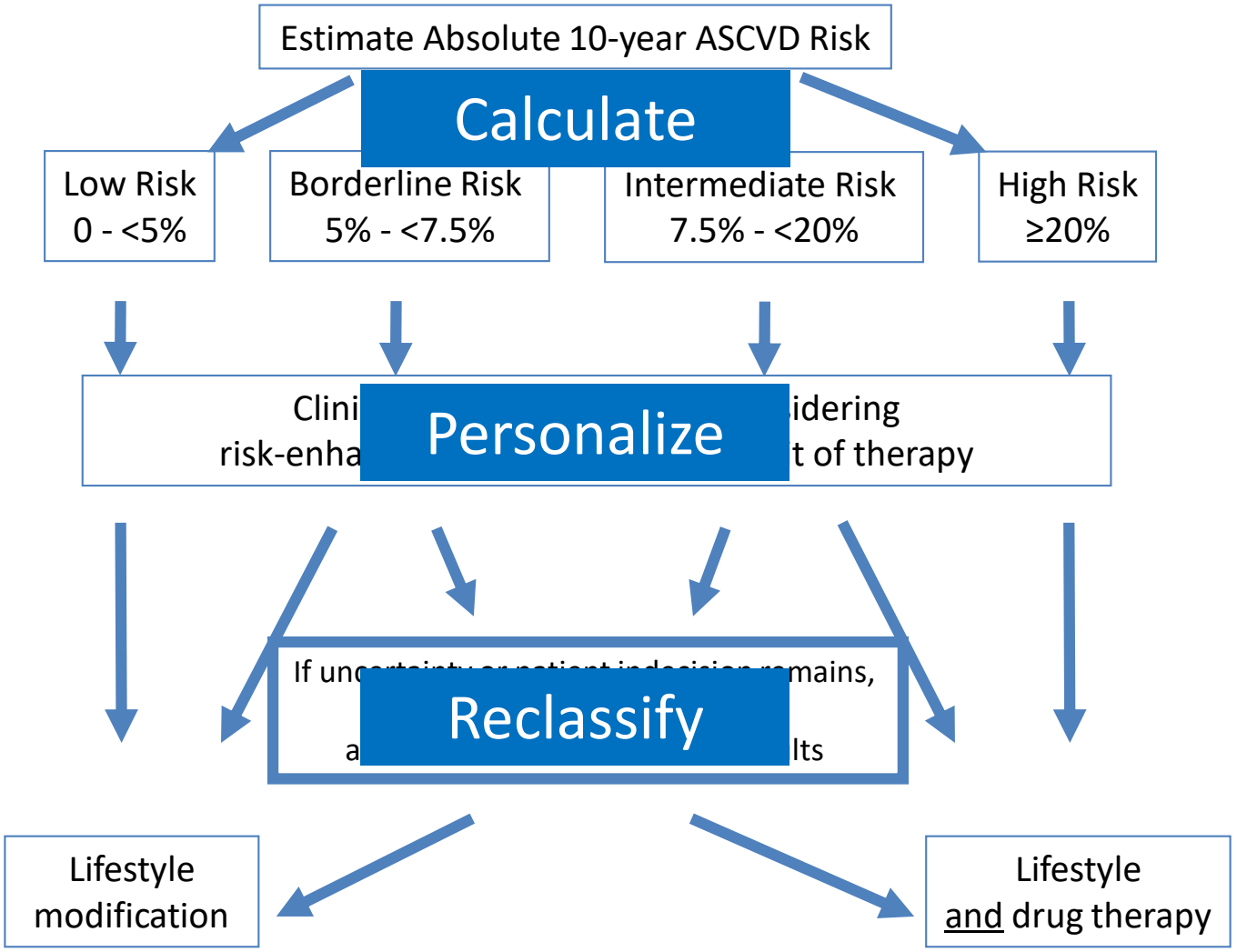


Figure 3 Unadjusted Kaplan–Meier cumulative incidence curves for hard atherosclerotic cardiovascular disease events by categories of coronary artery calcium and sex. n = 6783. Red dashed line shows 7.5% risk.

Budoff MJ et al., *European Heart Journal* 2018;0:1-10.

Approach to Risk Assessment in 1º Prevention: CPR



Credit: DLJ

Top Ten Take Home Messages

10. Assess adherence and percentage response to LDL-C–lowering medications and lifestyle changes with repeat lipid measurement 4 to 12 weeks after statin initiation or dose adjustment, repeated every 3 to 12 months as needed.

    - Responses to lifestyle and statin therapy are defined by percentage reductions in LDL-C levels compared with baseline.

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Case Example

Your patient is a 50-year old woman with newly diagnosed type 2 diabetes and HTN. She agrees to start atorvastatin 20 mg daily and to start a lifestyle program. You counsel her on a program adapted from the DPP.

- Baseline LDL-C: 144 mg/dL
- 2 mo. repeat LDL-C: 86 mg/dL (40% LDL-C reduction); patient hasn't started lifestyle program yet but intends to.
- LDL-C 4 mo. later after rigorous diet and exercise program: 72 mg/dL (additional 16% LDL-C reduction or 50% from baseline)

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Recommendations for Measurement of LDL-C and non-HDL-C

- In adults who are 20 years of age or older and not on lipid-lowering therapy, measurement of either a fasting or a nonfasting plasma lipid profile is effective in estimating ASCVD risk and documenting baseline LDL-C (I, B-R).

- If an initial nonfasting lipid profile reveals a triglyceride level of 400 mg/dL or higher, a repeat lipid profile in the fasting state should be performed for assessment of fasting triglyceride levels and baseline LDL-C (I, B-R).

- For patients with an LDL-C level less than 70 mg/dL, measurement of direct LDL-C or modified LDL-C estimate (Martin-Hopkins) is reasonable to improve accuracy over the Friedewald formula (IIa, C-LD).

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Recommendations for Older Adults (Primary Prevention)

- Adults 75 years or older:
  - Reasonable to start moderate-intensity statin if LDL-C is 70-189 mg/dL (IIb, B-R)
  - Reasonable to stop statin therapy when functional decline (physical or cognitive), multimorbidity, frailty, or reduced life expectancy limits the benefits of statin therapy (IIb, B-R)

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Recommendations Specific to Women

- Perform risk assessment and conduct a thorough menstrual and pregnancy history.
- When discussing lifestyle intervention and the potential benefit of statin therapy, consider the following:
  - *premature menopause (age <40 years)*
  - history of pregnancy-associated disorders (HTN, *preeclampsia*, gestational diabetes, small for gestational age infants, preterm deliveries) (I, B-NR)

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Recommendations Specific to Women Continued

- Counsel all sexually active women of childbearing age who are treated with a statin to use a reliable form of contraception (I, C-LD).
- In women who are treated with statin therapy and plan to become pregnant, stop the statin 1-2 months before pregnancy is attempted (I, C-LD).
- If a woman becomes pregnant while on statin therapy, stop the statin as soon as pregnancy is discovered (1, C-LD).

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Hypertriglyceridemia

- **In adults 20 years of age or older with moderate hypertriglyceridemia (fasting or nonfasting triglycerides 175 to 499 mg/dL), clinicians should address and treat lifestyle factors (obesity and metabolic syndrome), secondary factors (diabetes mellitus, chronic liver or kidney disease and/or nephrotic syndrome, hypothyroidism), and medications that increase triglycerides (I, B-NR).**

- **In adults 40 to 75 years of age with moderate or severe hypertriglyceridemia and ASCVD risk of 7.5% or higher, it is reasonable to reevaluate ASCVD risk after lifestyle and secondary factors are addressed and to consider a persistently elevated triglyceride level as a factor favoring initiation or intensification of statin therapy (IIa, B-R).**

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Hypertriglyceridemia con't

- **In adults 40 to 75 years of age with severe hypertriglyceridemia (fasting triglycerides ≥500 mg/dL and ASCVD risk of 7.5% or higher, it is reasonable to address reversible causes of high triglycerides and to initiate statin therapy (IIa, B-R).**

- **In adults with severe hypertriglyceridemia, it is reasonable to identify and address other causes of hypertriglyceridemia, and if triglycerides are persistently elevated or increasing, to further reduce triglycerides by implementation of a very low-fat diet, avoidance of refined carbohydrates and alcohol, consumption of omega-3 fatty acids, and, if necessary to prevent acute pancreatitis, fibrate therapy (IIa, B-R).**

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Additional Guideline Content

- Children and adolescents
- Other populations at risk
  - Ethnicity/race: Asian Americans, Hispanic/Latino Americans, Blacks
  - Adults with CKD
  - Adults with chronic inflammatory disorders and HIV
- Statin-safety and statin-associated side effects
- Implementation
- Cost and value considerations

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Guideline Implementation

- Need for multifaceted strategies: patient, clinician, health system, health plan
- Clinician-patient discussion and shared decision-making
  - Effective communication is crucial
  - Encourage pt to state what was heard, ask questions, express values/preferences, state ability to adhere to lifestyle changes and medications
  - Discuss potential for ASCVD risk reduction benefit, adverse effects, drug-drug interactions, patient preferences
- Interventions to foster adherence:
  - Telephone reminders, calendar reminders, multidisciplinary educational activities, simplification of drug regimen
- Identification of patients not receiving guideline-directed medical therapy; plan for addressing this problem

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Guideline Supplement, Table S7

Case Presentation

- 52-year-old South Asian woman presents to clinic for routine follow-up
  - PMH: HTN, preeclampsia with second pregnancy
  - FH: mother had MI at age 55
  - SH: denies tobacco, alcohol
  - Meds: lisinopril 10 mg PO daily
  - BP 142/86 mm Hg
  - Lipids (mg/dL): TC 225 HDL-C 35 LDL-C 150 TG 200
  - 10-yr ASCVD risk 4.7%

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According to the 2018 multisociety cholesterol guideline, which risk category is most applicable for this patient?

A. Low risk primary prevention
B. Borderline risk primary prevention
C. Intermediate risk primary prevention
D. High risk primary prevention

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According to the 2018 multisociety cholesterol guideline, which initial treatment strategy would you consider for this patient?

A. Lifestyle modification only
B. Lifestyle modification + moderate-intensity statin
C. Lifestyle modification + high-intensity statin
D. Lifestyle modification + high-intensity statin + ezetimibe

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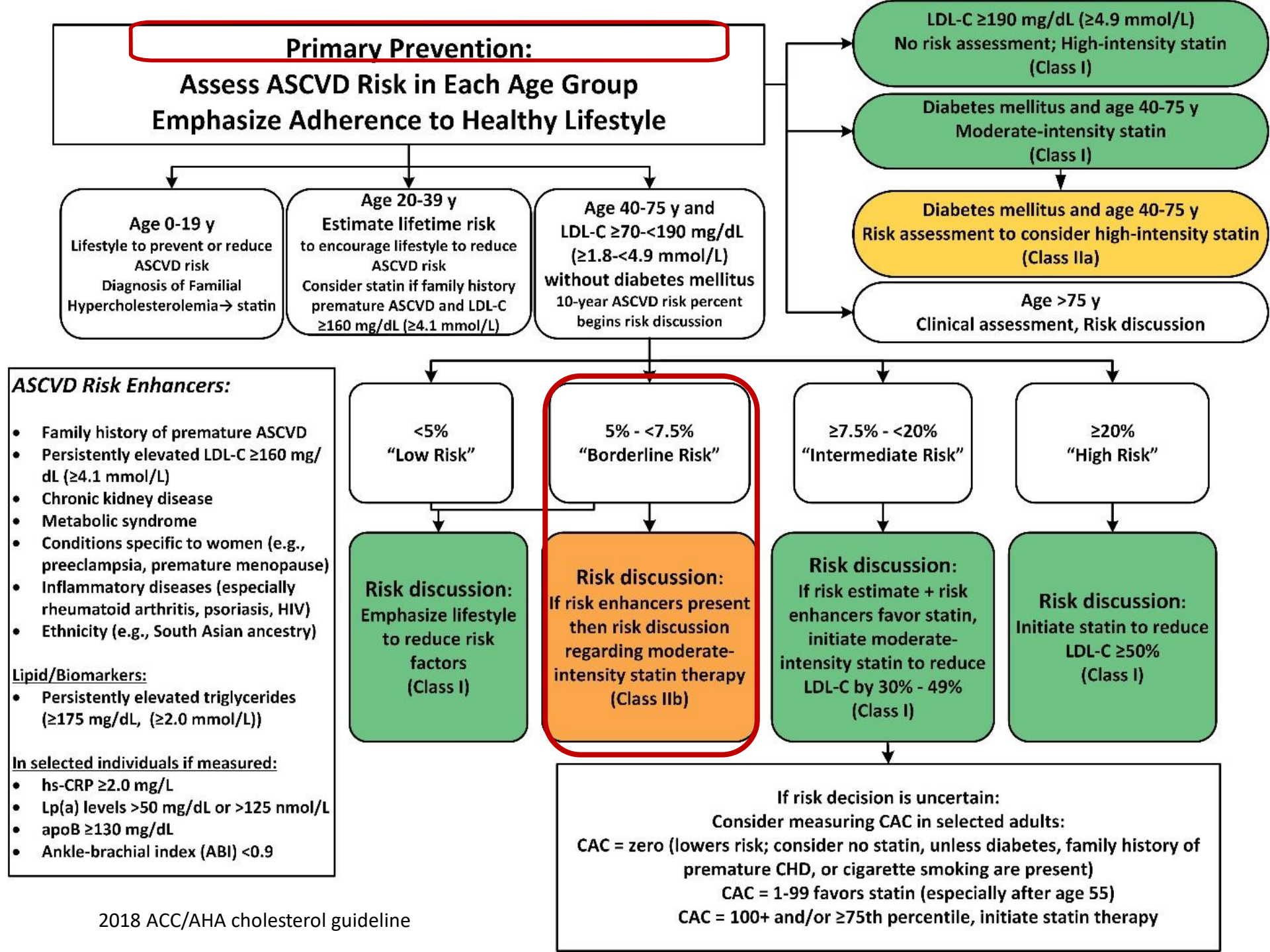

2018 ACC/AHA cholesterol guideline

Conclusions/Implications for Nurses

- 2018 Cholesterol Guideline is comprehensive, yet "user-friendly", and allows for a more tailored approach to primary prevention of ASCVD.
- Nurses should become familiar with the 10 take-home messages and where to locate other key information in the guideline.
- Nurses play an important role in the clinician-patient discussion:
  - respond to questions after a prescription is given, clarify information, address adverse effects, communicate with pharmacist, etc.
  - key clinicians in lifestyle counseling and providing patient with PCNA resources
- Many nurses are well-positioned to conduct education and QI projects that facilitate guideline implementation.

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Thank You!

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