AETC AIDS Education & Training Center Program Southeast

Webcast Wednesday
Metabolic March Madness Part 2: Updates in Dyslipidemia

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March 15, 2023

Disclosures

- The activity planners and speakers do not have any financial relationships with commercial entities to disclose.

- The speakers will not discuss any off-label use or investigational product during the program.

Objectives

- Discuss updates in the management of dyslipidemia in persons with HIV
- Apply evidence-based recommendations to non-pharmacologic and pharmacologic treatment
- Identify counseling pearls for pharmacologic and non-pharmacologic therapies

Abbreviations

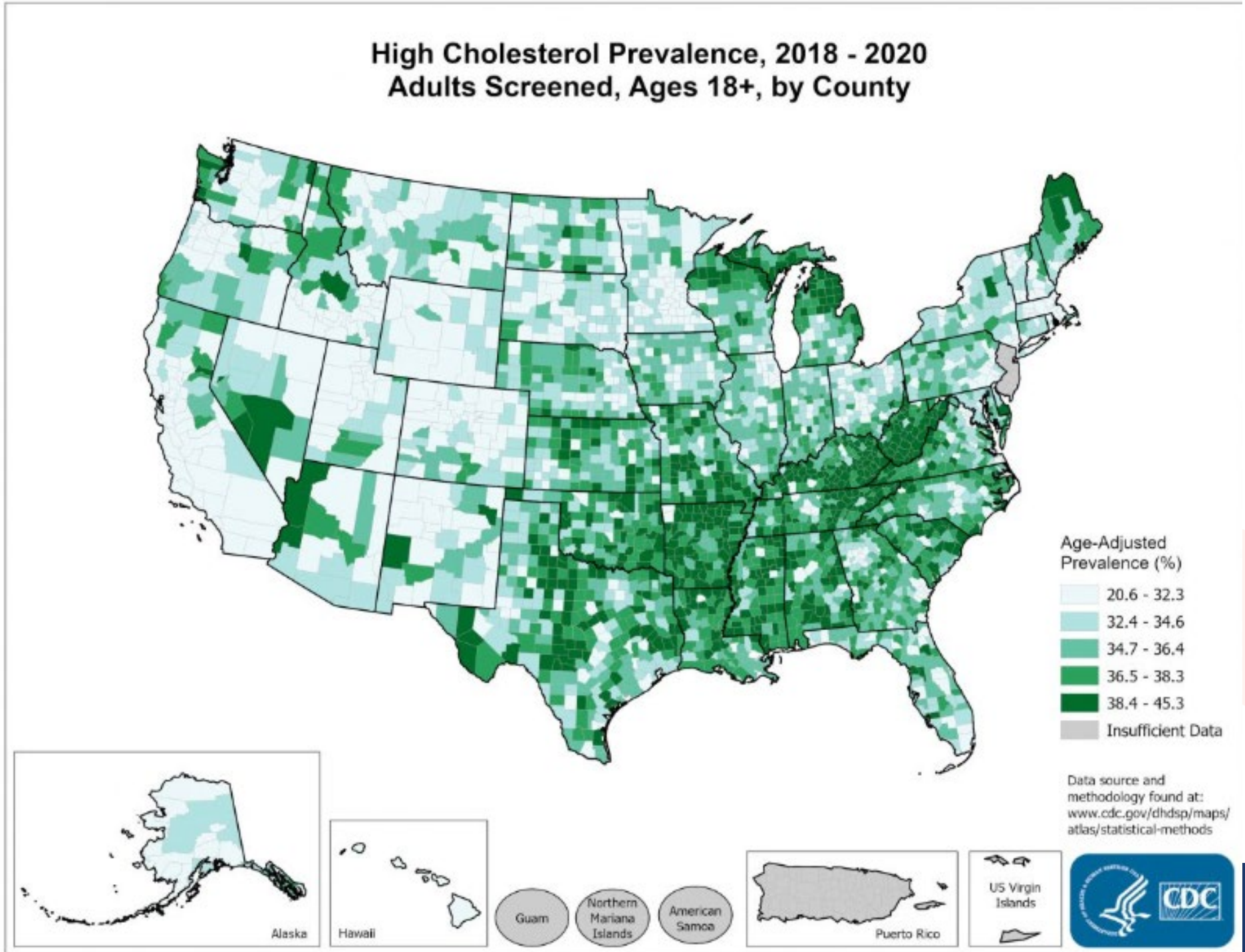
- Total cholesterol (TC)
- Triglycerides (TG)
- High density lipoprotein (HDL)
- Low density lipoprotein (LDL)
- Therapeutic lifestyle changes (TLC)
- Coronary heart disease (CHD)
- Creatine kinase (CK or CPK)
- Liver function tests (LFTs)
- Heterozygous familial hypercholesterolemia (HeFH)
- Homozygous familial hypercholesterolemia (HoFH)
- Atherosclerotic cardiovascular disease (ASCVD)
- Major adverse cardiovascular events (MACE)
- Not to exceed (NTE)

Dyslipidemia Definition

- Elevation in total cholesterol (TC), elevation in low density lipoprotein (LDL), elevation in triglycerides (TG), or low high-density lipoprotein (HDL)
  - May be a combination of the above
- Dyslipidemia vs Hyperlipidemia???

Background

- 73.5 million (31.7%) Americans have high LDL
- Individuals with high total cholesterol are two times more likely to develop heart disease
- Only 55% of adults who need cholesterol lowering therapy are taking it
- 7% of U.S. children and adolescents 6-19 years of age have high TC
- HIV is an independent risk factor for CVD
- ARTs can increase the risk of dyslipidemia



National Center for Health Statistics. https://www.cdc.gov/cholesterol/facts.htm. Accessed March 2, 2023

Leading Causes of Death 2021

Condition	Number of Deaths
Heart Disease	695,547
Cancer	605,213
Covid-19	416,893
Unintentional injury	224,935
Stroke	162,890
Chronic lower respiratory diseases	142,342
Alzheimer's Disease	119,399
Diabetes	103,294
Chronic liver disease and cirrhosis	56,585
Kidney Disease	54,358

National Center for Health Statistics. National Vital Statistics System: mortality statistics (https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm). Accessed March 2, 2023.

Metabolic Syndrome

Risk Factor	Level
Abdominal obesity Men Women	Waist circumference > 102 cm (> 40 in) > 88 cm (> 35 in)
Triglycerides***	≥ 150 mg/dL
HDL cholesterol*** Men Women	 < 40 mg/dL < 50 mg/dL
Blood pressure***	Systolic ≥ 130 and/or diastolic ≥ 85 mm Hg
Fasting glucose***	≥100 mg/dl

***Drug treatment will be an alternative indicator

Should ART Be Modified?

- Consider switching a protease inhibitor to INSTI or an NNRTI
  - INSTI: dolutegravir, raltegravir, or bictegravir
    - Dolutegravir or bictegravir may cause weight gain
  - NNRTI: rilpivirine, efavirenz, or doravirine
- Tenofovir disproxil fumarate may have lipid-lowering effects
  - Monitor bone and renal

Should ART Be Modified?

- Switching ART instead of adding lipid-lowering therapy may assist in:
  - Reducing pill burden and polypharmacy
  - Reducing cost
  - Minimizing side effects
  - Reducing the drug–drug interaction
- Could virologic suppression be impacted?
- Consideration should be given with pleiotropic effects of statins

Detection and Evaluation

- Obtain lipoprotein levels
- Identify lipoprotein goals based on risk
- Manage through therapeutic lifestyle changes (TLC) alone (if possible) or in conjunction with pharmacologic therapy

Obtaining Lipid Levels

- Fasting lipoprotein profile should be performed when aged 20 and older
  - What about non fasting labs?
  - If TG are ≥400 mg/dl, repeat fasting labs

LDL Lab **Reference** Goals*

LDL Goal (mg/dl)	Classification
<100	Optimal
100-129	Near Optimal
130-159	Borderline High
160-189	High
≥190	Very High

***Patient Specific Goals Will Vary**

Calculated LDL

- Friedewald equation

  LDL= (TC-HDL)-(TG/5)

  - Avoid if TG >400 mg/dl or LDL is <70 mg/dl
    - Direct LDL better indicator

Other Goals

Total Cholesterol (mg/dl)	Classification
<200	Desirable
200-239	Borderline High
≥240	High

HDL (mg/dl)	Classification
Men ≥40	Optimal
Women ≥50	Optimal
Men or Women ≥60	High
Men or Women <40	Low

Triglyceride Goals

Triglyceride Goals (mg/dl)	Classification
<150	Normal
150-199	Borderline High
200-499	High
≥500	Very High

TLC Options

- Plant stanols and sterols
  - 2-3 grams may reduce LDL by 6-15%
  - Benecol®
  - Cholestoff Supplements®
- Psyllium
  - Reduces LDL and TC by 5-20%
- Increasing physical activity
- Increasing fatty fish consumptions (≥ two (3.5 ounce) servings/wk)
  - 20 grams will reduce CHD risk by 7%
  - Reduces TG
  - Examples (salmon, *tuna*, trout)
    - Herring, *mackerel*, sardines, anchovies
    - Lean fish (flounder, cod, flounder, haddock, shrimp)
- Red Yeast Rice?????

Pharmacologic Options

- HMG-CoA reductase inhibitors (Statins)
- Bile Acid Sequestrants (BAS)
- Cholesterol absorption inhibitors
- Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors (PCSK9i)
- Cholesterol synthesis inhibitor
- Nicotinic Acid
- Fibric Acid derivatives (fibrates)
- Omega-3-fatty acids

Pharmacologic Effect on Lipid Levels

Drug Class	TC	LDL	HDL	TG
Statins	15-60%↓	21-55%↓	2-10%↑	6-30%↓
BAS	20%↓	15-25%↓	3-5%↑	-- or↑
Nic. Acid	25%↓	10-25%↓	10-35%↑	20-50%↓
Fibrates	20-25%↓	20-25%↓ or ↑	6-18%↑	20-50%↓
Ezetimibe --- w/statin		10-18%↓ --- 25%↓		
PCSK9i	36-42%↓	43-64%↓		
Bempedoic Acid --- w/ezetimibe		15-30%↓ --- 40% ↓		

Drug Interactions: Statins and ART

- Contraindications with simvastatin and lovastatin:
  - Protease inhibitors
  - Potent CYP 3A4 inhibitors
  - Use of cobicistat as boosting agent with elvitegravir
- Atorvastatin and rosuvastatin may require a dose reduction with protease inhibitors and elvitegravir/cobicistat
- Data on fluvastatin are limited, but it is not likely to interact significantly with protease inhibitors
- Efavirenz decreases atorvastatin, pravastatin, and simvastatin levels by approximately 40 to 60%, which may require higher doses of the statin
  - Do not exceed maximum statin dose

Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

- Approved with lifestyle modifications and maximally tolerated statin therapy
  - Individuals with ASCVD who require additional lowering of LDL cholesterol or in those with HeFH or HoFH
- Evolocumab: Reduces risk of MI, stroke, and coronary revascularization in adults with ASCVD
  - Evidence of benefit in pediatrics ≥10 years of age in HeFH or HoFH
- Alirocumab: Reduces risk of MI, stroke, and unstable angina requiring hospitalization in adults with ASCVD

Alirocumab (Praluent®)

- 75 mg SubQ q2 wks
  - May increase to 150 mg after 4-8 weeks if not achieving desired effect

Evolocumab (Repatha®)

- 140 mg Subq q2 wks or 420 mg Subq q4 wks

- **Store refrigerated; however, allow to warm up to room temperature (30-40 min) prior to injection**
- **If necessary, they can be stored at room temperature for 30 days**
- **Common side effects: nasopharyngitis, injection site reaction**
  - **No evidence of cognitive dysfunction in clinical trials**
- **No known interactions with ART**

Pharmacologic Effect on Lipid Levels

Drug Class	TC	LDL	HDL	TG
Statins	15-60% ↓	21-55% ↓	2-10% ↑	6-30% ↓
BAS	20% ↓	15-25% ↓	3-5% ↑	-- or ↑
Nic. Acid	25% ↓	10-25% ↓	10-35% ↑	20-50% ↓
Fibrates	20-25% ↓	20-25% ↓ or ↑	6-18% ↑	20-50% ↓
Ezetimibe --- w/statin		10-18% ↓ --- 25% ↓		
PCSK9i	36-42% ↓	43-64% ↓		
Bempedoic Acid --- w/ezetimibe		15-30% ↓ --- 40% ↓		

Bempedoic Acid (Nexletol®)

- 180 mg PO once daily
- Dosing limits with simvastatin (NTE 20 mg) and pravastatin (NTE 40 mg)
  - Increased risk of myopathies if above doses are exceeded
- Counseling/considerations:
  - Tendon rupture: Use with caution in adults >60 years of age, those with CKD, and/or corticosteroid use
  - Hyperuricemia: Gout
  - Avoid in pregnancy
- No known interactions with ART
- Monitor lipids 4-12 weeks after initiation
- *CLEAR: (Concluded November 2022): Evaluation of Major Cardiovascular Events in Patients With, or at High Risk for, Cardiovascular Disease Who Are Statin Intolerant Treated With Bempedoic Acid (ETC-1002) or Placebo*

Hot off The Press-Bempedoic Acid and CV Outcomes (CLEAR Trial)

- Study conducted in 13,970 statin intolerant patients
- Bempedoic acid 180 mg once daily vs. placebo
- Primary endpoint: MACE
  - Death from CV causes
  - Nonfatal MI
  - Nonfatal stroke
  - Coronary revascularization
- LDL reduction 21% in bempedoic acid group

Nissen SE, Lincoff AM, Brennan D, et al. CLEAR Outcomes Investigators. Bempedoic Acid and Cardiovascular Outcomes in Statin-Intolerant Patients. N Engl J Med. 2023 Mar 4. doi: 10.1056/NEJMoa2215024.

New Drugs to Market

- Evinacumab (Evkeeza): 15 mg/kg IV q4 weeks
  - LDL reduction by approximately 47%
    - May have additional benefits in TG *reduction (studies ongoing)*
    - Can be used in pediatrics ≥ 12 years with HoFH
  - Most common side effects (>3%): nasopharyngitis, influenza-like illness, dizziness, rhinorrhea, nausea, extremity pain, and generalized weakness
  - Contraindicated in pregnancy (fetal toxicity)
- Inclisiran: 300 mg subq q6 months (after initial dose and again at 3 months)
  - LDL reduction by approximately 50%
  - Most common side effects (>3%): injection site reaction, arthralgia, UTI, diarrhea, bronchitis, extremity pain, and dyspnea
  - *Studies ongoing for cardiovascular outcomes (anticipated completion 2027)*

Omega-3 Fatty Acids

- Decrease triglycerides by approximately 20-50% (through diet)
- May increase risk of bleeding due to antiplatelet effects at higher doses
- Prescription product: Lovaza®, Epanova®, Vascepa®
  - Cardiovascular benefits with Vascepa® in secondary prevention?
    - Can consider in high-risk CVD patients with TG >150 mg/dl
- Available in OTC formulations
- Available through diet
- No known interactions with ART

Circulation
Volume 140, Issue 11, 10 September 2019;, Pages e596-e646
https://doi.org/10.1161/CIR.0000000000000678

ACC/AHA CLINICAL PRACTICE GUIDELINE

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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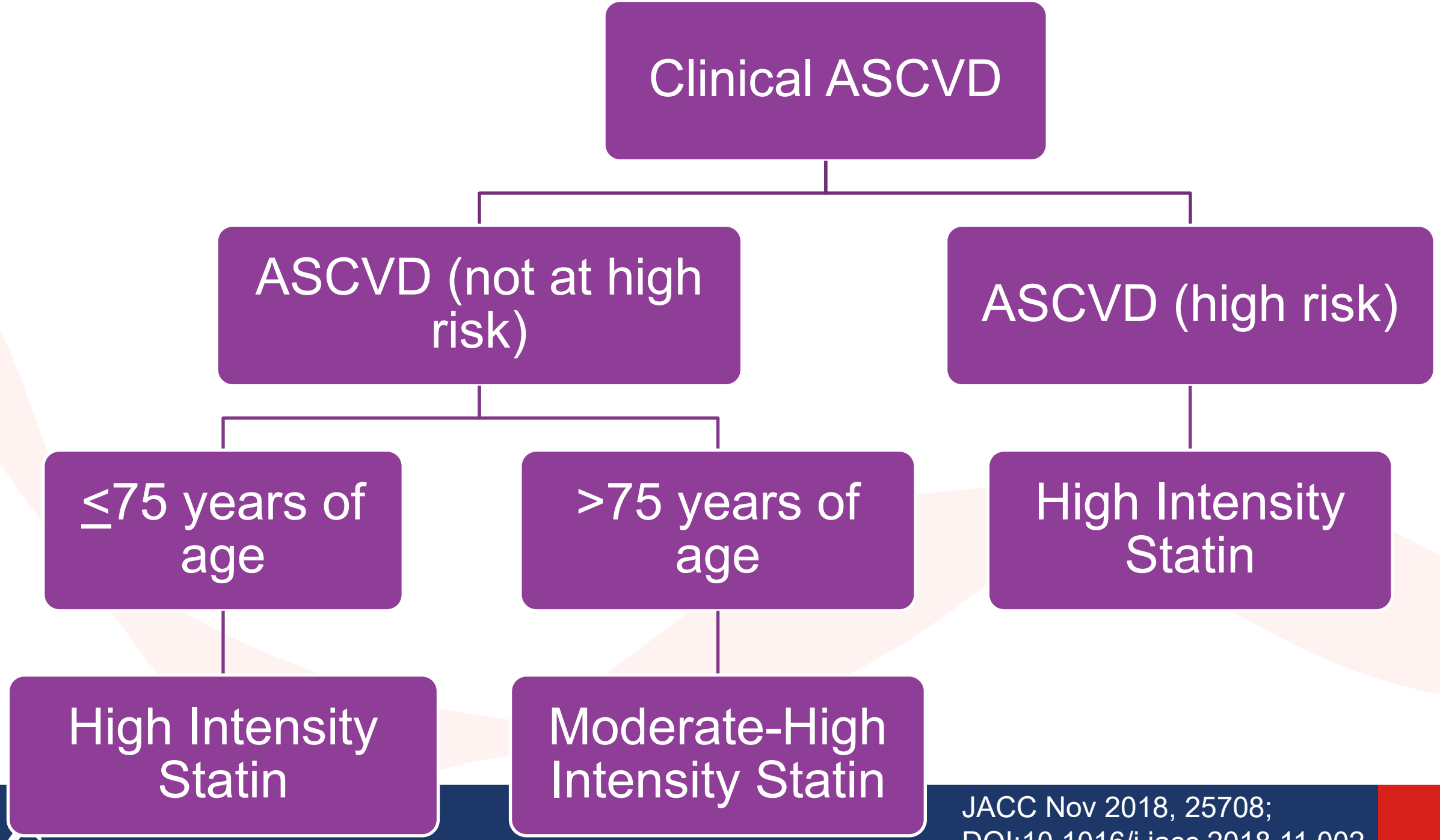
4 Major Statin Benefit Groups

- Clinical atherosclerotic cardiovascular disease (ASCVD)
- Primary elevations in LDL ≥190 mg/dl (not due to secondary causes)
- Individuals with Type I or Type II DM who are 40-75 years of age with LDL levels of 70-189 mg/dl without clinical ASCVD
- Individuals without clinical ASCVD or diabetes who are 40-75 years of age WITH LDL levels of 70-189 mg/dl and an estimated 10-year ASCVD risk ≥7.5%
  - Determined by estimated absolute 10-year risk of developing ASCVD

ASCVD

- Acute coronary syndromes
  - History of MI
  - Stable or unstable angina
  - Coronary or other arterial revascularization
- Stroke or TIA (ischemic)
- Peripheral arterial disease (atherosclerotic origin)



JACC Nov 2018, 25708;
DOI:10.1016/j.jacc.2018.11.002

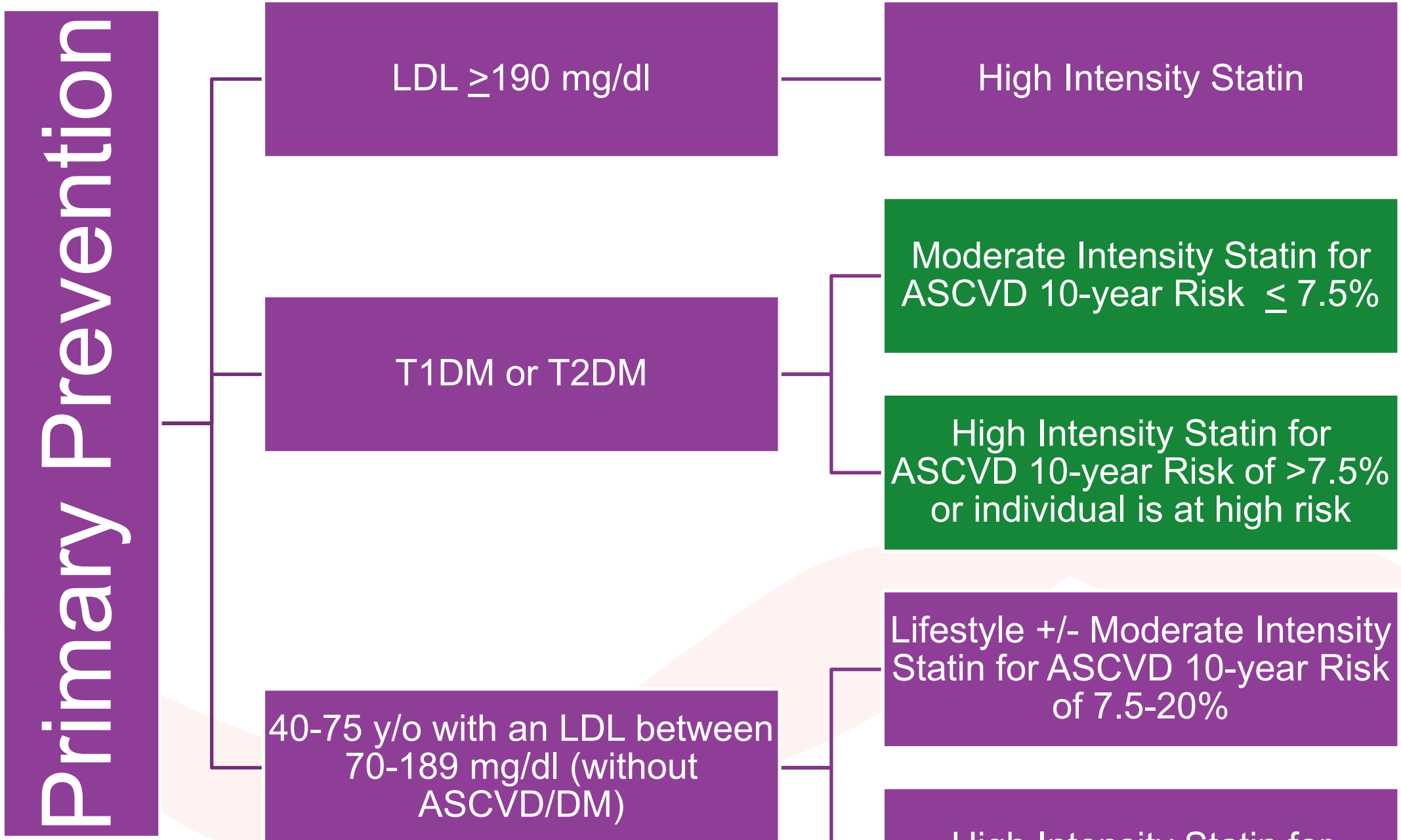
Very High Risk

Multiple ASCVD events

or

One ASCVD event + multiple high-risk conditions

High Risk Conditions	
Age ≥ 65	Congestive HF
HTN	CKD ≥ Stage 3
Heterozygous FH	Smoking
Hx of PCI or CABG outside of ASCVD event	LDL >100 mg/dl despite max tolerated statin and ezetimibe
DM	



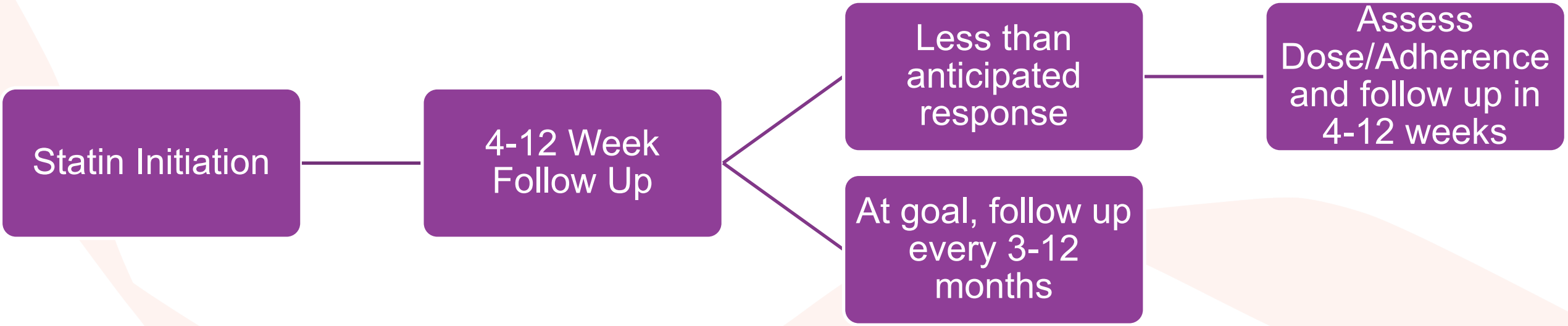
JACC Nov 2018, 25708;
DOI:10.1016/j.jacc.2018.11.002

High, Moderate, & Low Intensity Statin Therapy

High Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily Dose LDL lowering ≥50%	Daily Dose LDL lowering 30-49%	Daily Dose LDL lowering <30%
Atorvastatin 40 and 80 mg **Rosuvastatin 20 (40) mg**	**Rosuvastatin (5) 10 mg** **Atorvastatin 10 (20) mg** **Simvastatin 20-40 mg** Pravastatin 40 (80) mg Lovastatin 40 mg Fluvastatin XL 80 mg Fluvastatin 40 mg BID Pitavastatin 2-4 mg	Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg Pitavastatin 1 mg

****Statins in bolded red are considered primary statins**

Monitoring/Follow Up



LDL Reduction Add-on Therapy

Clinical ASCVD (very high risk) on maximally tolerated statin

(not achieving an LDL reduction of >50% and LDL-c <55 mg/dl)

Consider ezetimibe and/or PCSK9i

May consider bempedoic acid or inclisiran

2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;Aug 24:[Epub ahead of print]

Clinical ASCVD (not at very high risk) on maximally tolerated statin

(not achieving an LDL reduction of >50% and LDL <70 mg/dl)

- Consider ezetimibe
- May consider PCSK9i
- May consider bempedoic acid or inclisiran

2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;Aug 24:[Epub ahead of print]

Clinical ASCVD AND baseline LDL ≥190 mg/dl on maximally tolerated statin

(not achieving an LDL reduction of >50% and LDL <70 mg/dl)

Consider ezetimibe and/or PCSK9i

May consider bempedoic acid or inclisiran

2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;Aug 24:[Epub ahead of print]

Clinical ASCVD (at very high risk) AND baseline LDL ≥190 mg/dl on maximally tolerated statin

(not achieving an LDL reduction of >50% and LDL <55 mg/dl)

Consider ezetimibe and/or PCSK9i

May consider bempedoic acid or inclisiran

May consider evinacumab

2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;Aug 24:[Epub ahead of print]

Adults 40-75 years of age with diabetes and LDL <190 mg/dl without ASCVD on maximally tolerated statin

(not achieving an LDL reduction of >50% and LDL <70 mg/dl)

Consider ezetimibe

If LDL remains >70 mg/dl, may consider adding PCSK9i

2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;Aug 24:[Epub ahead of print]

Triglyceride Reduction Add-on Therapy

TG Considerations

- 175-499 mg/dl (fasting or non-fasting)
  - Address lifestyle and potential secondary causes
  - Consideration can be made in adding omega 3 fatty acids in certain high-risk populations
- 40-75 y/o with fasting lipids
  - TG ≥500 mg/dl and ASCVD >7.5%, add statin therapy and lifestyle modifications
  - If TG are persistently ≥500 and especially ≥1000 mg/dl
    - Add consumption/supplementation of omega 3 fatty acid and/or fibrate

Virani S, Morris P, Agarwala A, et al. 2021 ACC Expert Consensus Decision Pathway on the Management of ASCVD Risk Reduction in Patients With Persistent Hypertriglyceridemia. J Am Coll Cardiol. 2021 Aug, 78 (9) 960–993.

TG Reducing Plan of Action

Adults with ASCVD and fasting TG ≥150 mg/dl or non fasting TG ≥175 mg/dl and TG <500 mg/dl	Adults with DM (no ASCVD) and fasting TG ≥150 mg/dl or non fasting TG ≥175 mg/dl and TG <500 mg/dl	Adults ≥20 years (no DM or ASCVD) and fasting TG ≥150 mg/dl or non fasting TG ≥175 mg/dl and TG <500 mg/dl
May consider icosapent ethyl (Vascepa®) if LDL is ≤70 mg/dl	May consider icosapent ethyl (Vascepa®) if ≥50 years of age with 1 additional risk factor	Maximize statin

Virani S, Morris P, Agarwala A, et al. 2021 ACC Expert Consensus Decision Pathway on the Management of ASCVD Risk Reduction in Patients With Persistent Hypertriglyceridemia. J Am Coll Cardiol. 2021 Aug, 78 (9) 960–993.

Other Updates

- HFrEF: Consider a moderate intensity statin if life expectancy >3 years
- Patients of childbearing years
  - FDA called for the removal of the “Pregnancy Category X” label
  - Statin may be considered in patients with ASCVD
  - Statins should be discontinued in the majority of pregnancies
  - FDA states that now “statins are safe to use if you are not pregnant but can become pregnant”

Other Updates: HF and CKD

- HFrEF: Consider a moderate intensity statin if life expectancy >3 years
- CKD:
  - Not on dialysis
    - 40-75 y/o with LDL 70-189 mg/dl and ASCVD of >7.5% initiate moderate intensity statin + ezetimibe
  - Dialysis:
    - Continue statin if patient already on statin but DO NOT initiate statin therapy

Inflammatory Disorders and HIV

- 40-75 y/o with LDL 70-189 mg/dl and ASCVD of >7.5% initiate moderate or high intensity statin
- Consider drug interactions!!!

Patient Considerations

- Include patient in decision making
- Properly educate the patient
- Simplify regimen
- Consider cost
- Be supportive of short-term goals
- Incorporate regimen into patient's daily life
- Discuss lifestyle modifications
- Adherence and self monitoring

Cases: Libby Torr

- LT is a 60 YOF who presents to your lipid clinic. PMH includes MI (2006), HTN, HIV, and dyslipidemia. NKDA
- Meds: metoprolol tartrate 25 mg PO BID, amlodipine 10 mg PO daily, Biktarvy PO daily, and lisinopril 20 mg PO daily
- Fasting cholesterol labs today: All other labs WNL
  - TC: 261 mg/dl
  - LDL: 170 mg/dl
  - TG: 180 mg/dl
  - HDL: 55 mg/dl

Which Statin Benefit Group Is LT Most Associated With?

Clinical atherosclerotic cardiovascular disease (ASCVD)

0%

Primary elevations in LDL >190 mg/dl

0%

Individuals with Type I or Type II DM 40-75 years of age with LDL levels of 70-189 mg/dl without clinical ASCVD

0%

Individuals without clinical ASCVD or diabetes who are 40-75 years of age WITH LDL levels of 70-189 mg/dl and an estimated 1…

0%

Given LT's ASCVD, which statin would be most appropriate to initiate?

Simvastatin 80 mg

0%

Lovastatin 40 mg

0%

Lipitor 80 mg

0%

Rosuvastatin 10 mg

0%

What would LT's numeric LDL goal be?

<55-70 mg/dl

0%

<100 mg/dl

0%

<130 mg/dl

0%

<160 mg/dl

0%

Not enough information

0%

LT is likely to get to her numeric LDL goal with a statin alone

True

0%

False

0%

LT returned to clinic 1 year later but was only able to tolerate Lipitor 20 mg and now has an LDL of 110 mg/dl and TG of 140 mg/dl. She refuses injections. How would you proceed (assuming adherence)?

- Incliseran
- Vascepa
- Evolocumab
- Fenofibrate
- Ezetimibe/bempedoic acid combination

Cases: Zoe Corr

- ZC is a 57 YOF who presents to your lipid clinic. PMH includes T2DM, HTN, HIV, Obesity, and dyslipidemia.
- Meds: lisinopril 20 mg PO daily for HTN, metformin 1000 mg BID for T2DM, Biktarvy, and Crestor 10 mg PO daily
- NKDA; (-) ETOH (+) smoking
- Fasting cholesterol labs today: All other labs WNL
  - TC: 149 mg/dl
  - LDL: 90 mg/dl
  - TG: 120 mg/dl
  - HDL: 35 mg/dl

How would you address ZC's lipids?

Add Repatha

0%

Increase Crestor to 20 mg

0%

Add Nexletol

0%

Add ezetimibe

0%

Add Vascepa

0%

Assuming ZC returns _____weeks later to recheck her lipids after your recommended therapy change, her LDL is now 80 mg/dl. How would you proceed?

- No change necessary; ZC is at goal
- Increase Crestor to 80 mg
- Add ezetimibe 10 mg
- Add bempedoic acid
- Add Repatha

Chris Torr

- CT is a 57-year-old Hispanic female who presents to your clinic.
- PMH: T2DM, HIV and dyslipidemia
- NKDA
- Meds: atorvastatin 40 mg PO daily, Biktarvy once daily, and metformin 1000 mg BID

- Fasting cholesterol labs today: All other labs WNL except blood glucose is slightly elevated
  - TC: 250 mg/dl
  - LDL: -- mg/dl
  - TG: 700 mg/dl
  - HDL: 45 mg/dl

Which of the following lipid lowering medications/ options is BEST for CR?

Niaspan 500 mg PO qHS

Lovaza 2 grams PO BID

Gemfibrozil 600 mg PO BID

Ezetimibe 10 mg PO daily

Crestor 40 mg PO daily

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Metabolic March Madness Part 2: Updates in Dyslipidemia

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