AETC AIDS Education & Training Center Program Southeast

Webcast Wednesday
Metabolic Madness Part 2: Updates in Dyslipidemia

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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
- Only 55% of adults who need cholesterol lowering therapy are taking it
- HIV is an independent risk factor for CVD
  - 2 fold higher increase in ASCVD at a younger age
  - Women with HIV are at higher ASCVD risk than men with HIV at the same age
- ARTs can increase the risk of dyslipidemia

2022 vs. 2021 Leading Cause of Death

Condition	2022 Number of Deaths	2021 Number of Deaths
Heart Disease	703,041	695,547
Cancer	608,341	605,213
Unintentional injury	227,664	224,935
Covid-19	186,555	416,893
Stroke	165,391	162,890
Chronic lower respiratory diseases	147,367	142,342
Alzheimer's Disease	120,109	119,399
Diabetes	101,199	103,294
Kidney Disease	57,931	54,358
Chronic liver disease and cirrhosis	54,817	56,585

Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10-provisional.html on Mar 8, 2024

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
    - 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%↓		

Statin Considerations in HIV

- Randomized Trial to Prevent Vascular Events in HIV (Reprieve)
  - 45–75 year-old individuals with HIV on ART
  - Pitavastatin 4 mg daily was associated with a 35% reduction in MACE over a median of 5 years compared to placebo
  - Higher incidence of diabetes and muscle-related symptoms
- Other Recommendations
  - Benefit in using **pitavastatin 4 mg**, atorvastatin 20 mg, or rosuvastatin 10 mg when ASCVD 10 risk is 5%-19%

Grinspoon SK, Fitch KV, Zanni MV, et al. Pitavastatin to Prevent Cardiovascular Disease in HIV Infection. N Engl J Med. 2023 Aug 24;389(8):687-699. doi: 10.1056/NEJMoa2304146. Epub 2023 Jul 23. PMID: 37486775; PMCID: PMC10564556.

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

Drug Interactions

Primary Statins	ARV Drugs	Recommendations
Pitavastatin 4 mg once daily	INSTI: BIC, CAB, DTG, RAL NNRTI: DOR, EFV, ETR, RPV PI/r: ATV/r, DRV/r Other: LEN, MVC	No dosage adjustment
	INSTI: EVG/c PI/c: ATV/c, DRV/c Other: FTR	No data available; use standard dose and monitor for ADRs

Drug Interactions

Primary Statins	ARV Drugs	Recommendations
Atorvastatin 20 mg once daily	INSTI: BIC, CAB, DTG, RAL NNRTI: DOR, RPV Other: LEN, MVC	No dosage adjustment
	INSTI: EVG/c PI: DRV/c, DRV/r	Increase atorvastatin concentrations NTE atorvastatin 20 mg daily
	NNRTI: EFV, ETR	Decrease atorvastatin concentrations
	PI: ATV/c	Do not combine
	PI: ATV, ATV/r Other: FTR	Increase atorvastatin concentrations. Monitor for ADE

Drug Interactions

Primary Statins	ARV Drugs	Recommendations
Rosuvastatin 10 mg once daily	INSTI: BIC, CAB, DTG, RAL NNRTI: DOR, EFV, ETR, RPV Other: LEN, MVC	No dosage adjustment
	INSTI: EVG/c PI: DRV/r Other: FTR	Increase rosuvastatin concentrations Monitor for ADE
	PI: DRV/c	Increase rosuvastatin concentrations NTE rosuvastatin 20 mg
	PI: ATV, ATV/r, ATV/c	Increase rosuvastatin concentrations NTE rosuvastatin 10 mg

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

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
  - **Nonfatal MI**
  - **Coronary revascularization**
  - Death from CV causes
  - Nonfatal stroke
- 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.

Newer 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

Guidelines

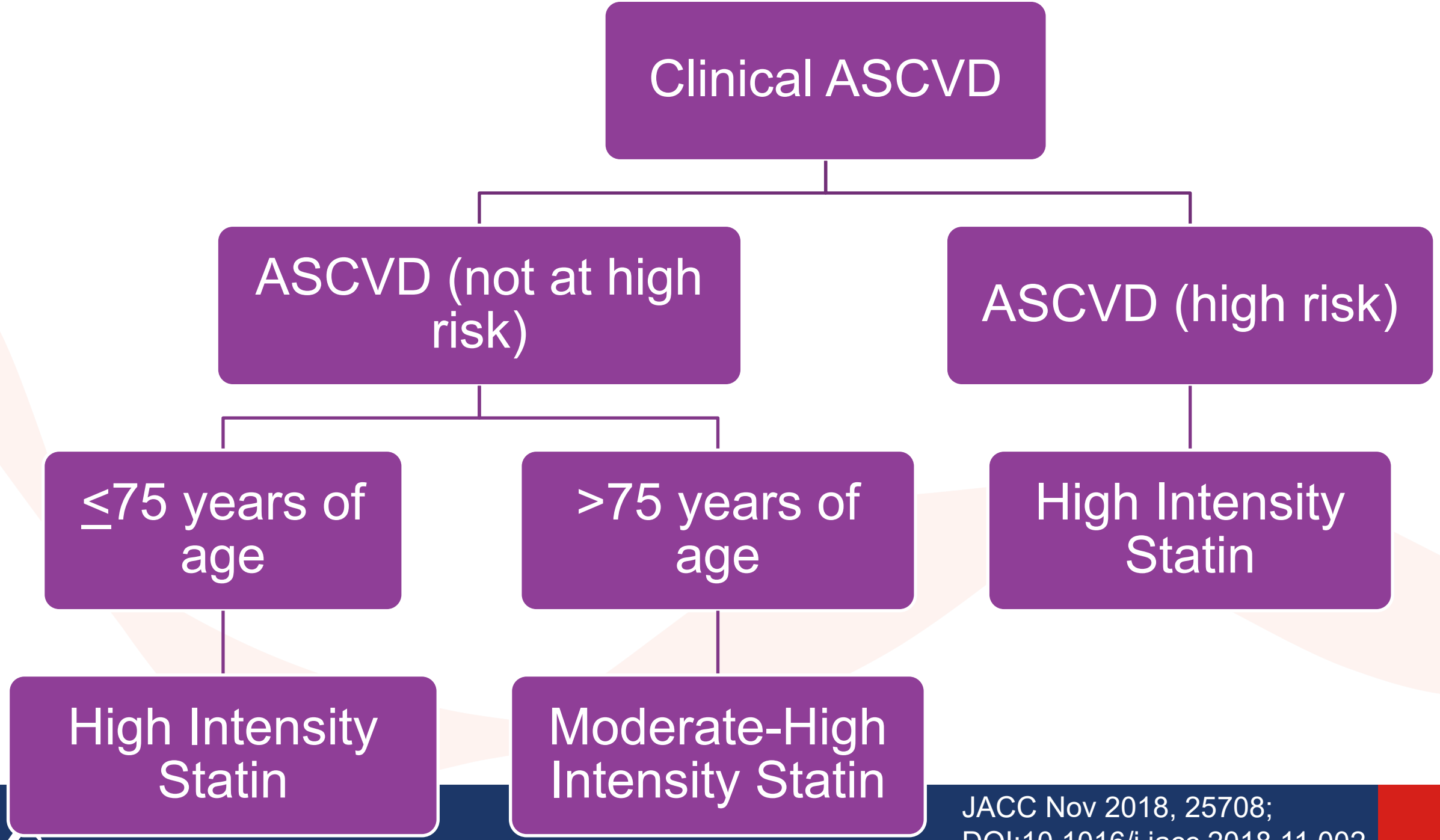
- 2024 Recommendations for the Use of Statin Therapy as Primary Prevention of Atherosclerotic Cardiovascular Disease in People with HIV (HIV.gov)
- 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk
- 2021 ACC Expert Consensus Decision Pathway on the Management of ASCVD Risk Reduction in Patients With Persistent Hypertriglyceridemia
- 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
- 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk
- 2017: American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) Guidelines for the Management of Dyslipidemia and Prevention of Cardiovascular Disease
- 2013: ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.
- 2002 with 2004 update: The National Cholesterol Education Program (NCEP) Adult Treatment Panel III

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
  - In PWH, a statin benefit can be seen when the 10-year ASCVD risk is **≥5%**

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

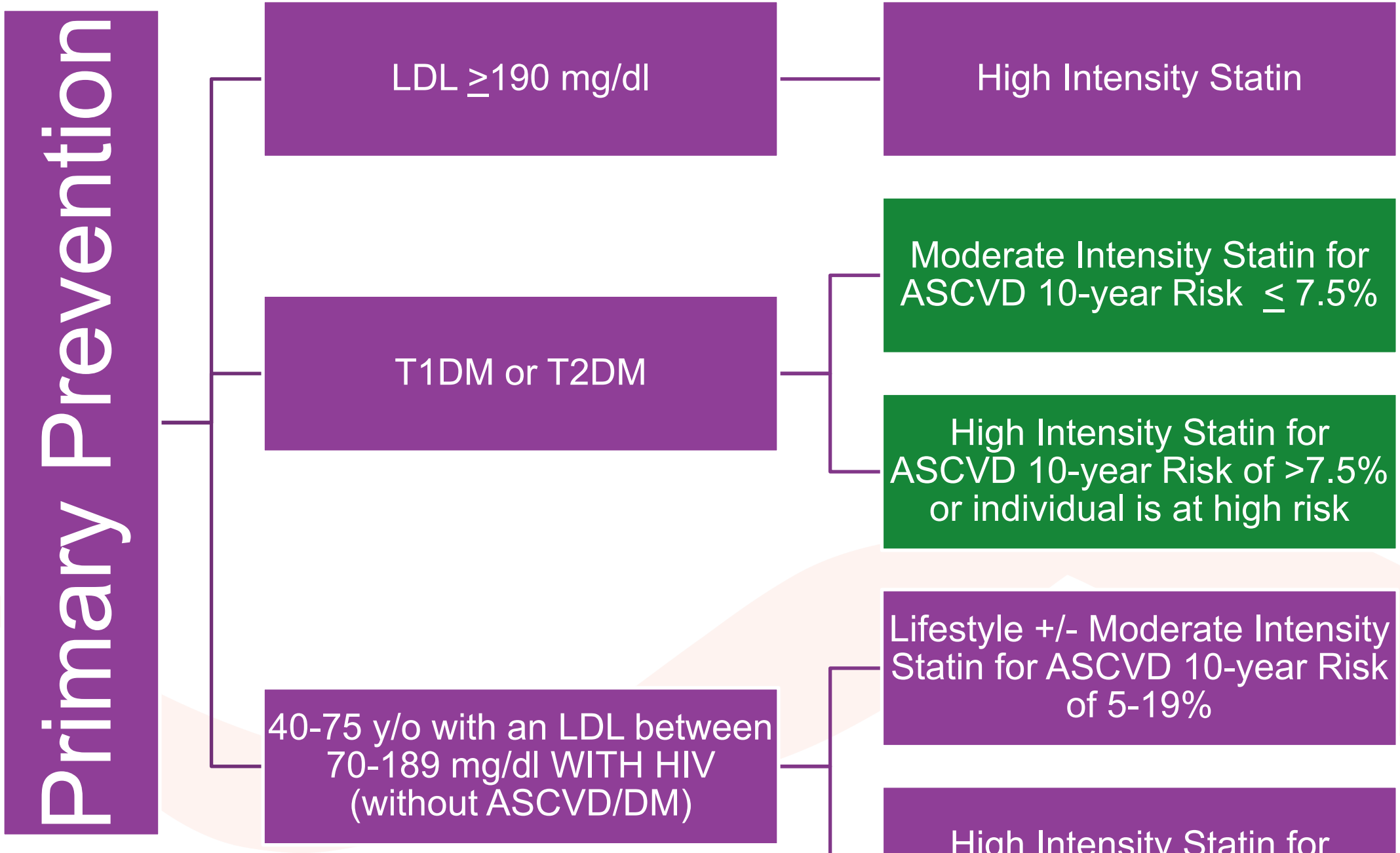
Very High Risk

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	



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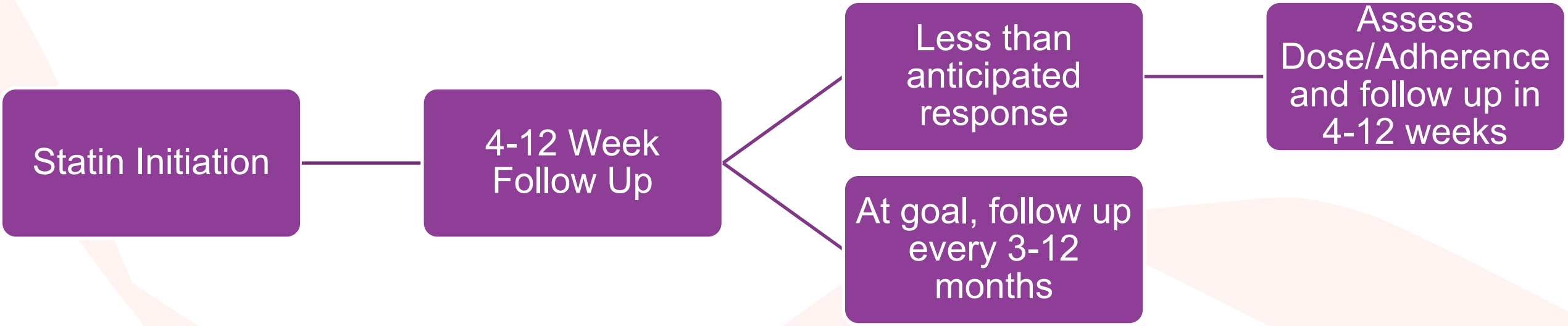
JACC Nov 2018, 25708;
DOI:10.1016/j.jacc.2018.11.002

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	**Pitavastatin 4 mg*** **Rosuvastatin 10 mg**** **Atorvastatin 20 mg**** Simvastatin 20-40 mg Pravastatin 40 (80) mg Lovastatin 40 mg Fluvastatin XL 80 mg Fluvastatin 40 mg BID	Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg Pitavastatin 1 mg ***AI Recommendation** ****All Recommendation**

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

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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

May consider icosapent ethyl (Vascepa®) if LDL is ≤70 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

May consider icosapent ethyl (Vascepa®) if ≥50 years of age with 1 additional risk factor

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

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

- 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 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

- Consider pitavastatin 4 mg, rosuvastatin 10 mg, or atorvastatin 20 mg in PWH with a 10-year ASCVD risk of 5-<20%
- Rosuvastatin 10 mg, pitavastatin 4 mg, and atorvastatin 80 mg have all demonstrated reductions in inflammatory and monocyte T-cell immune activation biomarkers among people with HIV
- 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

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