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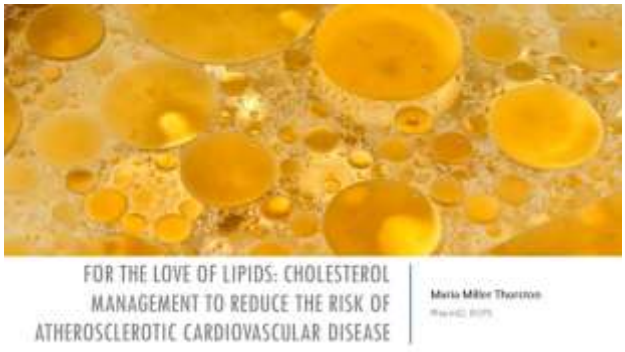
For the Love of Lipids: Cholesterol Management to Reduce the Risk of Atherosclerotic Cardiovascular Disease



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The guideline governing the management of blood cholesterol to reduce cardiovascular risk was recently revised at the end of 2018. Several critical changes were made to the guideline, including the identification of high risk and very high-risk factors, restructuring of patient groups in which to consider drug therapy, revised therapeutic targets, and incorporation of newer non-statin drugs to the clinical armamentarium. It is imperative to disseminate these updates to healthcare practitioners, so that they can provide evidence-based, patient-centered care as members of an interdisciplinary team.

Learning Objectives

Pharmacist

1. Recognize the relationship between dyslipidemia and atherosclerotic cardiovascular disease (ASCVD), including risk assessment
2. Identify key recommendations from the 2018 Guideline on the Management of Blood Cholesterol
3. Recognize the role of pharmacotherapy in dysplipidemia management to optimize pharmacotherapy plans and outcomes for patients with dyslipidemia

Pharmacy Technician

1. Recognize the relationship between dyslipidemia and atherosclerotic cardiovascular disease (ASCVD)
2. Recognize the role of pharmacotherapy in dyslipidemia management

Nurse

1. Recognize the relationship between dyslipidemia and atherosclerotic cardiovascular disease (ASCVD), including risk assessment
2. Identify key recommendations from the 2018 Guideline on the Management of Blood Cholesterol
3. Recognize the role of pharmacotherapy in dysplipidemia management to optimize pharmacotherapy plans and outcomes for patients with dyslipidemia

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Pharmacists, Pharmacy Technicians, Nurses

Universal Activity Number

Pharmacist	Pharmacy Technician	Nurse
0798-0000-19-083-L01-P	0798-0000-19-083-L01-T	0798-0000-19-083-L01-P

Credit Hours

1.25 Hour

Activity Type

Knowledge-Based

CE Broker Tracking Number

20-721450

Activity Release Date

May 20, 2019

Activity Offline Date

May 20, 2022

ACPE Expiration Date

May 20, 2022

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FOR THE LOVE OF LIPIDS: CHOLESTEROL MANAGEMENT TO REDUCE THE RISK OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE

Maria Miller Thurston
PharmD, BCPS

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LEARNING OBJECTIVES

1. Recognize the relationship between dyslipidemia and atherosclerotic cardiovascular disease (ASCVD), including risk assessment
2. Identify key recommendations from the 2018 Guideline on the Management of Blood Cholesterol
3. Recognize the role of pharmacotherapy in dyslipidemia management to optimize pharmacotherapy plans and outcomes for patients with dyslipidemia

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BACKGROUND

- Dyslipidemia
  - 95 million U.S. adults age 20 or older have total cholesterol levels higher than 200 mg/dL
  - No symptoms
    - Only 55% (43 million) of those who could benefit from cholesterol medicine are currently taking it
  - Raises the risk for heart disease → the leading cause of death

High Cholesterol Facts. Available from: http://www.cdc.gov/cholesterol/facts.htm

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WHAT IS ASCVD?

- Atherosclerotic Cardiovascular Disease*
  - Acute coronary syndrome (ACS)
  - History of myocardial infarction (MI)
  - Stable or unstable angina
  - Coronary or other arterial revascularization
  - Stroke or transient ischemic attack (TIA)
  - Peripheral artery disease (PAD)
  - Aortic aneurysm

*all conditions of atherosclerotic origin

2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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THERAPEUTIC OPTIONS

- Lifestyle modification
  - 2013 AHA/ACC Lifestyle Management Guideline
  - Heart healthy diet (phytosterols and soluble dietary fibers)
  - Regular aerobic exercise (40 minutes, 3-4x/week)
  - Tobacco avoidance
  - Weight loss/healthy weight maintenance
  - Often needs multidisciplinary effort over long periods of time
- Drug Therapy
  - Statin therapy
  - Non-statin agents

2013 AHA/ACC Lifestyle Management Guideline. Available from: https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437740.48606.d1
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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COMPARISON OF STATIN INTENSITY

High Intensity Statins	Moderate Intensity Statins	Low Intensity Statins
Lowers LDL by ≥ 50%	***Lowers LDL by 30-49%***	***Lowers LDL by < 30%***
Atorvastatin 40-80 mg Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Rosuvastatin 5-10 mg Simvastatin 20-40 mg Pravastatin 40-80 mg Lovastatin 40-80 mg Fluvastatin XL 80 mg Fluvastatin 40 mg BID Pitavastatin 1-4 mg	Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg

Drug name key:
Atorvastatin (Lipitor), Fluvastatin (Lescol), Lovastatin (Mevacor), Pitavastatin (Livalo), Pravastatin (Pravachol), Rosuvastatin (Crestor), Simvastatin (Zocor)

2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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STATIN CLINICAL CONSIDERATIONS

- Simvastatin FDA guidance released in 2011
- Rosuvastatin renally dosed
- Atorvastatin 80mg post-MI
- Pravastatin and rosuvastatin not significantly metabolized by CYP450 system (fewer drug interactions)
- Concept of lipophilicity: most hydrophilic → lipophilic
  - Pravastatin → rosuvastatin → atorvastatin → simvastatin
- Safety → side effects
  - Statin associated muscle symptoms (SAMS), diabetes, liver, memory

FDA Drug Safety Communication. Available from: http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm
Rosuvastatin (Crestor) Prescribing Information. Available from: http://www1.astrazeneca-us.com/pi/crestor.pdf
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625
Pravastatin (Pravachol) Prescribing Information. Available from: http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=897ad8b7-921d-eb02-a61c-3419e662a2da

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NON-STATIN AGENTS

- Ezetimibe (Zetia)
- PCSK9 Inhibitors
  - Alirocumab (Praluent) and evolocumab (Repatha)
  - Recently gained FDA approval
  - Dramatically reduce LDL-C level over and above statin therapy
  - Favorable short-term outcomes data
- Bile acid sequestrants (BAS)

Therapies for severe hypertriglyceridemia not considered

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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EZETIMIBE

- MOA: Reduces cholesterol absorption in small intestine
- Dosing: 10 mg PO daily, with or without food.
  - Take ≥ 2 hours before or ≥ 4 hours after BAS if used in combination
- Efficacy (LDL reduction): 13-20%
- Adverse events/safety
  - Low incidence of side effects
  - Upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity
  - Interacts with cyclosporine, fibrates, BAS

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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PCSK9 INHIBITORS

- Alirocumab and evolocumab
- MOA: Human monoclonal antibody to PCSK9.
  - Binds to PCSK9 and increases the number of LDL receptors available to clear circulating LDL
- Dosing:
  - Alirocumab—initiate 75 mg SQ every 2 weeks, may titrate Q2 weeks
  - Evolocumab—140 mg SQ every 2 weeks or 420 mg SQ once monthly

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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PCSK9 INHIBITORS

- Efficacy (LDL reduction when added to maximally tolerated statin):
  - Alirocumab 75 mg & 150 SQ: 45% & 58% decrease, respectively
  - Evolocumab 140 mg & 420 mg: 64% and 58% decrease, respectively
- Adverse events/safety:
  - Alirocumab—nasopharyngitis, injection site reactions, influenza
  - Evolocumab—nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions
  - Increases in self-reported cognitive adverse effects in RCTs with both agents
  - No clinically significant drug-drug interactions

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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BILE ACID SEQUESTRANTS (BAS)

- Colesevelam (Welchol), Cholestyramine (Questran), and Colestipol (Colestid)
- MOA: Bind bile acids to prevent reabsorption in the intestines → Increase LDL-C clearance from the body
- Dosing: Dependent on dosage formulation
  - Tablet, suspension, powder
- Efficacy (LDL reduction):
  - 15-30% (product, formulation and dose dependent)

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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BILE ACID SEQUESTRANTS (BAS)

- Not absorbed and do not cause systemic side effects
- Adverse events/safety:
  - Constipation, dyspepsia, nausea
  - Hypertriglyceridemia→ pancreatitis (avoid if TG ≥300 mg/dL)
  - Increased seizure activity or decreased phenytoin levels
  - Decreased INR in patients receiving warfarin
  - Increased TSH with thyroid hormone replacement therapy
  - Bowel obstruction or fecal impaction
  - Dysphagia or esophageal obstruction
  - Increased transaminases
  - Risk of many drug-drug interactions…

2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936
2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625

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EVOLUTION OF CHOLESTEROL GUIDELINES

- ATP III previously "go to" cholesterol guideline
- 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol
  - New risk assessment tool and eliminated LDL-C "goals"
  - Focus on appropriate "intensity" statin therapy based on benefit groups
- 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies
  - 2017 focused update

2013 ACC/AHA Blood Cholesterol Guideline. Available from: https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf
2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies. Available from: http://content.onlinejacc.org/article.aspx?articleid=2510936

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RISK ASSESSMENT: ASCVD RISK CALCULATOR

- Pooled cohort equations (PCE)
- "Starting point" for decision making in primary prevention
- https://my.americanheart.org/
  - Web, computer download & app!
- Multifactorial assessment
- 10-year risk
  - 40-79 years only
- Lifetime risk
  - 20-59 years only

Risk Factor	Accepted	Patient Value
Age	20-79 years	57
Sex	M or F	M
Race	AA/WH/Other	AA
Systolic BP	90-200 mm Hg	146
Diastolic BP	60-130 mmHg	86
Total Cholesterol	130-320 mg/dL	235
HDL-Cholesterol	20-100 mg/dL	37
LDL-Cholesterol	30-300 mg/dL	136
Diabetes	Y or N	N
Smoker	Y/Former/N	Y
BP Treatment	Y or N	Y
On Statin/Aspirin	Y or N	N

AA=African –American; BP=blood pressure; N=no; WH=white; Y=yes

10-Year Risk	Lifetime Risk
27.8%	69%

ACC ASCVD Risk Estimator Plus Available from: http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/

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STATIN BENEFIT GROUPS FROM 2013 GUIDELINE

- Clinical ASCVD (≥21 years)
  - High-intensity statin
- LDL >190 mg/dL (≥21 years)
  - High-intensity statin
- Diabetes (LDL 70-189 mg/dL and aged 40-75 years)
  - Moderate or high-intensity statin
- ≥ 7.5% estimated 10-y ASCVD risk (LDL 70-189 mg/dL and aged 40-75 years)
  - Moderate or high-intensity statin

2013 ACC/AHA Blood Cholesterol Guideline. Available from: https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf

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SELECT SUPPORTING NON-STATIN LITERATURE SINCE 2013

- HPS2-THRIVE → Niacin
  - No clinical benefit and potential for significant harms, despite further lowering of LDL-C
- IMPROVE-IT → Ezetimibe
  - Resulted in incremental lowering of LDL-C and reduced CV-related primary composite endpoint
- FOURIER → Evolocumab
- ODYSSEY Outcomes → Alirocumab
- REDUCE-IT → Icosapent ethyl (Vascepa)

Landray MJ, et al. Effects of extended-release niacin with laropiprant in high-risk patients. N Engl J Med. 2014;371:203–12.
Cannon CP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372:2387–97.
Sabatine MS, et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. N Engl J Med. 2017 May 4;376(18):1713-1722.
Schwartz GG et al. Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome. N Engl J Med. 2018 Nov 29;379(22):2097-2107.
Bhatt DL et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med. 2019 Jan 3;380(1):11-22.

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2018 ACC/AHA MULTISOCIETY GUIDELINE ON THE MANAGEMENT OF BLOOD CHOLESTEROL

- Defines "very high-risk ASCVD" group
- Clarifies risk factors
  - "major risk factors" and "risk-enhancing factors"
- Introduces coronary artery calcium (CAC) testing
- Restores LDL-C "targets" for certain populations
- Incorporates statin + non-statin therapy recommendations
- Encourages risk discussions with patients

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"VERY HIGH-RISK" ASCVD

- History of multiple major ASCVD events
  - ACS within 12 months, MI, ischemic stroke, symptomatic PAD*

OR

- One major event with multiple "high-risk conditions"
  - Age ≥65 years, heterozygous familial hypercholesterolemia (HeFH), prior coronary revascularization outside of the major ASCVD events, diabetes, hypertension, chronic kidney disease with estimated glomerular filtration rate 15-59 ml/min/1.72 cm^2, current smoker, and LDL-C ≥100 mg/dl despite maximally tolerated statin therapy and ezetimibe, congestive heart failure

*Defined as claudication with ankle-brachial index [ABI] <0.85 or previous revascularization or amputation

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OTHER RISK FACTORS

- Major risk factors
  - Cigarette smoking, Elevated blood pressure, LDL-C, Hemoglobin A1c [if indicated], and Calculated 10-year risk of ASCVD
- Risk-enhancing factors
  - Family history of premature ASCVD, LDL-C persistently ≥ 160 mg/dL, Metabolic syndrome, Chronic kidney disease, History of preeclampsia or premature menopause, Chronic inflammatory disorders, High-risk ethnic groups, Triglycerides persistently ≥ 175 mg/dL, Apolipoprotein B ≥ 130 mg/dL, High-sensitivity C-reactive protein ≥ 2.0 mg/L, ABI < 0.9, Lipoprotein (a) ≥ 50 mg/dL

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CORONARY ARTERY CALCIUM (CAC) TESTING

- CAT scan that measures amount of calcium build up in arteries of the heart
- Assessment of score
  - 0: Statin therapy may be withheld or delayed (i.e., no statin)
    - Except in cigarette smokers, patients with diabetes, and those with a strong family history of premature ASCVD
  - 1-99: Favors statin, especially after age 55
  - ≥100 (or ≥ 75th percentile): Initiate statin
- Patient pay cost of $75-350

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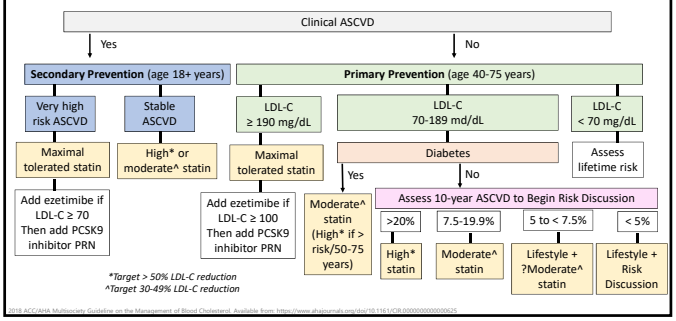
2018 ACC/AHA CHOLESTEROL GUIDELINE RECOMMENDATIONS



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CLINICAL ASCVD

- High intensity statin therapy (or maximally tolerated)
  - Target LDL-C reduction of ≥ 50%
- Moderate or high intensity statin therapy if > 75 years of age
  - Continuation of high intensity statin is reasonable
- If LDL-C remains ≥ 70 mg/dL → adding ezetimibe is reasonable
- Can be further classified as "stable" or very high risk" ASCVD

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VERY HIGH RISK

- High intensity or maximal tolerated statin
- If LDL-C remains ≥ 70 mg/dL → add ezetimibe first
- If LDL-C still remains ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL → adding PCSK9 inhibitor is reasonable
  - Long-term safety (>3 years) uncertain
  - Cost effectiveness is low at mid-2018 list prices

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SEVERE PRIMARY HYPERCHOLESTEROLEMIA (LDL > 190 MG/DL)

- High intensity or maximal tolerated statin
- If LDL-C remains ≥ 100 mg/dL → adding ezetimibe is reasonable
- If LDL-C remains ≥ 100 mg/dL + multiple risk factors → consider adding PCSK9 inhibitor

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DIABETES AND 40-75 YEARS OF AGE WITH LDL-C ≥ 70 MG/DL

- Moderate intensity statin therapy without calculating 10-year ASCVD risk
  - Target LDL-C reduction of 30-49%

OR

- High intensity statin therapy if higher risk (i.e., multiple risk factors or 50-75 years of age)
  - Diabetes-specific risk enhancers
    - Long duration (≥ 10 years for Type 2), albuminuria, eGFR < 60, retinopathy, neuropathy, ABI < 0.9
  - Target LDL-C reduction of ≥ 50%

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PRIMARY PREVENTION IN THOSE 40-75 YEARS OF AGE

- Clinician-patient risk discussion before starting statin therapy
  - Major risk factors & risk-enhancing factors → 10-year risk calculation
  - Benefits of lifestyle and stain therapies
  - Potential for adverse effects & drug-drug interactions
  - Cost considerations
  - Patient preferences & values in shared-decision making
- If risk status/decision is uncertain, consider measuring CAC in those with LDL-C ≥ 70 mg/dL and 10-year ASCVD risk 7.5-19.9%

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PRIMARY PREVENTION IN THOSE 40-75 YEARS OF AGE

- High Risk
  - High intensity statin therapy
    - Target LDL-C reduction of ≥ 50%
- Intermediate risk (10-year ASCVD risk 7.5-19.9%)
  - Moderate intensity statin therapy if LDL-C 70-189 mg/dL and discussion of treatment options favors statin therapy
    - Target LDL-C reduction of ≥ 30%
- Borderline risk (10-year ASCVD risk of 5 to < 7.5%):
  - Risk-enhancing factors may favor statin therapy in patients at

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SPECIAL POPULATIONS

- Very elderly
  - Moderate intensity statin therapy recommended, as indicated
- Hypertriglyceridemia
  - Treat when > 500 mg/dL to avoid pancreatitis
  - Fibrates, omega-3 fatty acids, niacin
- People living with HIV/AIDS
  - Drug interactions (e.g., protease inhibitors)
- Pregnancy
  - Discontinue statin 1-2 months prior or immediately (Category X)
  - Bile acid sequestrants & omega-3 fatty acids (Category B)
- Ethnicity Issues

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PATIENT CASE 1

- A 56 year old Caucasian female presents to clinic with the following past medical history and labs. She is not on any medications. What therapy would you recommend?
  - Clinical ASCVD – no
  - Diabetes – no
  - LDL – 202 mg/dL

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PATIENT CASE 2

- A 70 year old African American male presents to clinic with the following past medical history and labs. He is on rosuvastatin 40 mg PO daily. What therapy modification would you recommend?
  - Clinical ASCVD – yes
  - Diabetes – yes
  - Hypertension – yes
  - Smoker – yes
  - LDL – 120 mg/dL

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PATIENT CASE 3

- A 35 year old Asian male presents to clinic with the following medication history and labs. He is on simvastatin 40 mg PO QHS. What therapy modification would you recommend?
  - ASCVD – MI 3 years ago
  - Diabetes – no
  - LDL (last visit 3 months ago) – 168 mg/dL
  - LDL (today) – 100 mg/dL

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MONITORING

- Assess adherence and percentage response to LDL-C lowering medications & lifestyle changes
  - Compare to baseline level
- Lipid panel
  - 4-12 weeks after statin initiation or dose adjustment
  - Repeat every 3-12 months as needed
- Identify/manage adverse events and/or statin intolerance

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STATIN INTOLERANCE

- Muscle-related symptoms most common within first 2 weeks
  - Myalgias 1-10% incidence, rhabdomyolysis (CK > 10x ULN) rare
- Systematic, multifaceted approach
  - **Statin-Associated Muscle Symptom Clinical Index (SAMA-CI)**
  - Temporary discontinuation of statin therapy
  - Lower dosing
  - Re-challenge with 2-3 statins of differing metabolic pathways/lipophilicity
  - Intermittent (1-3x weekly) dosing of long half-life statins
- Referral to a lipid specialist

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SUMMARY

- Dyslipidemia is a prevalent and relevant condition today
- 2018 ACC/AHA Multisociety Guideline on the Management of Blood Cholesterol offers guidance on therapies for LDL-C lowering in the management of ASCVD risk
  - Pooled cohort equations for estimating cardiovascular risk
  - Identification of "very high risk" patient group
  - Statin therapy remains first-line for ASCVD risk reduction
  - Consider LDL-C targets for initiation of non-statin therapy
    - Ezetimibe preferred over PCSK9 inhibitors
  - Closely monitor patients for efficacy and tolerability of therapy
- Patient education and shared decision making are key!

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QUESTIONS?

For the Love of Lipids: Cholesterol Management to Reduce the Risk of Atherosclerotic Cardiovascular Disease

Maria Miller Thurston, Pharm.D., BCPS

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