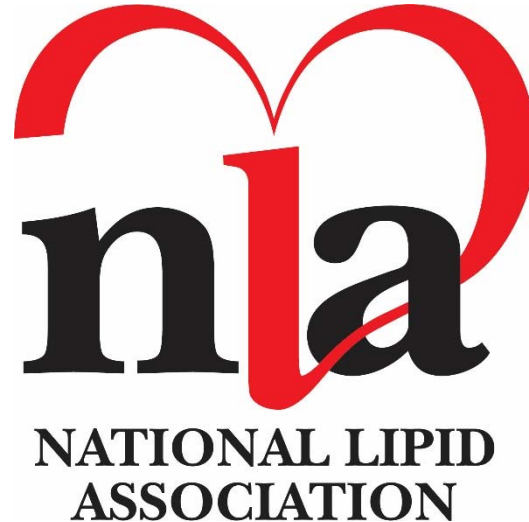


NLA Recommendations for Patient-Centered Management of Dyslipidemia

Part 2

Disclosures – Kevin C Maki, PhD

| AFFILIATION/FINANCIAL INTERESTS <i>(past 12 months)</i> | ORGANIZATION |
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NLA Expert Panel Steering Committee

Terry A. Jacobson, MD (Chair)
Kevin C. Maki, PhD
Carl E. Orringer, MD
Peter H. Jones, MD

**On Behalf of the NLA Part 2
Recommendations Expert Panel Working Group**

NLA Expert Panel Working Group*

Judith Aberg, MD

Harold Bays, MD

Piers Blackett, MD

Julie Bolick, MS, RDN

Lynne Braun, PhD, CNP

W. Virgil Brown, MD

Jonathon S. Coblyn, MD

Jeffrey Curtis, MD, MS, MPH

Stephen Daniels, MD, PhD

Martha Daviglius, MD, PhD

Thomas Dayspring, MD

Prakash Deedwania, MD

Sarah DeFerranti, MD

Carl J. Fichtenbaum, MD

Mary R. Dicklin, PhD

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Catherine McNeal, MD, PhD

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Samuel Gidding, MD

Scott Grundy, MD, PhD

Michael A. Horberg, MD

Matthew Ito, PharmD

Carol Kirkpatrick, PhD, RDN

Penny Kris-Etherton, PhD, RDN

Ralph La Forge, MSc

Rae-Ellen W. Kavey, MD, MPH

Katherine Liao, MD, MPH

Christopher T. Longenecker, MD

J. Antonio G. Lopez, MD

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Joyce Ross, MSN, CRNP

Geeta Sikand, MA, RDN

Nancy T. Smith, MS, RDN

Daniel Solomon, MD, MPH

James A. Underberg, MS, MD

Elaine Urbina, MD

Kris Vijay, MD

Robert Wild, MD, MPH, PhD

Don Wilson, MD

*Listed in alphabetical order.

NLA Expert Panel Section Chairs

Nutrition

Penny Kris-Etherton, PhD, RD
Geeta Sikand, MA, RDN, CLS
Kevin C. Maki, PhD, CLS

Exercise/Physical Activity

Ralph LaForge, MSc
Kevin C. Maki, PhD, CLS

Children and Adolescents

Don Wilson, MD
Stephen Daniels, MD, PhD

Women's Health

Pamela Morris, MD

From Pregnancy to Menopause

Robert Wild, MD, MPH, PhD,
NCMP

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Carl Orringer, MD
Scott Grundy, MD, PhD

Hispanics/Latinos

Martha Daviglius, MD, PhD

African Americans

Keith Ferdinand, MD

South Asians

Kris Vijay, MD
Prakash Deedwania, MD

American Indians/ Alaska Natives

Kevin C. Maki, PhD
Ralph La Forge, MSc

Patients Infected with HIV

Judith Aberg, MD

Patients with Rheumatoid Arthritis

Katherine Liao, MD, MPH

Patients with Residual Risk Despite Statin and Lifestyle Therapy

Peter Jones, MD
James McKenney, PharmD

Patient Adherence

Joyce Ross, MSN, CRNP
Lynne Braun, PhD, CNP

Team-Based Collaborative Care

Lynne Braun, PhD, CNP
Matthew Ito, PharmD
Joyce Ross, MSN, CRNP

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National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 2

Terry A. Jacobson, MD, FNLA, Chair, Kevin C. Maki, PhD, CLS, FNLA, Carl Orringer, MD, FNLA, Peter Jones, MD, FNLA, Penny Kris-Etherton, PhD, RDN, CLS, FNLA, Geeta Sikand, MA, RDN, CLS, FNLA, Ralph La Forge, MSc, FNLA, Stephen Daniels, MD, PhD, FNLA, Don Wilson, MD, FNLA, Pamela Morris, MD, FNLA, Robert Wild, MD, MPH, PhD, FNLA, NCMP, Scott Grundy, MD, PhD, Martha Daviglius, MD, PhD, Keith Ferdinand, MD, FNLA, Kris Vijay, MD, FNLA, Prakash Deedwania, MD, Judith Aberg, MD, Katherine Liao, MD, MPH, James McKenney, PharmD, FNLA, Joyce Ross, MSN, CRNP, FNLA, Lynne Braun, PhD, CNP, FNLA, Matthew Ito, Pharm D, FNLA, Julie Bolick, MS, RDN, CLS, FNLA, Mary R. Dicklin, PhD, Carol Kirkpatrick, PhD, RDN, CLS, FNLA, Katherine Rhodes, PhD, RDN, Nancy T. Smith, MS, RDN, CDE, CLS, Piers Blackett, MD, FNLA, Sarah DeFerranti, MD, Samuel Gidding, MD, FNLA, Rae-Ellen W. Kavey, MD, MPH, Brian McCrindle, MD, Catherine McNeal, MD, PhD, FNLA, Elaine Urbina, MD, Thomas Dayspring, MD, FNLA, NCMP, James A. Underberg, MS, MD, FNLA, J. Antonio G. Lopez, MD, FNLA, Amber Pirzada, MD, Carlos Jose Rodriguez, MD, MPH, FACC, Carl J. Fichtenbaum, MD, Joel E. Gallant, MD, Michael A. Horberg, MD, Christopher T. Longenecker, MD, Merle Myerson, MD, FNLA, E. Turner Overton, MD, Jonathon S. Coblyn, MD, Jeffrey Curtis, MD, MS, MPH, Jorge Plutzky, MD, FNLA, Daniel Solomon, MD, MPH, Harold Bays, MD, FNLA, W. Virgil Brown, MD, FNLA



Major Categories of the NLA Part 2 Recommendations

Lifestyle Therapies

- Nutrition
- Exercise/Physical Activity

Groups with Special Considerations

Improving Patient Outcomes

- Patient Adherence
- Team-based Collaborative Care

Groups with Special Considerations

The Lifespan - Children to Seniors

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African Americans

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Major Categories of the NLA Part 2 Recommendations

- Lifestyle Therapies
 - Nutrition
 - Exercise/Physical Activity
- Groups with Special Considerations
- Improving Patient Outcomes
 - Patient Adherence
 - Team-based Collaborative Care

Lifestyle Therapies: Nutrition

- The National Lipid Association (NLA) Expert Panel supports a cardioprotective eating pattern for the management of dyslipidemia and overall cardiovascular health that includes **<7% of energy from saturated fat, with minimal intake of *trans* fatty acids** to lower levels of atherogenic cholesterol (low-density lipoprotein cholesterol [LDL-C] and non-high-density lipoprotein cholesterol [non-HDL-C]).
- The cardioprotective eating pattern should **limit cholesterol intake to <200 mg/day** to lower levels of atherogenic cholesterol (LDL-C and non-HDL-C).
- There are individuals who are hyper-responders to dietary cholesterol because of genetic or other reasons. For known or suspected hyper-responders, further reduction in dietary cholesterol beyond the <200 mg/day that is recommended as part of the cardioprotective eating pattern for the management of dyslipidemia may be considered. Consumption of very low intakes of dietary cholesterol (near 0 mg/day) may be helpful for such individuals.

Lifestyle Therapies: Nutrition

- The NLA Expert Panel recommends any of the following **healthy dietary patterns, including an emphasis on a variety of plant foods and lean sources of protein for managing dyslipidemia: Dietary Approaches to Stop Hypertension (DASH), United States Department of Agriculture (USDA) (healthy U.S.-style), American Heart Association (AHA), Mediterranean-style, and vegetarian/vegan.** However, the dietary pattern should be individualized based on the patient's specific dyslipidemia. Also, patients' cultural and food preferences are important for guiding food selection to maximize dietary adherence. Nutritional counseling and follow-up/monitoring by a registered dietitian nutritionist is recommended whenever possible to individualize a patient's dietary pattern. Nutrition therapy should be included in those with other medical conditions, including diabetes.
- **If alcohol is consumed as part of a healthy dietary pattern, this should be in moderation** (≤ 7 drinks per week for women and ≤ 14 drinks per week for men; consumed in a non-binge pattern). One drink is equivalent to 12 oz. beer, 5 oz. wine, or 1.5 oz. distilled spirits.

Lifestyle Therapies: Nutrition

- **Dietary saturated fat may be partially replaced with unsaturated fats** (mono- and polyunsaturated fats), as well as proteins, to reach a goal of <7% of energy from saturated fats. This can be achieved, in part, by incorporating foods high in unsaturated fats, such as liquid vegetable oils and vegetable oil spreads, nuts and seeds, as well as lean protein foods, such as legumes, seafood, lean meats, and non- or low-fat dairy products, into the diet as replacements for foods high in saturated fats.
- **Weight loss of 5-10% body weight is generally recommended for overweight or obese** individuals to lower atherogenic lipoprotein lipids and improve other atherosclerotic cardiovascular disease (ASCVD) risk factors. A variety of dietary approaches can be implemented for weight loss. Any dietary approach will result in weight loss if energy intake is reduced. An energy-reduced healthy dietary pattern that meets nutrient needs is recommended for patients who are overweight or obese. Several healthy dietary patterns, such as the Mediterranean-style, DASH, USDA, and vegetarian diets, can be tailored to personal and cultural food preferences and appropriate calorie needs for weight control.

Lifestyle Therapies: Nutrition

- Eating patterns that contain a moderate quantity of carbohydrate, lower glycemic index and load, and higher protein, have been associated with modest benefits for weight loss and maintenance.
- **Plant sterols and stanols (~2 g/day) are recommended for cholesterol lowering, as well as viscous fibers (5 to 10 g/day or even greater, if acceptable to the patient), as adjuncts to other lifestyle changes.** However, individuals with phytosterolemia (sitosterolemia) should avoid foods that are fortified with stanols and sterols.
- **For patients with triglyceride (TG) levels ≥ 150 mg/dL, lifestyle therapy is indicated, including weight loss, if overweight or obese, physical activity, and restriction of alcohol, and sugars and refined starches. Partial replacement of sugars and refined starches with a combination of unsaturated fats, proteins, and high-fiber foods may help to reduce TG and non-HDL-C concentrations.**

Lifestyle Therapies: Nutrition

- **For patients with TG levels ≥ 1000 mg/dL (and selected patients with TG 500-999 mg/dL), a low-fat diet (<15% of energy) and alcohol abstinence are recommended initially to minimize chylomicronemia.** In patients with hypertriglyceridemia and diabetes, dietary carbohydrate should not be substantially increased to avoid worsening glycemia when reducing fat intake. Medium-chain TG oil may be used as a source of energy that will not induce chylomicron production. For patients without lipoprotein lipase deficiency, dietary fat may be liberalized with monitoring of the TG response once the TG concentration is <500 mg/dL.
- **Therapeutic dosages of eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) for TG reduction are 2.0 to 4.0 g/day. Use of these dosages of long-chain omega-3 fatty acids for TG-lowering should be done only under the supervision of a qualified clinician.** Clinicians are encouraged to educate patients on the importance of the amount of EPA + DHA in each capsule of dietary supplement or prescription products, and to take the appropriate number of capsules daily to achieve therapeutic levels. At present, prescription forms of EPA and EPA + DHA concentrates are only indicated for treatment of very high TG (≥ 500 mg/dL) to reduce the risk of pancreatitis.

Lifestyle Therapies: Nutrition

- For primary and secondary prevention of ASCVD, consuming ≥ 2 servings/week of fish/seafood (preferably oily) is recommended. One serving is equal to 3.5 to 4 oz. and should ideally not be prepared using deep-frying.
- For patients with known ASCVD, suggestive, but not conclusive, evidence from randomized controlled trials is available for a benefit of long-chain omega-3 fatty acid supplementation at ~ 1 g/day EPA + DHA on cardiac mortality, but not non-fatal ASCVD events. EPA + DHA supplements may be considered for such patients, especially those who do not consume the recommended intakes of EPA + DHA from dietary sources.
- For patients with heart failure, 1 g/day of EPA + DHA is recommended as an adjunct to heart failure therapy.
- An alpha-linolenic acid intake of 0.6 to 1.2% of energy is recommended.

Lifestyle Therapies: Nutrition

- **Consumption of at least three 1-oz. equivalent servings per day of fiber-rich whole grains is recommended.**
- **Consumption of ≥ 4 servings/week (1 oz. per serving) of nuts (including the legume, peanuts) is recommended**, because nut consumption has been consistently associated with reduced ASCVD risk. Nuts may be included in the diet as a protein food and as a source of healthy fat (predominantly unsaturated fatty acids).
- **Soy protein foods are one source of plant protein, among others (e.g., nuts, legumes), that may be used as a substitute for protein foods high in saturated fat as part of a cardioprotective eating pattern.**

Lifestyle Therapies: Nutrition

- **Nutrition education/medical nutrition therapy (MNT) by a registered dietitian nutritionist with follow-up and monitoring are recommended to promote long-term dietary adherence.** Clinicians should, when feasible, refer patients to a registered dietitian nutritionist for MNT to individualize a cardioprotective dietary pattern and promote successful lifestyle modifications.

Key References – Lifestyle Therapies: Nutrition

- 2015 Dietary Guidelines Advisory Committee, Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Scientific Report of the 2015 Dietary Guidelines Advisory Committee
<http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>
- Eckel RH, et al. 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk *J Am Coll Cardiol*. 2013:S0735-S1097.
- Griffin JD, Lichtenstein AH. Dietary Cholesterol and Plasma Lipoprotein Profiles: Randomized-Controlled Trials *Curr Nutr Rep*. 2013;2:274-282.

Major Categories of the NLA Part 2 Recommendations

- Lifestyle Therapies
 - Nutrition
 - **Exercise/Physical Activity**
- Groups with Special Considerations
- Improving Patient Outcomes
 - Patient Adherence
 - Team-based Collaborative Care

Lifestyle Therapies: Exercise/Physical Activity

- The recommended minimal quantity of exercise for supporting cardiovascular health and improving the lipid profile (lowering TG and sometimes raising HDL-C) is **150 min per week of moderate to higher intensity aerobic activity**. This level of physical activity is consistent with public health recommendations.
- To enhance the effects on TG and HDL-C, and produce reductions in LDL-C, as well as loss of body fat and weight, **≥2000 kcal per week of energy expenditure (generally 200 to 300 min per week)** of moderate or higher intensity physical activity is recommended.
- **Resistance exercise is also recommended to play a supportive role in maintaining strength, balance, and bone density.**

Key References – Lifestyle Therapies: Exercise/Physical Therapy

- Gordon D, et al. The Effects of Exercise Training on the Traditional Lipid Profile and Beyond *Curr Sports Med Rep.* 2014;13:253-259.
- Haskell WL, et al. Physical Activity and Public Health: Updated Recommendation for Adults from the American College of Sports Medicine and the American Heart Association *Med Sci Sports Exerc.* 2007;39:1423-1434.
- Mann S, et al. Differential Effects of Aerobic Exercise, Resistance Training and Combined Exercise Modalities on Cholesterol and the Lipid Profile: Review, Synthesis and Recommendations *Sports Med.* 2014;44:211-221.
- American College of Sports Medicine. *Guidelines for Exercise Testing and Prescription*, 9th Edition. 2013.
- Eckel RH, et al. 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk *J Am Coll Cardiol.* 2013:S0735-S1097.

Groups with Special Considerations

The Lifespan - Children to Seniors

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

African Americans

Hispanics/Latinos

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Groups with Special Considerations: Children and Adolescents

- **Universal lipid screening of all children, regardless of general health or the presence or absence of ASCVD risk factors, is recommended between 9-11 years of age, with repeat lipid screening at 20 years of age, or earlier if dyslipidemia is present.**
- **If a child or adolescent patient is screened and has a fasting or non-fasting non-HDL-C level ≥ 145 mg/dL, then additional follow-up is recommended.** Two fasting lipid profiles should be obtained and the results averaged for evaluation of the most appropriate course of action.

Groups with Special Considerations: Children and Adolescents

- Children at least 2 years of age with the following characteristics should be screened for dyslipidemia:
 - One or both biological parents are known to have hypercholesterolemia, or are receiving lipid-lowering medications
 - Have a family history of premature ASCVD in an expanded first degree pedigree (i.e., to include not only parents and siblings, but also aunts, uncles, and grandparents) in men <55 or women <65 years of age
 - Consideration should also be given to screening for those in whom family history is unknown (e.g., adopted)
- Children should be regularly screened for major risk factors and conditions associated with increased ASCVD risk, but there are no validated methods for risk scoring in patients <20 years of age.

Groups with Special Considerations: Children and Adolescents

- Decisions on target levels during treatment are a matter of clinical judgment, but age-appropriate, percentile-based cutpoints from the 2011 Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: **National Heart, Lung, and Blood Institute should be considered as the *upper limits* for therapeutic atherogenic cholesterol goal ranges for managing children and adolescents:**
 - **Non-HDL-C: 144 mg/dL**
 - **LDL-C: 129 mg/dL**
- **Cascade screening and reverse cascade screening are recommended to enhance detection of individuals at risk for familial hypercholesterolemia (FH).**
- An alternate treatment goal for pediatric FH patients in whom it may not be possible to achieve an LDL-C level of 130 mg/dL, is a 50% reduction in LDL-C.

Groups with Special Considerations: Children and Adolescents

- Diet and other lifestyle interventions, including increased physical activity and weight management when overweight/obesity is present, are recommended for lowering elevated LDL-C, non-HDL-C, and TG in children and adolescents. Dietary management strategies should be guided by a registered dietitian nutritionist whenever feasible.
- Children ≥ 8 years of age are potential candidates for pharmacologic treatment for lipid lowering. The following treatment plans can be considered:
 - **Administer pharmacologic agents, primarily statins, when LDL-C level is ≥ 190 mg/dL and/or non-HDL-C is ≥ 220 mg/dL.**
 - Consider additional risk factors in addition to elevated LDL-C and/or non-HDL-C and follow the treatment algorithm from the 2011 Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: National Heart, Lung, and Blood Institute.

Groups with Special Considerations: Children and Adolescents

- **Statins and bile acid sequestrants are pharmacologic agents with evidence for efficacy and safety in children and adolescents. There is limited evidence on the safety and efficacy of cholesterol absorption inhibitors in children and adolescents.**
- Consideration should be given to measurement of pretreatment fasting glucose or glycated hemoglobin levels, liver enzymes, and creatine kinase in pediatric patients for whom a statin is prescribed.
- Potential side effects with lipid-altering pharmacotherapy should be monitored in pediatric patients according to the recommendations from the respective 2014 NLA statin safety task force.

Background – Groups with Special Considerations: Children and Adolescents

TABLE 9-1 Acceptable, Borderline-High, and High Plasma Lipid, Lipoprotein, and Apolipoprotein Concentrations for Children and Adolescents

| Category | Low, mg/dL ^a | Acceptable, mg/dL | Borderline-High, mg/dL | High, mg/dL ^a |
|---------------------|-------------------------|-------------------|------------------------|--------------------------|
| TC | — | <170 | 170–199 | ≥200 |
| LDL cholesterol | — | <110 | 110–129 | ≥130 |
| Non-HDL cholesterol | — | <120 | 120–144 | ≥145 |
| Apolipoprotein B | — | <90 | 90–109 | ≥110 |
| Triglycerides | | | | |
| 0–9 y | — | <75 | 75–99 | ≥100 |
| 10–19 y | — | <90 | 90–129 | ≥130 |
| HDL cholesterol | <40 | >45 | 40–45 | — |
| Apolipoprotein A-1 | <115 | >120 | 115–120 | — |

Values for plasma lipid and lipoprotein levels are from the NCEP Expert Panel on Cholesterol Levels in Children. Non-HDL cholesterol values from the Bogalusa Heart Study are equivalent to the NCEP Pediatric Panel cut points for LDL cholesterol. Values for plasma apolipoprotein B and apolipoprotein A-1 are from the National Health and Nutrition Examination Survey III. Note that values shown are in mg/dL; to convert to SI units, divide the results for TC, LDL cholesterol, HDL cholesterol, and non-HDL cholesterol by 38.6; for triglycerides, divide by 88.6.

^a Low cut points for HDL cholesterol and apolipoprotein A-1 represent approximately the 10th percentile. The cut points for high and borderline-high represent approximately the 95th and 75th percentiles, respectively.

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. *Pediatrics*. 2011;128:S213-S256.

Background – Groups with Special Considerations: Children and Adolescents

TABLE 9-2 Recommended Cut Points for Lipid and Lipoprotein Levels in Young Adults

| Category | Low, mg/dL | Borderline-Low, mg/dL | Acceptable, mg/dL | Borderline-High, mg/dL | High, mg/dL |
|---------------------|------------|-----------------------|-------------------|------------------------|-------------|
| TC | — | — | <190 | 190–224 | ≥225 |
| LDL cholesterol | — | — | <120 | 120–159 | ≥160 |
| Non-HDL cholesterol | — | — | <150 | 150–189 | ≥190 |
| Triglycerides | — | — | <115 | 115–149 | ≥150 |
| HDL cholesterol | <40 | 40–44 | >45 | — | — |

Values provided are from the Lipid Research Clinics Prevalence Study. The cut points for TC, LDL cholesterol, and non-HDL cholesterol represent the 95th percentile for 20- to 24-year-old subjects and are not identical with the cut points used in the most recent NHLBI adult guidelines, Adult Treatment Panel III (“Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults”), which are derived from combined data on adults of all ages. The age-specific cut points given here are provided for pediatric care providers to use in managing this young adult age group. For TC, LDL cholesterol, and non-HDL cholesterol, borderline-high values are between the 75th and 94th percentiles, whereas acceptable values are at the <75th percentile. The high triglyceride cut point represents approximately the 90th percentile; borderline-high values are between the 75th and 89th percentiles, and acceptable values are at the <75th percentile. The low HDL cholesterol cut point represents approximately the 25th percentile; borderline-low values are between the 26th and 50th percentiles, and acceptable values are at the >50th percentile.

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. *Pediatrics*. 2011;128:S213-S256.

Background – Groups with Special Considerations: Children and Adolescents

Major Risk Factors and Conditions in Children and Adolescents

| Criteria | Moderate Risk | High Risk |
|---------------------------------|--|--|
| Body mass index | ≥95 th percentile – 96 th percentile | ≥97 th percentile |
| Hypertension | High blood pressure without medication | High blood pressure with medication |
| Cigarette smoking | -- | Current smoker |
| HDL-C | <40 mg/dL | -- |
| Predisposing medical conditions | Kawasaki disease with regressed coronary aneurysms Chronic inflammatory disease* HIV infection Nephrotic syndrome | Kawasaki disease with current coronary aneurysms Type 1 and 2 diabetes mellitus Post-orthotopic heart transplant Chronic kidney disease/end stage renal disease/post-renal transplant |

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. *Pediatrics*. 2011;128:S213-S256.

Background – Groups with Special Considerations: Children and Adolescents

International Diabetes Federation’s definition of the at risk group and metabolic syndrome in children and adolescents

| Age group (years) | Obesity (WC) | Triglycerides | HDL-C | Blood pressure | Glucose |
|---------------------|--|---|--|--|---|
| 6–<10† 10–<16 | ≥90 th percentile ≥90 th percentile or adult cut-off if lower | ≥1.7 mmol/L (≥150 mg/dL) | <1.03 mmol/L (<40 mg/dL) | Systolic BP ≥130 or diastolic BP ≥85 mm Hg | FPG ≥5.6 mmol/L (100 mg/dL)** or known T2DM |
| 16+(Adult criteria) | WC ≥ 94cm for Europid males and ≥ 80cm for Europid females, with ethnic-specific values for other groups*) | ≥1.7 mmol/L (≥150 mg/dL) or specific treatment for high triglycerides | <1.03mmol/L (<40 mg/dL) in males and <1.29mmol/L (<50 mg/dL) in females, or specific treatment for low HDL | Systolic BP ≥130 or diastolic BP ≥85 mm Hg or treatment of previously diagnosed hypertension | FPG ≥5.6 mmol/L (100 mg/dL)** or known T2DM |

BP: blood pressure; HDL-C, high-density lipoprotein cholesterol; FPG, fasting plasma glucose; IDF, International Diabetes Federation; T2DM, type 2 diabetes mellitus; WC, waist circumference.

*For those of South and South-East Asian, Japanese, and ethnic South and Central American origin, the cutoffs should be ≥90 cm for men, and ≥80 cm for women. The IDF Consensus group recognise that there are ethnic, gender and age differences but research is still needed on outcomes to establish risk.

†Metabolic syndrome cannot be diagnosed, but further measurements should be made if there is a family history of metabolic syndrome, T2DM, dyslipidemia, cardiovascular disease, hypertension and/or obesity.

**For clinical purposes, but not for diagnosing the Mets, if FPG 5.6-6.9 mmol/L (100-125 mg/dl) and not known to have diabetes, an oral glucose tolerance test should be performed.

Diagnosing the metabolic syndrome requires the presence of central obesity plus any two of the other four factors.

Zimmet P, et al. The Metabolic Syndrome in Children and Adolescents - an IDF Consensus Report. *Pediatr Diabetes*. 2007;8:299-306.

Groups with Special Considerations

Throughout the Lifespan

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African Americans

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Groups with Special Considerations: Women's Health

- In general, women should be treated according to the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with the following special considerations.
- **First-line cholesterol-lowering drug therapy, unless contraindicated, is moderate- to high-intensity statin.** The statin dosage may be increased or the patient switched to a more efficacious agent, if goal levels of atherogenic cholesterol are not achieved. Statin therapy should be a consideration for patients at very high risk (i.e., ASCVD or diabetes mellitus with ≥ 2 major ASCVD risk factors), even if the pre-treatment levels of atherogenic cholesterol are below the treatment goals.

Groups with Special Considerations: Women's Health

- Non-statin drug therapy with cholesterol absorption inhibitor, bile acid sequestrant, fibric acid, nicotinic acid, or long-chain omega-3 fatty acid concentrates (the latter currently indicated only for very high TG) may be considered for women with contraindications for, or intolerance to, statin therapy, or in combination with statin therapy for patients who need additional lowering of atherogenic cholesterol to achieve treatment goals.
- **Women taking statins may be at increased risk for certain adverse events, particularly myalgia.** Variations between men and women observed in clinical studies of statin-related myalgia incidence may have been related to differences in age, comorbidities, body composition, and polypharmacy.

Background – Groups with Special Considerations: Women’s Health

Meta-analysis of benefits of statin on ASCVD in primary and secondary prevention in men and women

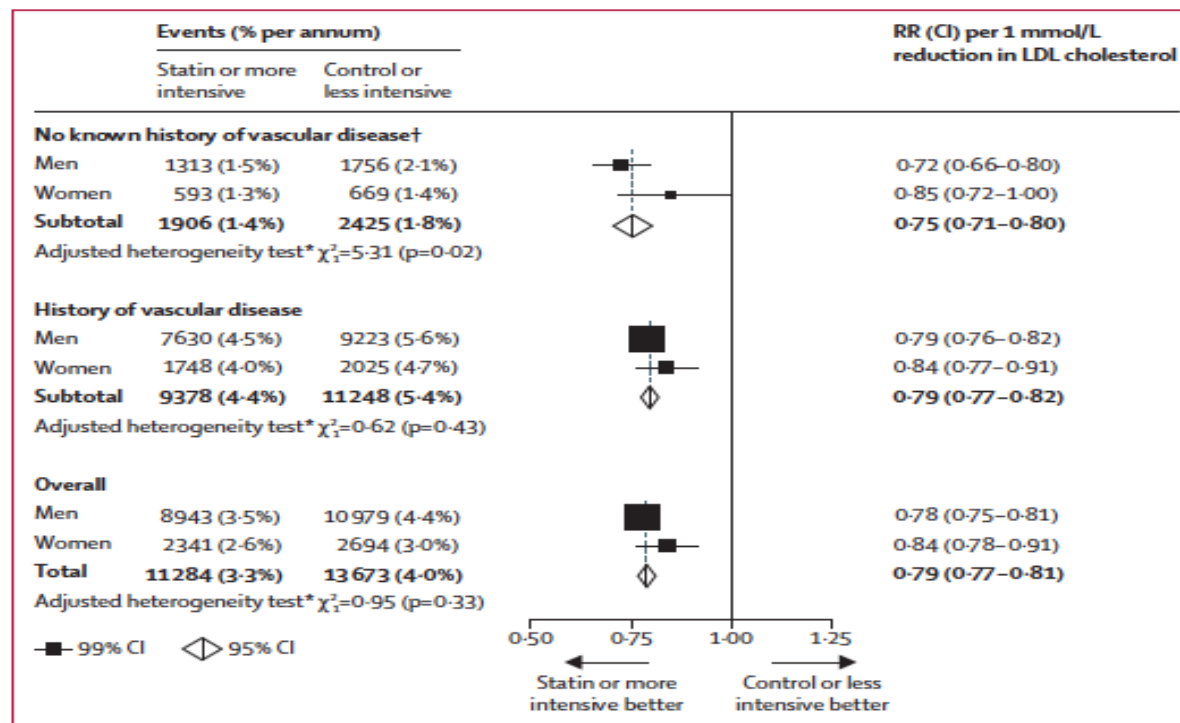


Figure 1: Effects on major vascular events per 1.0 mmol/L reduction in LDL cholesterol, subdivided by history of vascular disease and sex
 RR=rate ratio. *Adjusted heterogeneity test calculated from a Cox model that corrects for non-sex differences between women and men (appendix pp 12–14). †Results for men with no known history of vascular disease included 189 versus 264 first major vascular events from participants recruited into WOSCOPS in which information on previous stroke was not available.

Cholesterol Treatment Trialists’ (CTT) Collaboration, et al. Efficacy and Safety of LDL-lowering Therapy Among Men and Women: Meta-analysis of Individual Data from 174,000 Participants in 27 Randomised Trials *Lancet*. 2015;385:1397-1405. 35

Background – Groups with Special Considerations: Women’s Health

Meta-analysis of statin therapy in primary prevention according to level of risk in women

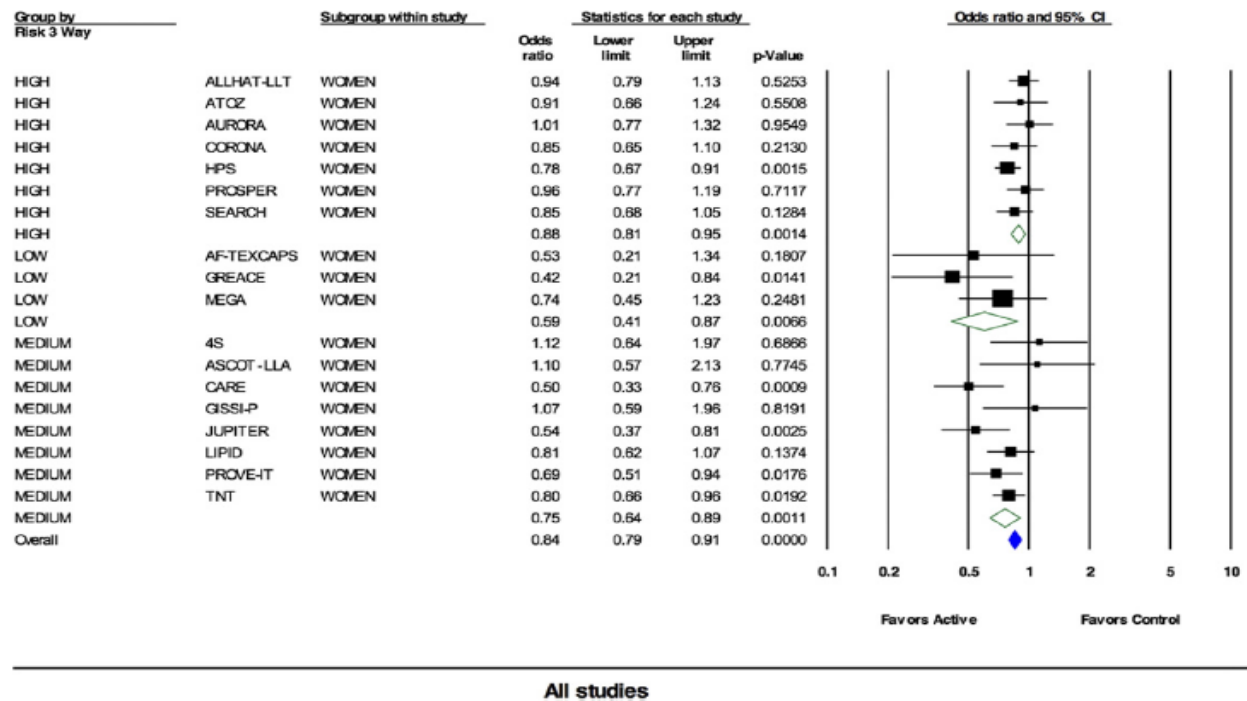


Figure 2 Forest Plot for the Primary Event by Level of Risk of Participants In Each Study In Women

Solid squares represent the odds ratios in individual trials and have a size proportional to the inverse of the variance. Horizontal lines, diamonds, and squares denote the 95% confidence intervals (CIs) for individual trials and summary statistics. Pooled estimates were computed from a random effects model. Trial acronyms as in Table 1.

Groups with Special Considerations

Throughout the Lifespan

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African Americans

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Groups with Special Considerations: From Pregnancy to Menopause

- **Women should be screened for dyslipidemia before pregnancy or as part of the routine obstetrical laboratory examination.**
- **For women taking lipid-lowering medications prior to pregnancy, all, except bile acid sequestrants, should be stopped when the woman becomes pregnant, or is trying to become pregnant.**
- **Women should be educated on the importance of pregnancy avoidance when lipid-altering therapies other than bile acid sequestrants are used.**
- **Total cholesterol and TG levels in women with normal pregnancies should not exceed 250 mg/dL.** If they do, the clinician should consider and evaluate preexisting or acquired medical or obstetrical conditions, including hypothyroidism, chronic kidney disease, liver disease, uncontrolled diabetes mellitus, or preeclampsia.

Groups with Special Considerations: From Pregnancy to Menopause

- **Hypercholesterolemia during pregnancy and breast feeding, especially in women with FH, may be treated with bile acid sequestrants.**
- **Women with FH may be treated with LDL apheresis during pregnancy and breast feeding.**
- Very high TG (≥ 500 mg/dL) may be treated during pregnancy with diet/lifestyle management plus prescription omega-3 fatty acids; fenofibrate or gemfibrozil may be administered beginning early in the second trimester, based on clinical judgment. These agents may be used during breast feeding.

Groups with Special Considerations: From Pregnancy to Menopause

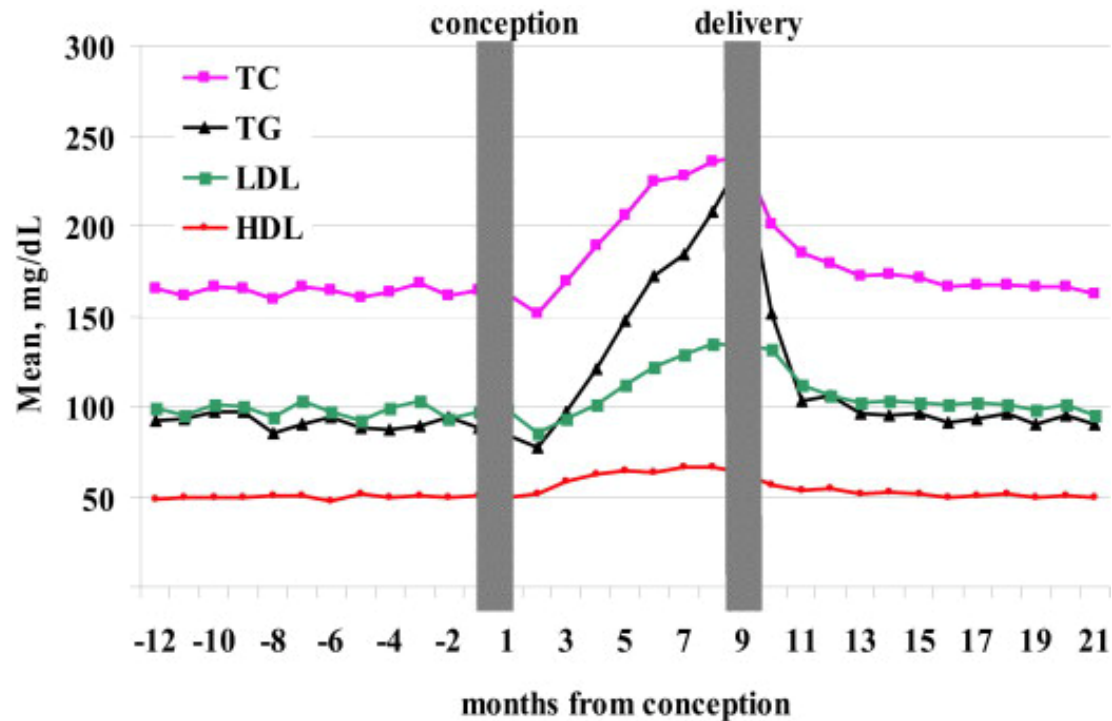
- **Polycystic ovarian syndrome (PCOS) is a high-risk condition for dyslipidemia, metabolic syndrome, and obstetrical complications of preeclampsia, hypertension, diabetes, and premature delivery.** All patients with PCOS, regardless of age, should undergo initial lipid and diabetes screening and more frequent follow-up screening is recommended, even if initial values are normal.
- The approach to risk stratification and atherogenic cholesterol treatment goals for women with PCOS should be the same as described for all patients with dyslipidemia in the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015).
- Therapeutic management of dyslipidemia in PCOS should focus on diet, exercise, and lipid-lowering medication, if needed. Use of metformin should also be considered to lower TG and reduce insulin resistance.

Groups with Special Considerations: From Pregnancy to Menopause

- **Contraceptive choice impacts dyslipidemia.** Combined oral contraceptives should generally not be used by women ≥ 35 years of age who smoke because of additive stroke and myocardial infarction (MI) risk.
- Sex hormone therapy (HT) should not be used for prevention or treatment of ASCVD.
- Sex HT is an option for treatment of significant symptoms during the menopause transition for women at minimal risk for ASCVD.

Background – Groups with Special Considerations: From Pregnancy to Menopause

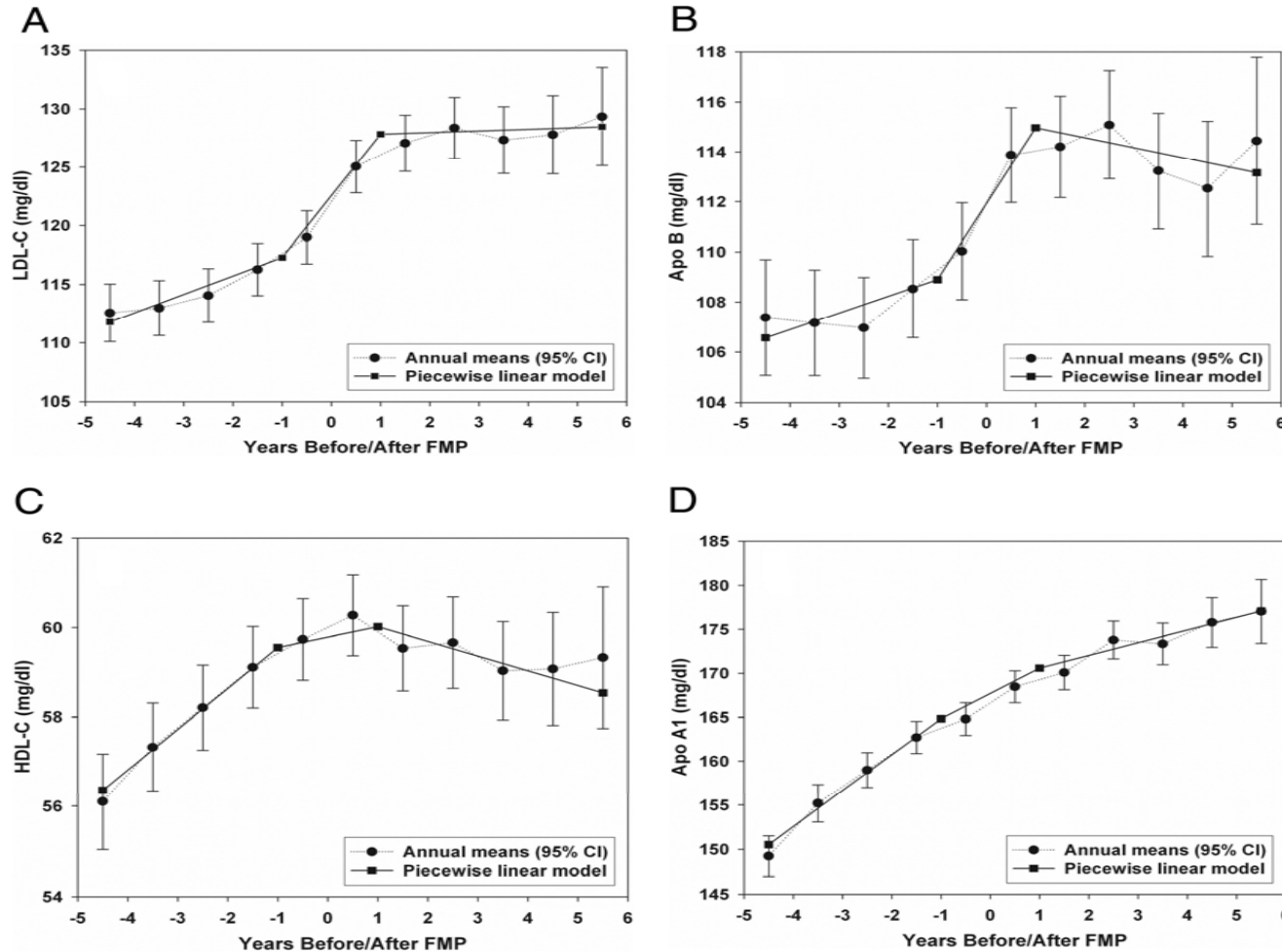
Lipid values in normal pregnancies



Wiznitzer A, et al. *Am J Obstet Gynecol.* 2009;201:482.e1-8.

Background – Groups with Special Considerations: From Pregnancy to Menopause

Women in menopausal transition in the Study of Women’s Health Across the Nation



Matthews KA, et al. Are Changes in Cardiovascular Disease Risk Factors in Midlife Women Due to Chronological Aging or to the Menopausal Transition? *J Am Coll Cardiol.* 2009;54:2366-2373.

Background – Groups with Special Considerations: From Pregnancy to Menopause

Lipid lowering agents and pregnancy categories*

| Lipid-lowering class or agent | Pregnancy category [†] |
|-------------------------------|---------------------------------|
| Statins | X |
| Fibrates | C |
| Ezetimibe | C |
| Niacin | C |
| Cholestyramine | C |
| Omega-3 fatty acids | C |
| Colesevelam | B |
| Mipomersen | B |

*These categories were removed from drug labeling per the new FDA labeling guidance effective June 30, 2015, and instead drug labeling will include a summary of the risks of using a drug during pregnancy and lactation, discussion of data supporting that summary, and relevant information to assist health care providers in treatment decisions for pregnancy (8.1), lactation (8.2), and females and males of reproductive potential (U.S. FDA 2015).

[†]Categories previously established by the FDA to indicate the potential of a drug to cause birth defects if used during pregnancy: B (animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women), C (animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks), and X (studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits).

U.S. FDA. Pregnancy and lactation labeling final rule. 2015.

Kusters DM, et al. Statin Use During Pregnancy: a Systematic Review & Meta-analysis *Expert Rev Cardiovasc Ther.* 2012;10:363-378.

Wild RA, et al. A Consensus Statement by the Androgen Excess and Polycystic Ovary Syndrome Society *J Clin Endocrinol Metab.* 2010;95:2038-2049.

Groups with Special Considerations

Throughout the Lifespan

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African Americans

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Groups with Special Considerations: Older Adults

- Primary prevention strategies in patients 65-79 years of age should be managed in accordance with the NLA Recommendations for the Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015).
- **For patients age ≥ 65 to < 80 years of age with ASCVD or diabetes mellitus, moderate or high intensity statin therapy should be considered after a careful consideration of the risk-benefit ratio.**
- **For secondary prevention in patients ≥ 80 years of age, moderate intensity statin therapy should be considered based upon a provider-patient discussion of the risks and benefits of such therapy, consideration of drug-drug interactions, polypharmacy, concomitant medical conditions including frailty, cost considerations, and patient preference.**

Groups with Special Considerations: Older Adults

- Risk calculators such as the American College of Cardiology(ACC)/AHA Pooled Cohort Risk Calculator or the Adult Treatment Panel (ATP) III Framingham Risk Calculator can be used in select older individuals with one additional risk factor to further assess risk, using the thresholds for high risk of:
 - $\geq 15\%$ 10-year risk for a hard ASCVD event (MI, stroke, or death from coronary heart disease [CHD] or stroke) with the Pooled Cohort Equations; and
 - $\geq 10\%$ 10-year risk for a hard CHD event (MI or CHD death) using the ATP III Framingham Risk Calculator.

However, these risk calculators have several limitations for use in older patients, since advanced age is often the predominate driver of increased ASCVD risk, and this may result in overtreatment of lower risk older individuals.

Groups with Special Considerations: Older Adults

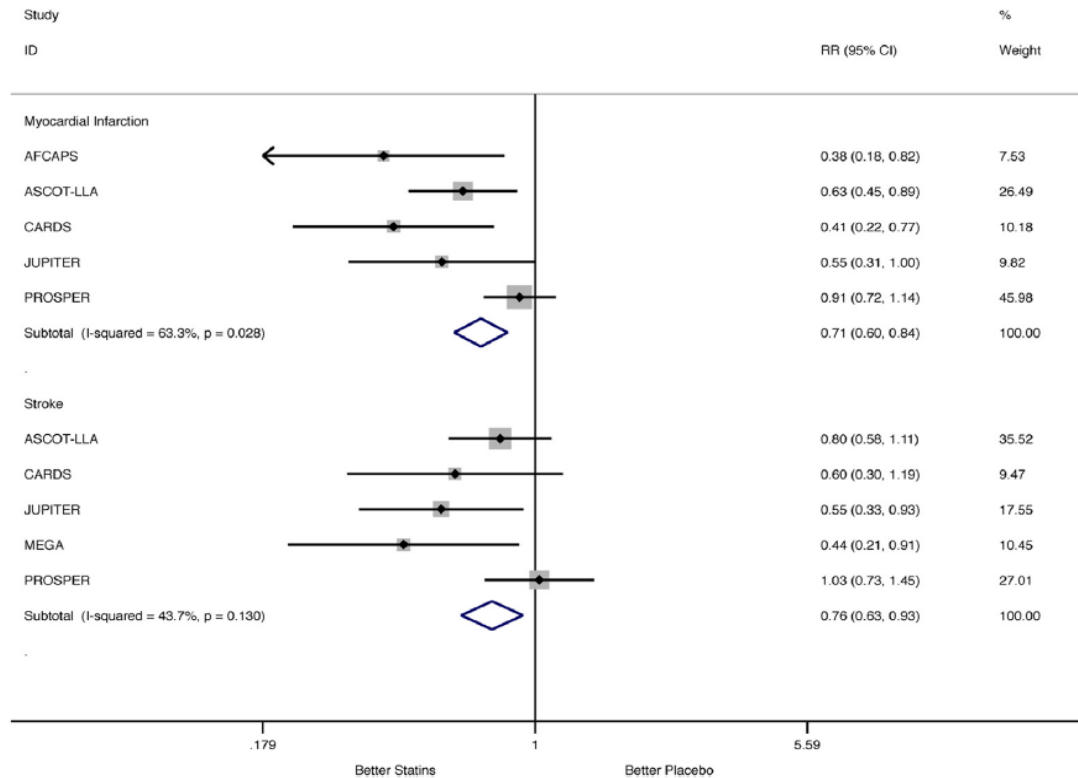
- Older, primary prevention patients who are statin-eligible should undergo a patient-centered discussion with their provider about the risks and benefits of statin therapy so that they can make a more informed decision about taking statins over the long term.
- If the older primary prevention patient is unable to achieve atherogenic cholesterol goals after a minimum 3-6 month trial on lifestyle modification, the provider should discuss the pros and cons of drug therapy and, if feasible, prescribe moderate intensity statin therapy, particularly for patients with one or more ASCVD risk factor aside from age, with risk exceeding the high risk threshold using the Pooled Risk Equation or ATP III Framingham Risk Calculator.
- **Coronary artery calcium (CAC) scoring may be useful to further assess risk in older patients for whom questions remain about whether to prescribe drug therapy.**

Groups with Special Considerations: Older Adults

- If statin intolerance is an issue, consideration should be given to the use of alternate statin regimens such as low intensity statin therapy or non-daily moderate intensity statin therapy, low dose statin combination therapy with ezetimibe, bile acid sequestrants, or niacin, or non-statin monotherapy (i.e., ezetimibe or bile acid sequestrant) or their combination, with a goal of at least a 30% reduction in LDL-C.

Background – Groups with Special Considerations: Older Adults

Meta-analysis of randomized trials of statins vs. placebo in elderly subjects (≥ 65 years) without CVD ($n = 24,674$)



Gray squares represent relative risks (RRs) in trials. The 95% confidence intervals (CIs) for individual trials are denoted by lines and those for the pooled RRs by open diamonds. Meta-analysis is performed by fixed effects model. AFCAPS/TexCAPS = Air Force/Texas Coronary Atherosclerosis Prevention Study; ALLHAT-LLT = Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial; ASCOT-LLA = Anglo-Scandinavian Cardiac Outcomes Trial Lipid-Lowering Arm; CARDS = Collaborative Atorvastatin Diabetes Study; JUPITER = Justification for the Use of statins in Prevention: an Intervention Trial Evaluating Rosuvastatin; MEGA = Management of Elevated Cholesterol in the Primary Prevention Group of Adult Japanese; PROSPER = Prospective Study of Pravastatin in the Elderly at Risk.

Savarese G, et al. Benefits of Statins in Elderly Subjects Without Established Cardiovascular Disease: a Meta-analysis *J Am Coll Cardiol.* 2013;62:2090-2099.

Background – Groups with Special Considerations: Older Adults

Table 2. Statin Trials for Secondary Prevention in Older Adults

| Trial (ref) | Intervention | Age Subgroup (n) | All-Cause Death RRR%/ARR% | CHD Death RRR%/ARR% | CHD Events RRR%/ARR% | Stroke RRR%/ARR% | Comment |
|--------------------------------|--------------|------------------|---------------------------|--------------------------|---|--------------------|--|
| 4S ⁵³ | S20-40 vs PL | 65–70 (1021) | 34/6.2* | 43/6.0 | 34/13.3 33/7.1† | NR | ↓CV admissions by 21% |
| LIPID ⁵⁴ | P40 vs PL | 65–75 (3514) | 21/4.5 | 24/2.9* | 26/3.3 | 12/1.3 | |
| CARE ⁵⁵ | P40 vs PL | 65–75 (1283) | NR | 45/4.5 | 32/9* 39/6.7‡ | 40/2.9 | 32% RRR/5.2% ARR for PCI/CABG |
| HPS ⁵⁶ | S40 vs PL | 70–80 (5806) | NR | NR | 18/5.1‡ | NR | 9.2% ARR in primary end point in patients 75–80 y (n=1263) |
| PROSPER ⁵⁷ | P40 vs PL | 70–82 (5804) | NS | 24/0.9 | 19/2.1‡ | NS | 25% ↑ cancer risk with P40 |
| PROVE-IT TIMI 22 ⁵⁸ | A80 vs P40 | ≥70 (634) | NR | NR | 40/8 LDL-C < 70 vs LDL-C ≥70 mg/dL (in death/MI/UAP*) | NR | AE rate similar to young |
| TNT ⁵⁹ | A80 vs A10 | 65–75 (3809) | NS | NS | 19/2.3* (A80 vs A10) | 21/0.9-NS | ↑LFTs w A80 vs A10 |
| SAGE ⁶⁰ | A80 vs P40 | 65–85 (893) | 67/2.7 | 67/0.9 based on 8 deaths | 29/3.1‡ (P=0.11) | Too few to compare | ↑LFTs w A80 vs P40 |
| Meta-analysis ⁶¹ | | 65–82 (19569) | 22/3.1* | 30/2.6 | 17/2.1‡ 26/2.3 NFMI | 25/1.7 | 30%↓PCI/CABG |

A indicates atorvastatin; AE, adverse events; ARR, absolute risk reduction; CABG, coronary artery bypass grafting; CARE, The Cholesterol and Recurrent Events; CHD, coronary heart disease; CV, cardiovascular; HPS, Heart Protection Study; LDL-C, low-density lipoprotein cholesterol; LIPID, Long-Term Intervention with Pravastatin in Ischaemic Disease; LFTs, liver function tests; MI, myocardial infarction; NFMI, nonfatal myocardial infarction; NR, not reported; NS, not significant; P, pravastatin; PCI, percutaneous coronary intervention; PL, placebo; PROSPER, PROspective Study of Pravastatin in the Elderly at Risk; PROVE IT–TIMI 22, Pravastatin or Atorvastatin Evaluation and Infection Therapy–Thrombolysis in Myocardial Infarction 22; S, simvastatin; w, with; RRR, relative risk reduction; SAGE, Study Assessing Goals in the Elderly; TNT, Treating New Targets; and UAP, unstable angina.

*Primary end point.

†NFMI.

‡Death or NFMI.

Fleg JL, et al. Secondary Prevention of Atherosclerotic Cardiovascular Disease in Older Adults: a Scientific Statement from the American Heart Association *Circulation*. 2013;128:2422-2446.

Groups with Special Considerations

Throughout the Lifespan

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African Americans

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Ethnic and Racial Groups

- **Hispanics/Latinos**
- African Americans
- South Asians
- American Indians/Alaska Natives

Groups with Special Considerations: Hispanics/Latinos

- In general, patients of Hispanic/Latino ethnicity should be treated according to the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with the following special considerations.
- **Clinicians should be aware that Hispanics/Latinos in the United States are a diverse population group tracing their ancestry to Mexico, the Caribbean (Puerto Rico, Cuba, and the Dominican Republic), Central America (El Salvador and Guatemala), and South America. ASCVD risk factor burden varies widely among individuals of Hispanic/Latino descent, depending, in part, on their country of origin.**

Groups with Special Considerations: Hispanics/Latinos

- **Hispanics/Latinos tend to have a greater prevalence of high TG and low HDL-C than non-Hispanic whites (NHWs), leading to higher levels of non-HDL-C, and an increased likelihood for discordance between LDL-C and non-HDL-C concentrations.** LDL-C levels tend to be higher in Hispanic men compared with NHW men.
- **Hispanics/Latinos have higher prevalence of type 2 diabetes mellitus, obesity, and metabolic syndrome compared to NHWs, particularly among women.**
- Some cardiovascular risk equations (e.g., Framingham equations) may overestimate risk in Hispanic/Latino individuals.

Background – Groups with Special Considerations: Hispanics/Latinos

Mean levels of LDL-C, HDL-C and TG for adults ≥ 20 years of age according to race/ethnicity and sex from the 2015 AHA Heart Disease and Stroke Statistics

| | Non-Hispanic White | | Hispanic | |
|--------------|--------------------|-------|----------|-------|
| | Men | Women | Men | Women |
| LDL-C, mg/dL | 113.8 | 116.8 | 120.1 | 114.8 |
| HDL-C, mg/dL | 47.7 | 58.5 | 45.4 | 54.3 |
| TG, mg/dL | 117.7 | 104.0 | 134.7 | 109.7 |

Mozaffarian D, et al. Heart Disease and Stroke Statistics--2015 Update: a Report from the American Heart Association *Circulation*. 2015;131:e29-e322.

Jacobson TA, et al. National Lipid Association Recommendations for Patient-centered Management of Dyslipidemia: Part 1- Full Report *J Clin Lipidol*. 2015;9:129-169.

Ethnic and Racial Groups

- Hispanics/Latinos
- African Americans
- South Asians
- American Indians/Alaska Natives

Groups with Special Considerations: African Americans

- In general, African Americans (AAs) should be treated according to the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with the following special considerations.
- Clinicians should be aware that AAs as a group are at increased risk for ASCVD.
- **Because attributable ASCVD risk in AAs is less driven by dyslipidemia than in NHWs, particular attention should be given to assessing non-lipid risk factors, such as hypertension, overweight and obesity, type 2 diabetes mellitus, and physical inactivity, when ascertaining ASCVD risk.**
- **AAs have a lower incidence of metabolic syndrome than NHWs, due to lower prevalence of high TG and low HDL-C. However, the incidence of type 2 diabetes mellitus is higher in AAs.**

Groups with Special Considerations: African Americans

- **Because AA race/ethnicity is included in the 2013 ACC/AHA Pooled Cohort Equations for estimating 10-year ASCVD risk, this may be the preferable risk calculator to use in patients of AA race/ethnicity.**
- **Because lipoprotein (a) [Lp(a)] levels tend to be higher in AA patients, measuring Lp(a) for risk refinement may be considered in AA patients, particularly in those with a family history of premature ASCVD not explained by other risk factors.**
- **Clinicians should not withhold statin therapy from at risk AA patients with asymptomatic creatine kinase levels that exceed, but are <3.0 times, the standard upper limits of normal. When practical, normative upper limits for creatine kinase that are adjusted for age, race, and sex should be used.**

Background – Groups with Special Considerations: African Americans

Table 8-1. High Total and LDL Cholesterol and Low HDL Cholesterol

| Population Group | Prevalence of Total Cholesterol ≥200 mg/dL, 2012 Age ≥20 y | Prevalence of Total Cholesterol ≥240 mg/dL, 2012 Age ≥20 y | Prevalence of LDL Cholesterol ≥130 mg/dL, 2012 Age ≥20 y | Prevalence of HDL Cholesterol <40 mg/dL, 2012 Age ≥20 y |
|---------------------|--|--|--|---|
| Both sexes, n (%)* | 100 100 000 (42.8) | 30 900 000 (13.1) | 73 500 000 (31.7) | 44 600 000 (19.9) |
| Males, n (%)* | 45 300 000 (40.4) | 13 000 000 (11.6) | 34 900 000 (31.0) | 32 400 000 (28.9) |
| Females, n (%)* | 54 830 000 (44.9) | 17 900 000 (14.4) | 38 600 000 (32.0) | 12 200 000 (10.4) |
| NH white males, % | 39.9 | 11.5 | 29.4 | 28.7 |
| NH white females, % | 45.9 | 15.3 | 32.0 | 10.2 |
| NH black males, % | 37.4 | 8.8 | 30.7 | 20.0 |
| NH black females, % | 40.7 | 10.9 | 33.6 | 10.3 |
| Hispanic males, % | 46.2 | 14.8 | 38.8 | 33.8 |
| Hispanic females, % | 43.4 | 13.7 | 31.8 | 12.8 |

Prevalence of total cholesterol ≥200 mg/dL includes people with total cholesterol ≥240 mg/dL. In adults, levels of 200 to 239 mg/dL are considered borderline high. Levels of ≥240 mg/dL are considered high.

HDL indicates high-density lipoprotein; LDL, low-density lipoprotein; and NH, non-Hispanic.

*Total data for total cholesterol are for Americans ≥20 years of age. Data for LDL cholesterol, HDL cholesterol, and all racial/ethnic groups are age adjusted for age ≥20 years.

Source for total cholesterol ≥200 mg/dL, ≥240 mg/dL, LDL, and HDL: National Health and Nutrition Examination Survey (2009–2012), National Center for Health Statistics, and National Heart, Lung, and Blood Institute. Estimates from National Health and Nutrition Examination Survey 2009 to 2012 (National Center for Health Statistics) were applied to 2012 population estimates.

Mozaffarian D, et al. Heart Disease and Stroke Statistics--2015 Update: a Report from the American Heart Association *Circulation*. 2015;131:e29-e322.

Background – Groups with Special Considerations: African Americans

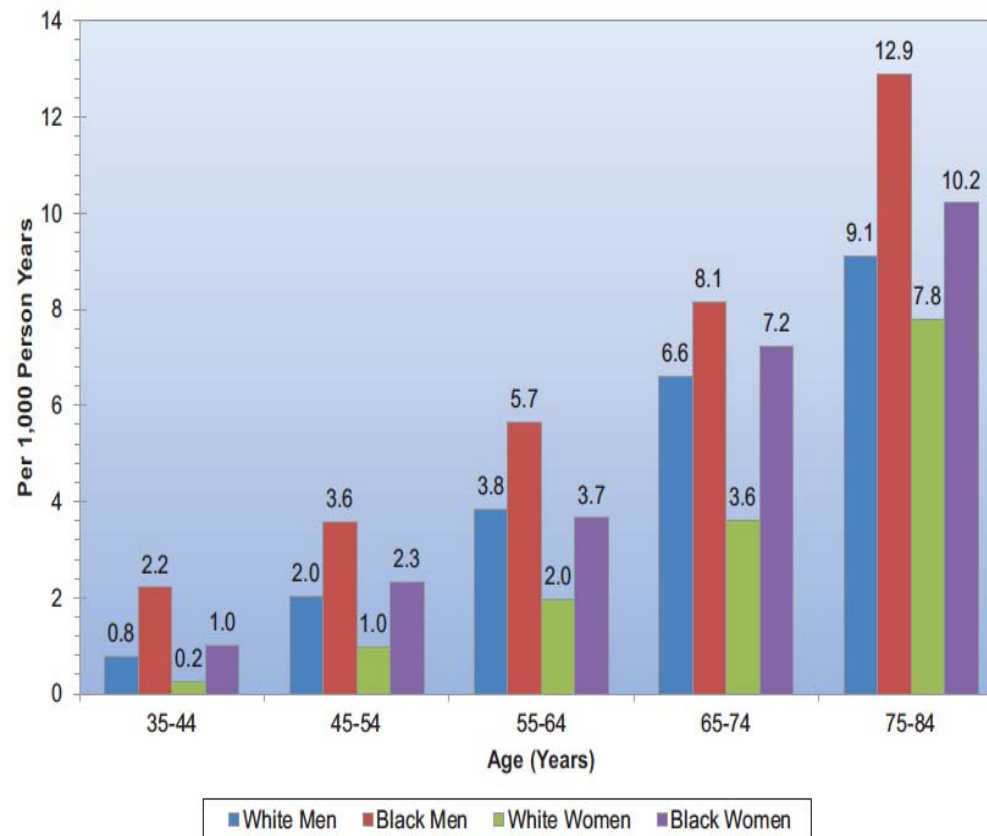


Chart 19-5. Incidence of myocardial infarction by age, sex, and race (Atherosclerosis Risk in Communities Surveillance: 2005-2011).

Source: Unpublished data from Atherosclerosis Risk in Communities study, National Heart, Lung, and Blood Institute.

Mozaffarian D, et al. Heart Disease and Stroke Statistics--2015 Update: a Report from the American Heart Association *Circulation*. 2015;131:e29-e322.

Ethnic and Racial Groups

- Hispanics/Latinos
- African Americans
- **South Asians**
- American Indians/Alaska Natives

Groups with Special Considerations: South Asians

- In general, patients of South Asian (SA) ethnicity should be treated according to the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with the following special considerations.
- **Clinicians should be aware that SAs (including individuals who trace their ancestry to Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan, and Sri Lanka; and also members of the SA diaspora – past generations of SAs who originally settled in other parts of the world, including Africa, Canada, the Caribbean, Europe, the Middle East, and other parts of Asia and the Pacific Islands) as a group are at increased risk for ASCVD. [*HR > 2.0 vs. NHWs*]**
- **Patients of SA descent in the United States have a greater prevalence of insulin resistance than NHWs, and some of the metabolic disturbances that accompany this condition include high TG, low HDL-C, and dysglycemia.**

Groups with Special Considerations: South Asians

- SAs have increased prevalence of metabolic syndrome compared to NHW Americans. **Clinicians should be aware that Asians have different waist circumference cutpoints for defining overweight/obesity for definition of the metabolic syndrome than those recommended for Caucasian populations (≥ 37 inches [≥ 94 cm] for men and ≥ 32 inches [≥ 80 cm] for women).**
- Clinicians should be aware that risk assessment methods may under- or over-estimate ASCVD risk when used in populations different from those in which they were developed. ASCVD risk equations may underestimate risk for SAs in particular, although the degree of underestimation is uncertain. Clinicians should consider this when making decisions about risk stratification and treatment.

Groups with Special Considerations: South Asians

- Due to the possibility of genetic variation in drug metabolism (as demonstrated mainly in studies of Chinese and Japanese patients), starting with a moderate intensity statin dosage and titrating upward to reach atherogenic cholesterol goals, or downward if intolerance occurs, is recommended for patients of Asian ethnicity.
- Because SAs are at increased risk for diabetes, vigilant monitoring for the potential of new-onset diabetes with statin treatment is warranted.

Background – Groups with Special Considerations: South Asians

CHD incidence from a multi-ethnic population study in Northern California (n = 13,448)

| Group (Number With CAD) | HR | 95% Confidence Interval | p Value |
|---|-----|-------------------------------|---------|
| Adjusted* HR of various ethnic groups vs. white | | | |
| White (4,478) | 1.0 | — | — |
| African American (2,055) | 0.8 | 0.8–0.9 | <0.001 |
| Hispanic (282) | 0.9 | 0.8–1.0 | 0.2 |
| All Asian | 1.0 | 0.9–1.0 | 0.2 |
| Chinese (262) | 0.8 | 0.7–0.9 | <0.001 |
| Japanese (95) | 0.9 | 0.7–1.1 | 0.18 |
| Filipino (263) | 1.2 | 1.0–1.3 | 0.02 |
| Other Asian (24) | 0.8 | 0.5–1.1 | 0.17 |
| South Asian† (56) | 2.4 | 1.9–3.2 | <0.001 |
| Additional models for South Asian people vs. white as referent | | | |
| Age- and sex-adjusted model | 2.3 | 1.7–2.9 | <0.001 |
| Added covariates‡ | 2.3 | 1.8–3.0 | <0.001 |
| Adjusted* HR of CAD in South Asian people vs. ethnicities other than white as referent | | | |
| African American | 2.9 | 2.2–3.8 | <0.001 |
| Hispanic | 2.8 | 2.1–3.8 | <0.001 |
| Chinese | 3.3 | 1.4–3.3 | <0.001 |
| Japanese | 3.2 | 2.3–4.6 | <0.001 |
| Filipino | 2.3 | 1.7–3.1 | <0.001 |
| Other Asian | 2.8 | 2.1–5.6 | <0.001 |

Hajra A, et al. Risk of Coronary Disease in the South Asian American Population *J Am Coll Cardiol.* 2013;62:644-645.

Background – Groups with Special Considerations: South Asians

Table 2 Current recommended waist circumference thresholds for abdominal obesity by organizations

| Population | Organization (reference) | Recommended waist, cm | |
|-----------------------------------|--|---------------------------|--------------------------|
| | | Men | Women |
| Caucasian | WHO, 2000 ¹¹² | ≥94 (increased risk) | ≥80 cm (increased risk) |
| | | ≥102 (still greater risk) | ≥88 (still greater risk) |
| United States | AHA/NHLBI (ATP III*) (NCEP 2002) ²⁶ | ≥102 | ≥88 |
| Canada | Health Canada (Health Canada 2003 ¹¹³ ; Khan et al 2006) ¹¹⁴ | ≥102 | ≥88 |
| European | European Cardiovascular Societies (Graham et al 2007) ¹¹⁵ | ≥102 | ≥88 |
| Asian | WHO (Hara et al 2006) ¹¹⁶ | ≥90 | ≥80 |
| Japanese | Japanese Obesity Society (Oka et al 2008) ^{117,118} | ≥85 | ≥90 |
| China | Cooperative Task Force (Zhou 2002) ¹¹⁹ | ≥85 | ≥80 |
| Middle Eastern, Mediterranean | IDF (Alberti et al 2005) ¹²⁰ | ≥94 | ≥80 |
| Sub-Saharan African | IDF (Alberti et al 2005) ¹²⁰ | ≥94 | ≥80 |
| Ethnic Central and South American | IDF (Alberti et al 2005) ¹²⁰ | ≥90 | ≥80 |
| Europid | IDF (Alberti et al 2005) ¹²⁰ | ≥94 | ≥80 |
| Asian (including Japanese) | IDF (Alberti et al 2005) ¹²⁰ | ≥90 | ≥80 |

AHA, American Heart Association; ATP, Adult Treatment Panel; IDF, International Diabetes Federation; NCEP, National Cholesterol Education Program; WHO, World Health Organization.

*Recent American Heart Association/NHLBI guidelines for metabolic syndrome recognize an increased risk for cardiovascular disease and diabetes at waist-circumference thresholds of ≥94 cm in men and ≥80 in women and identify these as optional cut points for individuals or populations with increased insulin resistance.^{112,121}

Expert Dyslipidemia Panel, Grundy SM. An International Atherosclerosis Society Position Paper: Global Recommendations for the Management of Dyslipidemia *J Clin Lipidol*. 2013;7:561-565.

Palaniappan LP, et al. Asian Americans Have Greater Prevalence of Metabolic Syndrome Despite Lower Body Mass Index *Int J Obes (Lond)*. 2011;35:393-400.

Ethnic and Racial Groups

- Hispanics/Latinos
- African Americans
- South Asians
- American Indians/Alaska Natives

Groups with Special Considerations: American Indians/Alaska Natives

- **Clinicians should be aware that American Indians (AIs)/Alaska Natives (ANs) have higher prevalence and incidence rates for ASCVD, and that certain ASCVD risk factors (e.g., obesity, metabolic syndrome, diabetes mellitus, and cigarette smoking) are more common among AIs/ANs than NHWs, whereas prevalence values for hypertension and hypercholesterolemia are comparable or slightly elevated compared to NHWs.**
- In general, clinicians should screen for and manage dyslipidemia in AI/AN patients using the approach outlined in the NLA Expert Panel Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015). **Because of the high frequencies of obesity, metabolic syndrome, and diabetes mellitus in AI/AN populations, strong emphasis should be placed on lifestyle therapies.**

Groups with Special Considerations: American Indians/Alaska Natives

- Clinicians should generally assess risk in AI/AN patients using the risk assessment approach outlined in the NLA Expert Panel Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015).

Groups with Special Considerations

Throughout the Lifespan

Children and Adolescents

Women's Health

From Pregnancy to Menopause

Older Adults

Ethnic and Racial Groups

Hispanics/Latinos

African American

South Asians

American Indians/Alaska Natives

High Risk Conditions and Residual Risk

Patients Infected with HIV

Patients with Rheumatoid Arthritis

Residual Risk Despite Statin and Lifestyle Therapy

Groups with Special Considerations: Patients Infected with HIV

- **Clinicians should be aware that patients with human immunodeficiency virus (HIV) are at increased risk for ASCVD. The association between HIV infection and ASCVD risk is independent of the risk associated with major established ASCVD risk factors.**
- A fasting lipid panel should be obtained in all newly identified HIV-infected patients before and after starting antiretroviral therapy.
- For primary prevention of ASCVD, HIV infection may be counted as an additional ASCVD risk factor for risk stratification.

Groups with Special Considerations: Patients Infected with HIV

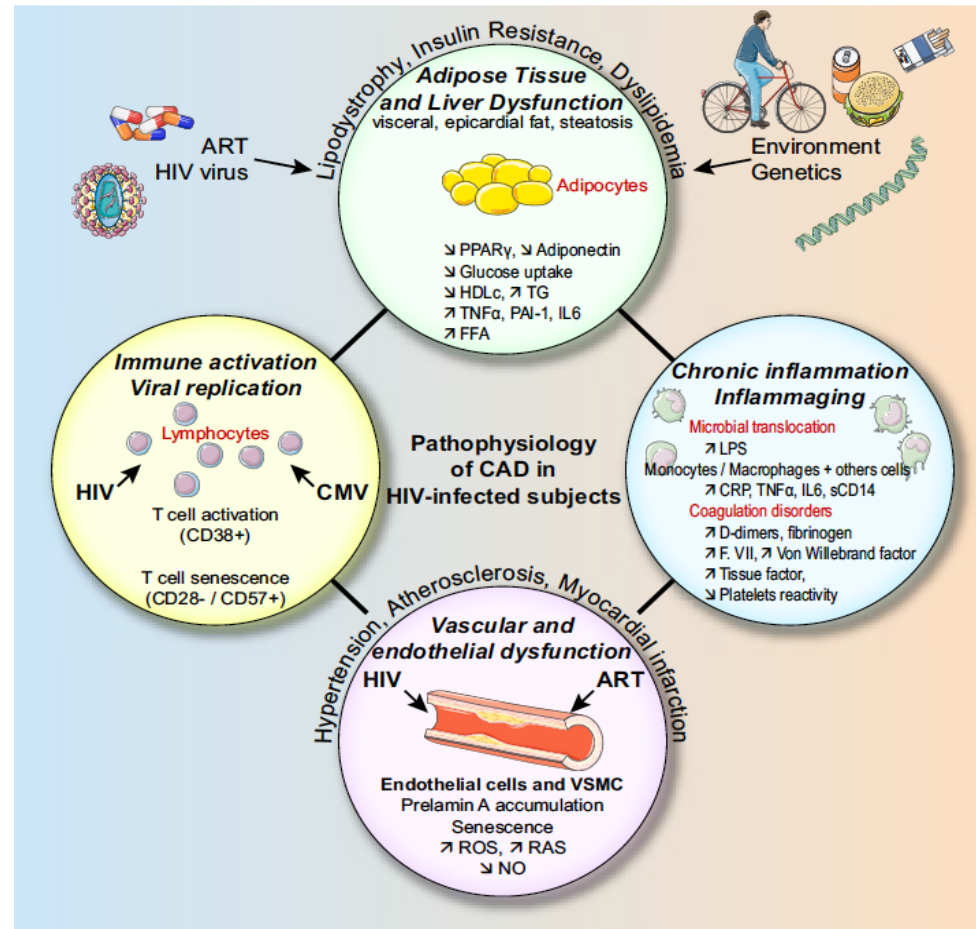
- Risk stratification is based on the NLA Recommendations for the Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with initial risk stratification based on the number of major ASCVD risk factors (with the caveat that the presence of **HIV infection may be counted as an additional risk factor**), the use of risk prediction tools, such as the ATP III Framingham Risk Score or the ACC/AHA Pooled Cohort Equations if two risk factors are present, and the use of other clinical indicators to help inform clinical judgment, if needed.
- The non-HDL-C and LDL-C goals described in the NLA Part 1 Recommendations should be followed for HIV-infected patients (Jacobson 2015). Atherogenic cholesterol goals may not be attainable in all patients, but there is incremental benefit to lowering non-HDL-C and LDL-C to approach these goal levels.

Groups with Special Considerations: Patients Infected with HIV

- Elevated TG ≥ 500 mg/dL that is refractory to lifestyle modification or changes in antiretroviral therapy (if an option) should generally be treated with either a fibrate (fenofibrate preferred) or prescription omega-3 fatty acids. After TG is lowered (< 500 mg/dL), non-HDL-C and LDL-C should be reassessed for appropriate management.
- **Statin therapy is first line for elevated LDL-C and non-HDL-C; however, interactions between statins and antiretroviral agents and other medications must be considered prior to initiating lipid-lowering therapy.** The NLA Expert Panel recommends using atorvastatin, rosuvastatin, or pitavastatin as the generally preferred agents in HIV-infected patients.

Background: Groups with Special Considerations: Patients Infected with HIV

Hypotheses for pathophysiology of ASCVD in HIV-infected patients taking ART



Boccaro F, et al. HIV and Coronary Heart Disease: Time for a Better Understanding *J Am Coll Cardiol.* 2013;61:511-523.

Groups with Special Considerations: Patients with Rheumatoid Arthritis

- **Clinicians should be aware that patients with rheumatoid arthritis (RA) are at increased risk for ASCVD.** The association of RA and systemic lupus erythematosus with ASCVD risk raises concern that other inflammatory conditions may also be associated with increased ASCVD risk. However, **only RA has been studied sufficiently to accurately quantify the degree to which it increases ASCVD risk.**
- The association between RA and ASCVD risk is independent of the risk associated with major established ASCVD risk factors. **RA may be counted as an additional ASCVD risk factor for risk stratification.**

Groups with Special Considerations: Patients with Rheumatoid Arthritis

- Risk stratification is based on the NLA Recommendations for the Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015) with initial risk stratification based on the number of major ASCVD risk factors (with the caveat that the presence of RA may be counted as an additional risk factor), the use of risk prediction tools, such as the ATP III Framingham Risk Score or the ACC/AHA Pooled Cohort Equations if two risk factors are present, and the use of other clinical indicators to help inform clinical judgment, if needed.
- Clinicians should be vigilant in ensuring that RA patients are routinely assessed for cardiovascular risk factors, such as hypertension, dyslipidemia, diabetes, family history of early-onset ASCVD, and smoking. Calculation of lifetime ASCVD risk can be considered for patients age 20-59 years.

Groups with Special Considerations: Patients with Rheumatoid Arthritis

- Statins are generally the first-line treatment for dyslipidemia in RA.
- At this time, atherogenic cholesterol treatment goals for patients with RA and other inflammatory diseases are the same as described in the NLA Recommendations for Patient-Centered Management of Dyslipidemia – Part 1 (Jacobson 2015).
- **If an RA patient has had lipid levels checked during an RA flare, it is recommended that the lipids be re-checked when their disease is controlled.**

Background – Groups with Special Considerations: Patients with Rheumatoid Arthritis

RA treatments with manufacturer package inserts recommending frequency of lipid measurements

| RA treatment | Rates of dyslipidemia | Recommendations | Comments |
|---------------------------------|-----------------------|---|--|
| Tofacitinib (Pfizer 2014) | >10% | 4-8 weeks after initiation | Increases in total-C, LDL-C and HDL-C <ul style="list-style-type: none"> • Maximum increases within 6 weeks of initiation |
| Tocilizumab (Genentech 2014) | >10% | 4-8 weeks after initiation, then at ~24-week intervals | Increases in total-C, LDL-C, HDL-C and triglycerides |

Pfizer Labs. Xeljanz Prescribing Information, 2014. <http://labeling.pfizer.com/ShowLabeling.aspx?id=959>

Genentech Inc. Actemra Prescribing Information, 2014. http://www.gene.com/download/pdf/actemra_prescribing.pdf

Crowson CS, et al. Usefulness of risk scores to estimate the risk of cardiovascular disease in patients with rheumatoid arthritis
Am J Cardiol. 2012;110:420-424.

Groups with Special Considerations: Patients with Residual Risk Despite Statin and Lifestyle Therapy

- For patients not at goal levels for atherogenic cholesterol on maximally tolerated statin therapy, consideration should be given to adding non-statin lipid-altering therapy to ongoing statin therapy for further lowering of atherogenic cholesterol, as long as the patient has sufficient ASCVD risk to warrant it, and the expected treatment benefit outweighs the risk for adverse consequences.
- Recommended statin combination therapies to consider for further lowering of atherogenic cholesterol are, in the following order: first – ezetimibe 10 mg every day, second – colesevelam 625 mg 3 tablets twice a day (or 3.75 g powder form every day or in divided doses), and third – extended release niacin titrated to a maximum of 2000 mg, daily.

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Groups with Special Considerations: Patients with Residual Risk Despite Statin and Lifestyle Therapy

- **Until the CV outcomes trials are completed with PCSK9 inhibitors, these drugs should be considered primarily in: 1) patients with ASCVD who have LDL-C ≥ 100 mg/dL (non-HDL-C ≥ 130 mg/dL) while on maximally-tolerated statin (\pm ezetimibe) therapy; and 2) heterozygous FH patients without ASCVD who have LDL-C ≥ 130 mg/dL (non-HDL-C ≥ 160 mg/dL) while on maximally-tolerated statin (\pm ezetimibe) therapy.**
- **In addition, PCSK9 inhibitor use may be considered for selected high risk patients with ASCVD (e.g., recurrent ASCVD events) who have atherogenic cholesterol levels below the specified values, but above their treatment goals (i.e., LDL-C ≥ 70 mg/dL [non-HDL-C ≥ 100 mg/dL]). Such use would be based on clinical judgment, weighing the potential benefits relative to the ASCVD event risk and the risks and costs of therapy.**

Groups with Special Considerations: Patients with Residual Risk Despite Statin and Lifestyle Therapy

- **PCSK9 inhibitor use may also be considered in selected high or very high risk patients who meet the definition of statin intolerance (as previously defined by the NLA Statin Expert Panel) and who require substantial additional atherogenic cholesterol lowering, despite the use of other lipid lowering therapies.** Such use would be based on clinical judgment, weighing the potential benefits relative to the ASCVD event risk and the risks and costs of therapy.
- **Fibrates and prescription omega-3 fatty acids are first-line drug choices for patients with TG \geq 500 mg/dL, although consideration may be given to using statin therapy as a first-line drug in patients with TG 500-999 without a history of pancreatitis.**

Groups with Special Considerations: Patients with Residual Risk Despite Statin and Lifestyle Therapy

- **Fibrates and prescription omega-3 fatty acids are first-line drug choices for patients with TG \geq 500 mg/dL, although consideration may be given to using statin therapy as a first-line drug in patients with TG 500-999 without a history of pancreatitis.**
- **In patients with elevated TG (200 to 499 mg/dL) on maximum tolerated statin therapy who are at their LDL-C goal but not their non-HDL-C goal, the addition of therapies that primarily lower TG and VLDL-C (fibrates, high-dose omega-3 fatty acids) may be considered to help achieve atherogenic cholesterol goals.** Subgroup analyses from cardiovascular outcomes studies provide suggestive evidence of reduced ASCVD event risk with the addition of a TG-lowering agent to statin therapy, particularly in patients with the combination of elevated TG and low HDLC.

Background – Groups with Special Considerations: Patients with Residual Risk Despite Statin and Lifestyle Therapy

| Study | Statin Therapy | Combination Drug | LDL-C Reduction with Statin Alone | LDL-C Reduction with Combination Therapy | LDL-C Lowering Attributed to the Added Drug |
|---|--|----------------------------------|-----------------------------------|--|---|
| Bile Acid Sequestrants Plus Statin Combination Therapy | | | | | |
| Ytre-Arne et al ⁶ | Simvastatin 40 mg/d | Cholestyramine 12g bid | -40% | -57% | -18% |
| Jacob et al ⁷ | Lovastatin 80 mg/d | Cholestyramine 8 g/d | -28% | -40% | -18% |
| | Pravastatin 40 mg/d | Cholestyramine 8 g/d | -30% | -39% | -9% |
| Knapp et al ⁸ | Simvastatin 10 mg/d | Colesevelam 3.8 g/d | -28% | -42% | -18% |
| Hunninghake et al ⁹ | Atorvastatin 10 mg/d | Colesevelam 3.8 g/d | -38% | -48% | -10% |
| Ezetimibe Plus Statin Combination Therapy | | | | | |
| Davidson et al ¹⁰ | Simvastatin various doses | Ezetimibe 10 mg/d | -36% | -50% | -14% |
| Ballantyne et al ¹¹ | Atorvastatin various doses | Ezetimibe 10 mg/d | -42% | -54% | -12% |
| Gagne et al ¹² | Various statins at various doses | Ezetimibe 10 mg/d | -4% | -25% | -21% |
| Gagne et al ¹³ | Simvastatin or atorvastatin with dose increased from 40mg to 80 mg/d | Ezetimibe 10 mg/d | -7% | -27% | -20% |
| Cannon ¹⁴ | Simvastatin 40 mg | Ezetimibe 10 mg/d | -25% | -44% | -19% |
| Niacin Plus Statin Combination Therapy | | | | | |
| Vacek et al ¹⁵ | Lovastatin 20 mg/d | Niacin SR [†] 1200 mg/d | -23% | -35% | -12% |
| Advicor Prescribing Information ¹⁶ | Lovastatin 20 mg/d | Niacin ER [†] 1000 mg/d | -24% | -31% | -7% |
| | Lovastatin 40 mg/d | Niacin ER 1000 mg/d | -29% | -37% | -8% |
| | Lovastatin 40 mg/d | Niacin ER 2000 mg/d | -29% | -43% | -14% |

†SR = sustained release, ER = extended release

Major Categories of the NLA Part 2 Recommendations

- Lifestyle Therapies
 - Nutrition
 - Exercise/Physical Activity
- Groups with Special Considerations
- Improving Patient Outcomes
 - Patient Adherence
 - Team-based Collaborative Care

Improving Patient Outcomes: Patient Adherence

- **The provider should assess adherence to both lifestyle and atherogenic cholesterol-lowering medications at every patient encounter.**
- **A multidisciplinary health care team (such as the patient's primary health care provider; nurses; nurse practitioners; pharmacists; physician assistants; registered dietitian nutritionists, including certified diabetes educators in some practices; exercise specialists; social workers; community health workers; and licensed professional counselors, psychologists, and health educators) is desirable to identify medication non-adherence and to facilitate strategies to improve adherence by helping patients overcome real (or perceived) barriers to adherence.**

Improving Patient Outcomes: Patient Adherence

- **The multi-faceted approach should be employed by clinicians to improve medication adherence, including:**
 - a) simplify the regimen;**
 - b) provide clear education using visual aids and simple, low-literacy educational materials;**
 - c) engage patients in decision-making, addressing their specific needs, values, and concerns;**
 - d) address perceived barriers of taking medication;**
 - e) identify suboptimal health literacy and use “teach-back” techniques to increase patient understanding of those behaviors needed to be successful;**
 - f) screen and eliminate drug-drug and drug-disease interactions leading to low adherence or drug discontinuation; and**
 - g) praise and reward successful behaviors.**

Background – Improving Patient Outcomes: Patient Adherence

Self-reported reasons for primary non-adherence of statin from telephone survey of Kaiser Permanente Southern California members (n = 73)

| Did not pick up cholesterol medication due to/because... | % Yes (n) |
|---|-----------|
| General concerns about medication | 63.0 (46) |
| Decided to try lifestyle modification | 63.0 (46) |
| Fear of side effects | 53.4 (39) |
| Did not think medication was needed | 38.9 (28) |
| Did not believe condition was life threatening | 34.7 (25) |
| Fear of drug interactions | 16.4 (12) |
| Already took too many medications and did not want to take any more | 16.4 (12) |
| Financial hardship | 12.3 (9) |
| Did not understand why provider prescribed medication | 11.0 (8) |
| Did not understand purpose of medication | 8.2 (6) |
| Did not think medication would be effective for condition | 6.9 (5) |
| Inconvenient dosing regimen | 4.1 (3) |
| Change in health insurance/drug benefit | 2.7 (2) |

Harrison TN, et al. Primary Nonadherence to Statin Therapy: Patients' Perceptions *Am J Managed Care*. 2013;19:e133-e139.

Smith DH, et al. A Randomized Trial of Direct-to-patient Communication to Enhance Adherence to Beta-blocker Therapy Following Myocardial Infarction *Arch Intern Med*. 2008;168:477-483.

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- Groups with Special Considerations
- Improving Patient Outcomes
 - Patient Adherence
 - **Team-based Collaborative Care**

Improving Patient Outcomes: Team-Based Collaborative Care

- **Health care teams for optimal lipid and ASCVD risk management may include, where available: the patient; the patient’s primary health care provider; nurses; nurse practitioners; pharmacists; physician assistants; registered dietitian nutritionists, including certified diabetes educators in some practices; exercise specialists; social workers; community health workers; and licensed professional counselors, psychologists, and health educators.**
- Health care team members should coordinate care support among various team members, use evidence-based guidelines/recommendations for dyslipidemia management, establish a structured plan for monitoring patient progress, and provide patients with a variety of tools and resources to improve their own care.
- Team-based collaborative care may be incorporated into the Patient Centered Medical Home as a strategy to address shortfalls in patient health care quality, access, continuity, and cost.

Background – Improving Patient Outcomes: Team-Based Collaborative Care

- Agency for Healthcare Research and Quality. Patient Centered Medical Home Resource Center. <http://pcmh.ahrq.gov/page/defining-pcmh>
- Proia K, et al. Team-based Care and Improved Blood Pressure Control: a Community Guide Systematic Review *Am J Prev Med*. 2014;47:86-99.

Abbreviations/Acronyms Used

- **AA** = African American
- **ACC** = American College of Cardiology
- **AHA** = American Heart Association
- **AI** = American Indian
- **AN** = Alaska Native
- **ART** = antiretroviral therapy
- **ASCVD** = atherosclerotic cardiovascular disease
- **ATP** = Adult Treatment Panel
- **CAC** = coronary artery calcium
- **CHD** = coronary heart disease
- **DASH** = Dietary Approaches to Stop Hypertension
- **DHA** = docosahexaenoic acid
- **EPA** = eicosapentaenoic acid
- **FH** = familial hypercholesterolemia
- **HDL-C** = high-density lipoprotein cholesterol
- **HIV** = human immunodeficiency virus
- **HT** = hormone therapy
- **LDL-C** = low-density lipoprotein cholesterol
- **Lp(a)** = lipoprotein(a)
- **MI** = myocardial infarction
- **MNT** = medical nutrition therapy
- **NHW** = non-Hispanic white
- **NLA** = National Lipid Association
- **Non-HDL-C** = non-high-density lipoprotein cholesterol
- **PCOS** = polycystic ovary syndrome
- **RA** = rheumatoid arthritis
- **SA** = South Asian
- **TG** = triglycerides
- **USDA** = United States Department of Agriculture

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