2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Preventive Cardiology, Association of Black Cardiologists, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease

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Citation

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ACC/AHA Blood Cholesterol Guideline Panel Members

Neil J. Stone, MD, MACP, FAHA, FACC, *Chair*
Jennifer G. Robinson, MD, MPH, FAHA, *Vice Chair*
Alice H. Lichtenstein, DSc, FAHA, *Vice Chair*

Anne C. Goldberg, MD, FACP, FAHA
Conrad B. Blum, MD, FAHA
Robert H. Eckel, MD, FAHA, FACC
Daniel Levy, MD*
David Gordon, MD*
C. Noel Bairey Merz, MD, FAHA, FACC
Donald M. Lloyd-Jones, MD, ScM, FACC, FAHA
J. Sanford Schwartz, MD
Patrick McBride, MD, MPH, FAHA
Sidney C. Smith, Jr, MD, FACC, FAHA
Karol Watson, MD, PhD, FACC, FAHA
Susan T. Shero, MS, RN*
Peter W.F. Wilson, MD, FAHA

*Ex-Officio Members.

Acknowledgements

Methodology Members
Karen M. Eddleman, BS
Nicole M. Jarrett
Ken LaBresh, MD
Lev Nevo, MD
Janusz Wnek, PhD

National Heart, Lung, and Blood Institute
Glen Bennett, M.P.H.
Denise Simons-Morton, MD, PhD

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Conflict of Interest/Relationships With Industry

1) All panel members disclosed conflict of interest information to the full panel in advance of the deliberations

2) Members with conflicts recused themselves from voting on any aspect of the guideline where a conflict might exist

3) All 16 members of the NHLBI ATP IV Panel transitioned to the ACC/AHA guideline Expert Panel

4) Independent contractors performed the systematic review with the assistance of the Expert Panel and provided methodological guidance to the Expert Panel

NHLBI Charge to the Expert Panel

Evaluate higher quality randomized controlled trial (RCT) evidence for cholesterol-lowering drug therapy to reduce ASCVD risk

- Use Critical Questions (CQs) to create the evidence search from which the guideline is developed
  - Cholesterol Panel: 3 CQs
  - Risk Assessment Work Group: 2 CQs
  - Lifestyle Management Work Group: 3 CQs
- RCTs and systematic reviews/meta-analyses of RCTs independently assessed as fair-to-good quality
- Develop recommendations based on RCT evidence

Systematic Review Process

- The Expert Panel constructed CQs relevant to clinical practice.
- The Expert Panel identified (a priori) inclusion/exclusion (I/E) criteria for each CQ.
- An independent contractor developed a literature search strategy, based on I/E criteria, for published clinical trial reports for each CQ.
- An independent contractor executed a systematic electronic search of the published literature from relevant bibliographic databases for each CQ.
- The date for the overall literature search was from January 1, 1995 through December 1, 2009.
- However, RCTs with the ASCVD outcomes of MI, stroke, and cardiovascular death published after that date were eligible for consideration until July 2013.

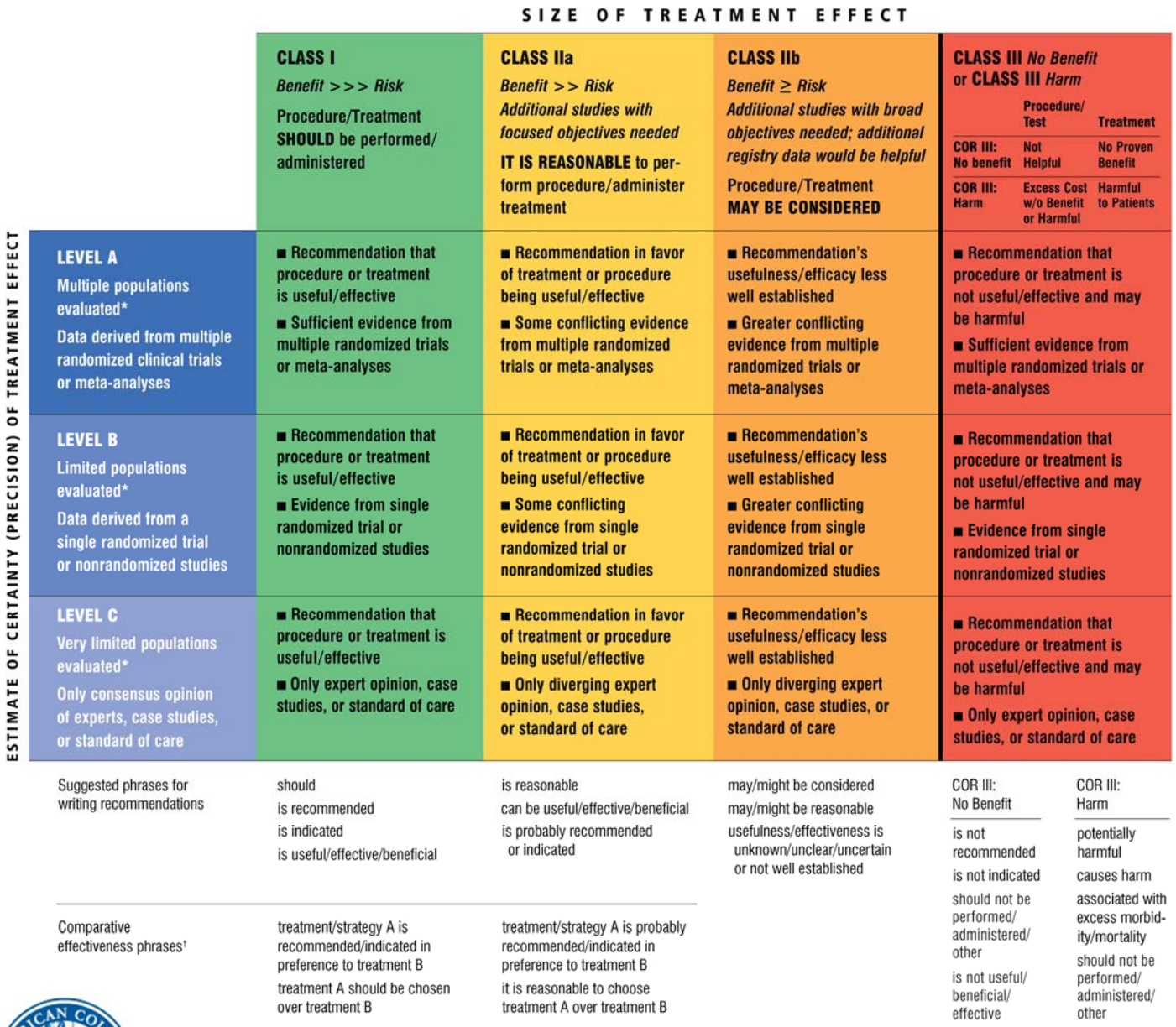
NHLBI Grading the Strength of Recommendation

Grade	Strength of Recommendation*
A	**Strong recommendation:** There is high certainty based on evidence that the net benefit is substantial.
B	**Moderate recommendation:** There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.
C	**Weak recommendation:** There is at least moderate certainty based on evidence that there is a small net benefit.
D	**Recommendation against:** There is at least moderate certainty based on evidence that it has no net benefit or that risks/harms outweigh benefits.
E	**Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Panel recommends.")** Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Panel thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.
N	**No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.")** Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Panel thought no recommendation should be made. Further research is recommended in this area.

Quality Rating the Strength of Evidence

Type of Evidence	Quality Rating*
• Well-designed, well-executed† RCTs that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • MAs of such studies. Highly certain about the estimate of effect. Further research is unlikely to change the Panel's confidence in the estimate of effect.	High
• RCTs with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies § and well-designed, well-executed observational studies ‖. • Meta-analyses of such studies. Moderately certain about the estimate of effect. Further research may have an impact on the Panel's confidence in the estimate of effect and may change the estimate.	Moderate
• RCTs with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. Low certainty about the estimate of effect. Further research is likely to have an impact on the Panel's confidence in the estimate of effect and is likely to change the estimate.	Low

Classification of Recommendations and Levels of Evidence



SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/Test / Treatment COR III: No benefit — Not Helpful / No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/ efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

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4 Statin Benefit Groups

- Clinical ASCVD*
- LDL–C ≥190 mg/dL, Age ≥21 years
- Primary prevention - Diabetes: Age 40-75 years, LDL–C 70-189 mg/dL
- Primary prevention - No Diabetes**: ≥7.5%† 10-year ASCVD risk, Age 40-75 years, LDL–C 70-189 mg/dL

* Atherosclerotic cardiovascular disease

**Requires discussion between clinician and patient before statin initiation

† Statin therapy may also be considered in those with 5-<7.5% 10-year ASCVD risk or when a risk-based treatment decision is uncertain

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Vignettes: ***Putting a face on patients in whom ASCVD risk reduction works***

- 63 yo man with STEMI, discharged on a high-intensity statin
- 26 yo woman with elevated LDL–C of 220 mg/dL, noted in teens + family history CHD
- 44 yo woman with diabetes, well-controlled hypertension and micro-albuminuria
- 56 yo African-American woman with multiple ASCVD risk factors
- 57 yo white man with LDL-C 165 mg/dl

Guideline Scope

- Focus on *treatment of blood cholesterol to reduce ASCVD risk in adults*
- Emphasize adherence to a heart healthy lifestyle as foundation of ASCVD risk reduction
    - See Lifestyle Management Guideline
- Identify individuals *most likely to benefit* from cholesterol-lowering therapy
    - 4 statin benefit groups
- Identify safety issues

New Perspective on LDL–C & Non-HDL–C Goals

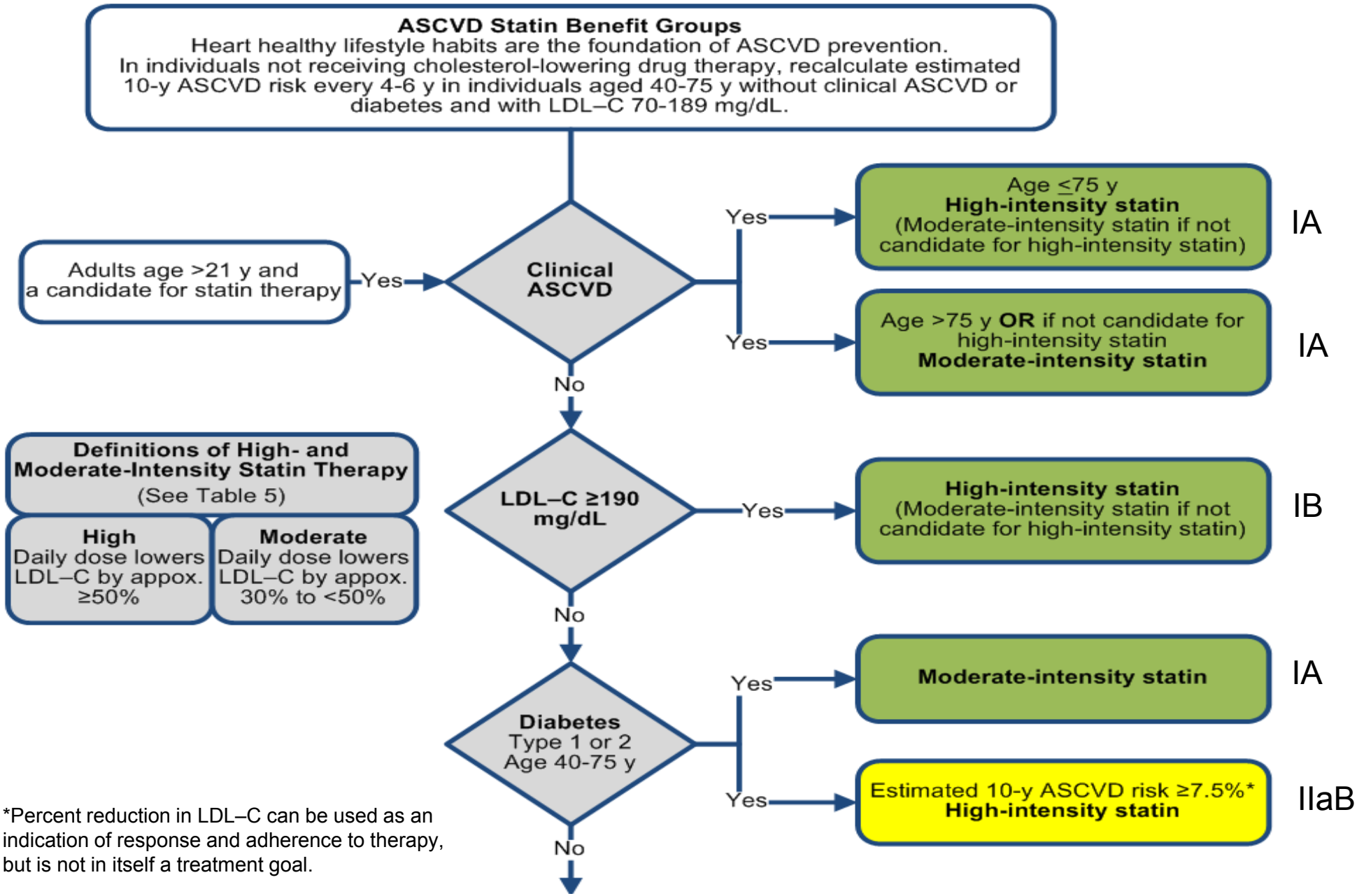
- Lack of RCT evidence to support titration of drug therapy to specific LDL–C and/or non-HDL–C goals
- Strong evidence that *appropriate intensity of statin therapy* should be used to reduce ASCVD risk *in those most likely to benefit*
- Quantitative comparison of statin benefits with statin risk
- Nonstatin therapies – did not provide ASCVD risk reduction benefits or safety profiles comparable to statin therapy

Why Not Continue to Treat to Target?

***Major difficulties*:**

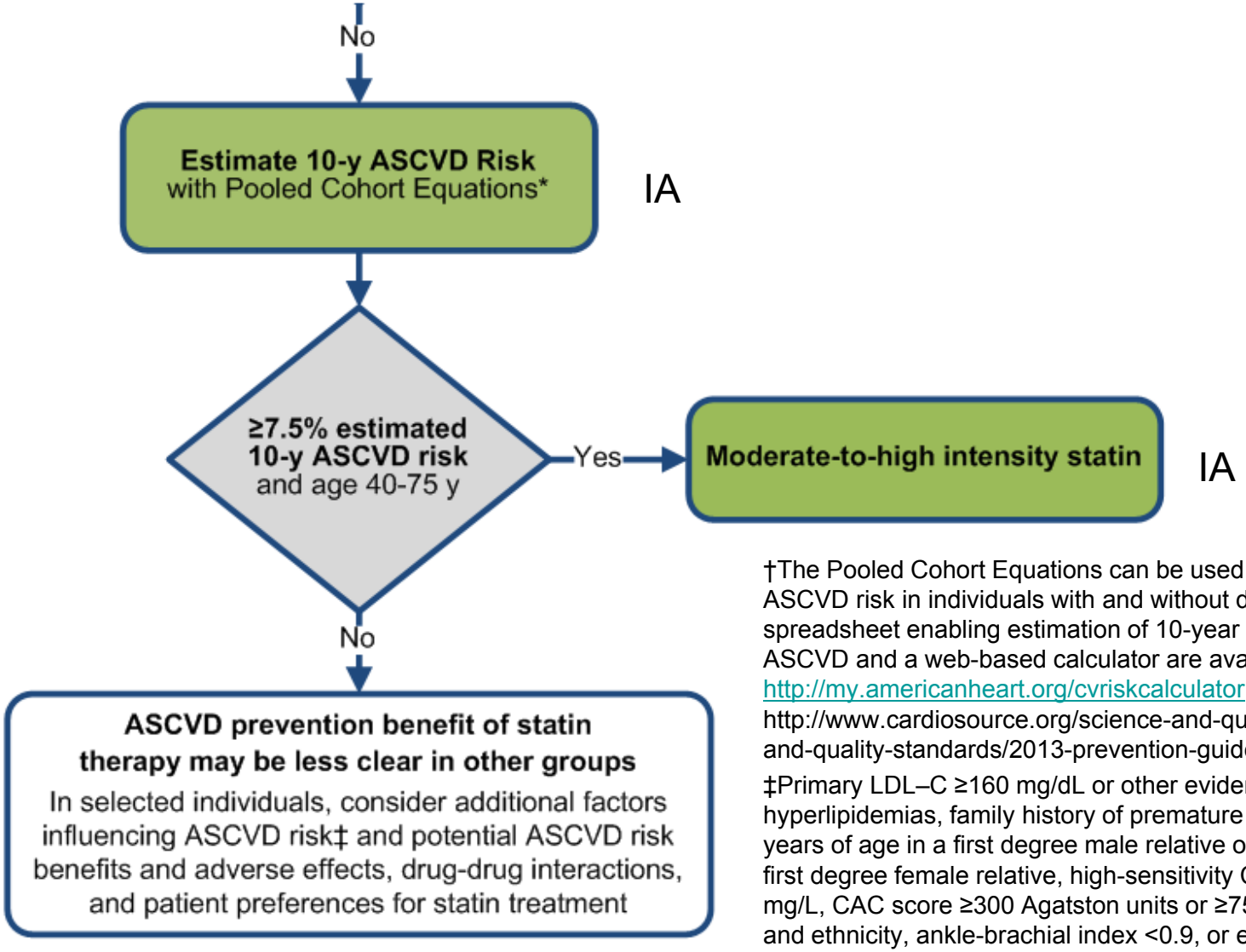
1. Current RCT data do not indicate what the target should be
2. Unknown magnitude of additional ASCVD risk reduction with one target compared to another
3. Unknown rate of additional adverse effects from multidrug therapy used to achieve a specific goal
4. Therefore, unknown net benefit from treat-to-target approach

4 Statin Benefit Groups



*Percent reduction in LDL–C can be used as an indication of response and adherence to therapy, but is not in itself a treatment goal.

4 Statin Benefit Groups (con't)



†The Pooled Cohort Equations can be used to estimate 10-year ASCVD risk in individuals with and without diabetes. A downloadable spreadsheet enabling estimation of 10-year and lifetime risk for ASCVD and a web-based calculator are available at http://my.americanheart.org/cvriskcalculator and http://www.cardiosource.org/science-and-quality/practice-guidelines-and-quality-standards/2013-prevention-guideline-tools.aspx.

‡Primary LDL–C ≥160 mg/dL or other evidence of genetic hyperlipidemias, family history of premature ASCVD with onset <55 years of age in a first degree male relative or <65 years of age in a first degree female relative, high-sensitivity C-reactive protein ≥2 mg/L, CAC score ≥300 Agatston units or ≥75 percentile for age, sex, and ethnicity, ankle-brachial index <0.9, or elevated lifetime risk of ASCVD.

Intensity of Statin Therapy

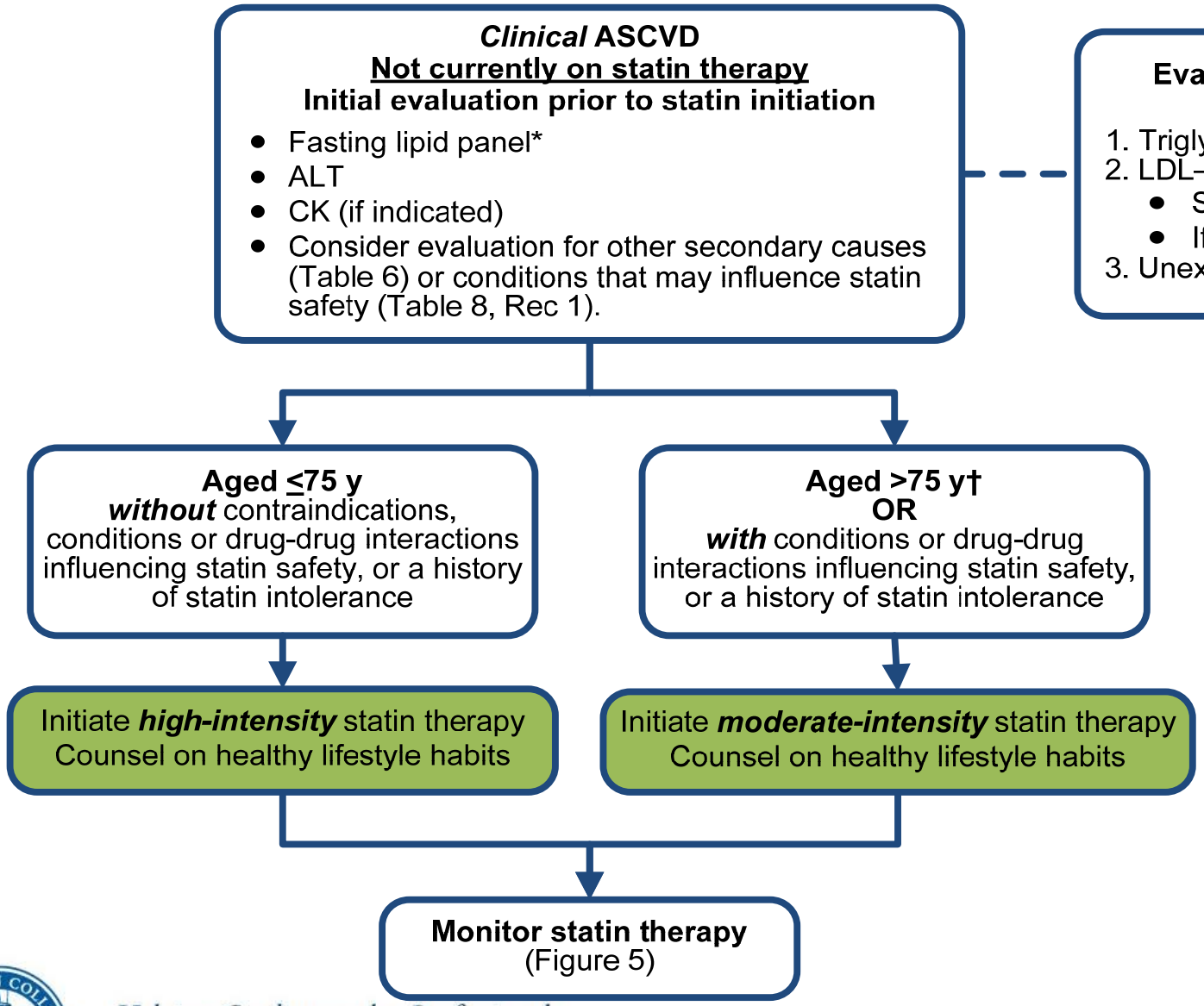
Table 5. High- Moderate- and Low-Intensity Statin Therapy (Used in the RCTs reviewed by the Expert Panel)*

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL–C on average, by approximately ≥50%	Daily dose lowers LDL–C on average, by approximately 30% to <50%	Daily dose lowers LDL–C on average, 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 mg** *Fluvastatin XL 80 mg* **Fluvastatin 40 mg bid** *Pitavastatin 2–4 mg*	*Simvastatin 10 mg* **Pravastatin 10–20 mg** **Lovastatin 20 mg** *Fluvastatin 20–40 mg* *Pitavastatin 1 mg*

*Individual responses to statin therapy varied in the RCTs and should be expected to vary in clinical practice. There might be a biologic basis for a less-than-average response.
†Evidence from 1 RCT only: down-titration if unable to tolerate atorvastatin 80 mg in IDEAL (Pedersen et al).
‡Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.

Clinical ASCVD

Initiating Statin therapy



*Fasting lipid panel preferred. In a nonfasting individual, a nonfasting non-HDL–C >220 mg/dL may indicate genetic hypercholesterolemia that requires further evaluation or a secondary etiology. If nonfasting triglycerides are >500 mg/dL, a fasting lipid panel is required.
†It is reasonable to evaluate the potential for ASCVD benefits and for adverse effects, and to consider patient preferences, in initiating or continuing a moderate- or high-intensity statin, in individuals with ASCVD >75 years of age.

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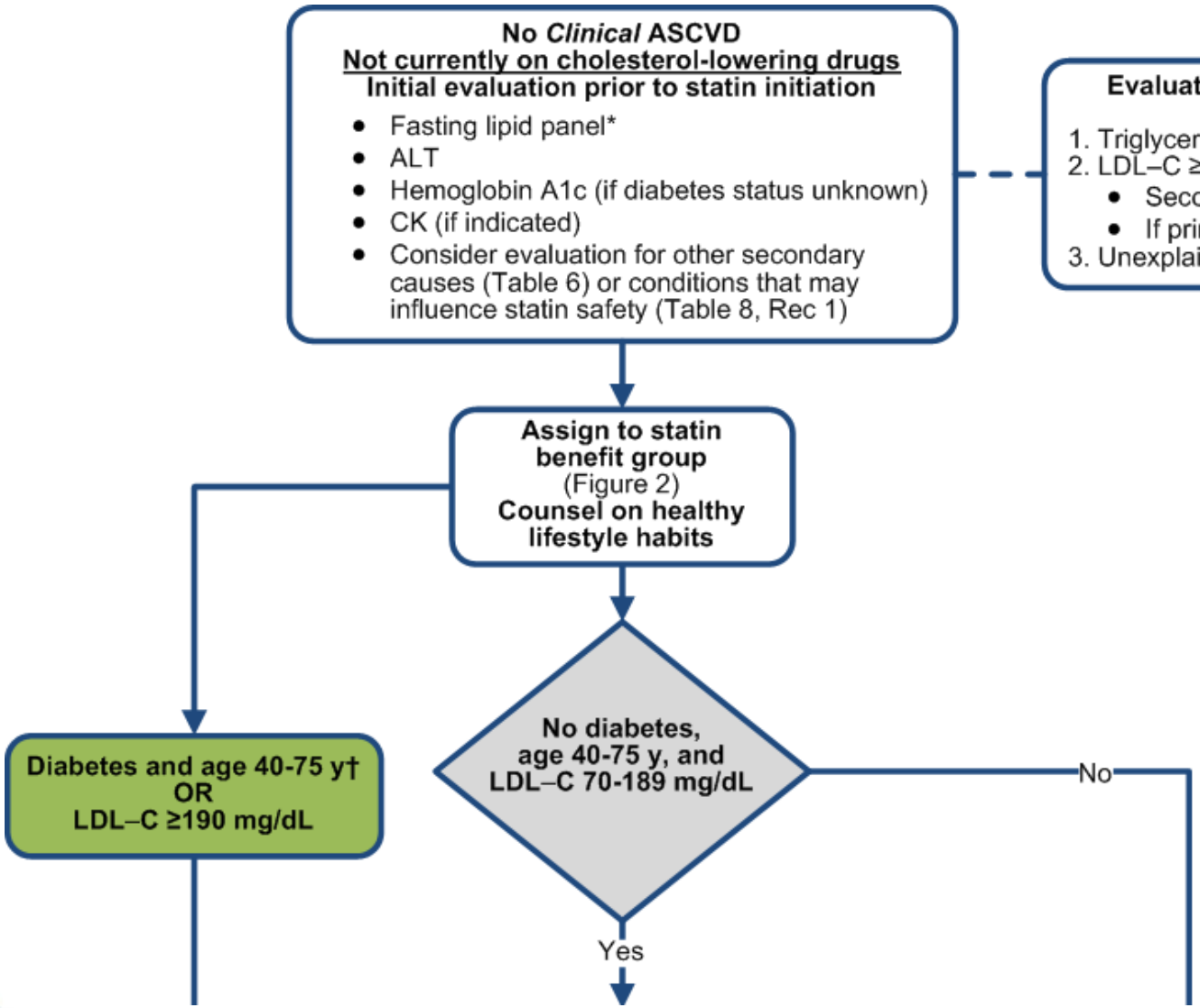
Primary Prevention

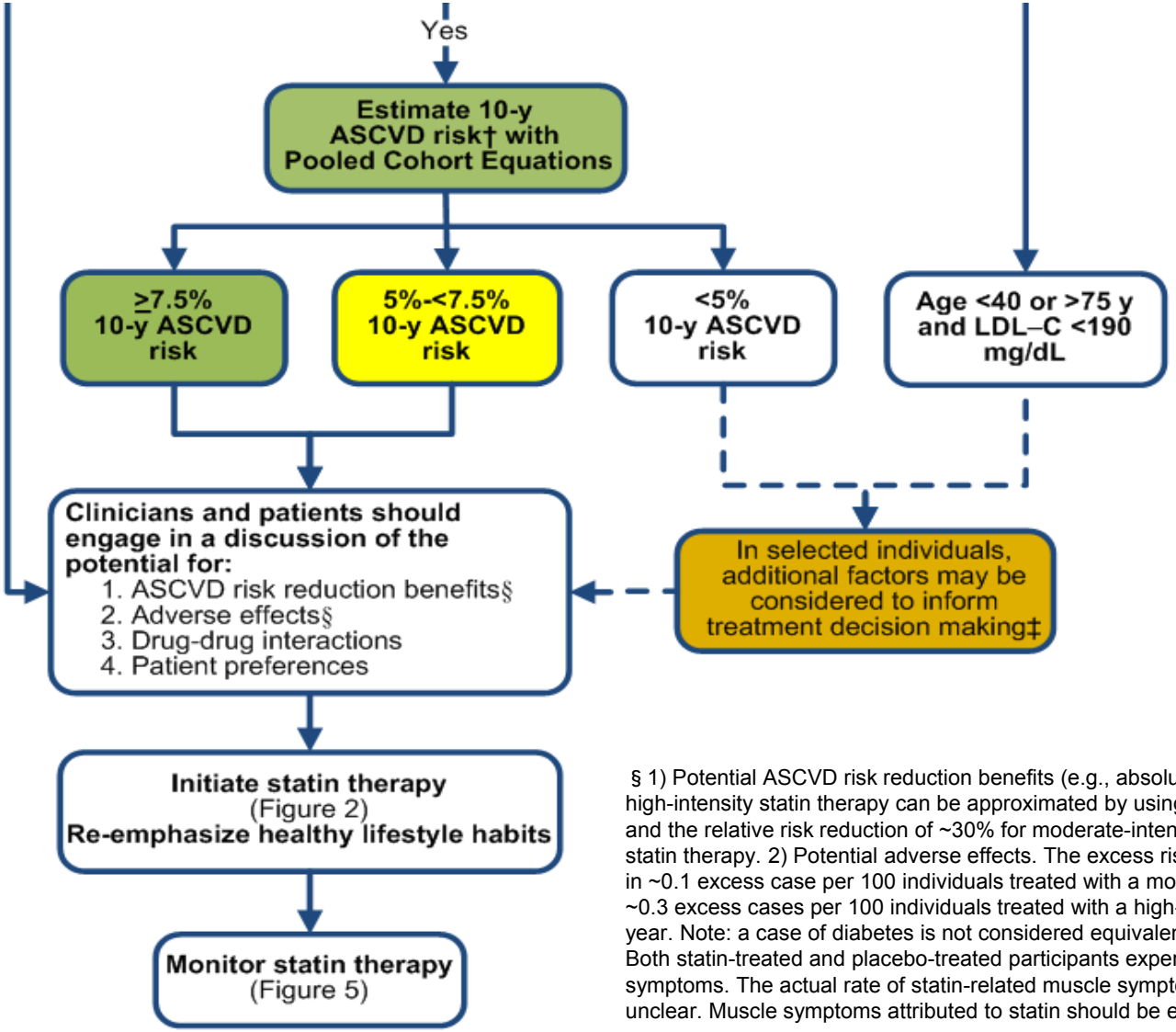
Initiating Statin Therapy



*Fasting lipid panel preferred. In a nonfasting individual, a nonfasting non-HDL–C >220 mg/dL may indicate genetic hypercholesterolemia that requires further evaluation or a secondary etiology. If nonfasting triglycerides are >500 mg/dL, a fasting lipid panel is required.

Primary Prevention

Initiating Statin Therapy (con't)



†The Pooled Cohort Equations can be used to estimate 10-year ASCVD risk in individuals with and without diabetes. A downloadable spreadsheet enabling estimation of 10-year and lifetime risk for ASCVD and a web-based calculator are available at http://my.americanheart.org/cvriskcalculator and http://www.cardiosource.org/science-and-quality/practice-guidelines-and-quality-standards/2013-prevention-guideline-tools.aspx.

‡These factors may include primary LDL–C ≥160 mg/dL or other evidence of genetic hyperlipidemias, family history of premature ASCVD with onset <55 years of age in a first degree male relative or <65 years of age in a first degree female relative, sensitivity-C-reactive protein ≥2 mg/L ≥300 Agatston units or ≥75 percentile for age, sex, and ethnicity (For additional information, see http://www.mesa-nhlbi.org/CACReference.aspx), ABI <0.9, or lifetime risk of ASCVD. Additional factors that may aid in individual risk assessment may be identified in the future.

§ 1) Potential ASCVD risk reduction benefits (e.g., absolute risk reduction from moderate- or high-intensity statin therapy can be approximated by using the estimated 10-year ASCVD risk and the relative risk reduction of ~30% for moderate-intensity statin or ~45% for high-intensity statin therapy. 2) Potential adverse effects. The excess risk of diabetes is the main consideration in ~0.1 excess case per 100 individuals treated with a moderate-intensity statin for 1 year and ~0.3 excess cases per 100 individuals treated with a high-intensity statin treated patients for 1 year. Note: a case of diabetes is not considered equivalent to a fatal or nonfatal MI or stroke. Both statin-treated and placebo-treated participants experienced the same rate of muscle symptoms. The actual rate of statin-related muscle symptoms in the clinical population is unclear. Muscle symptoms attributed to statin should be evaluated in Table 8, Safety Rec 8.

Primary Prevention
Global Risk Assessment

- To estimate 10-year *ASCVD** risk
  - New Pooled Cohort Risk Equations
  - White and black men and women
- More accurately identifies higher risk individuals for statin therapy
  - Focuses statin therapy on those most likely to benefit
  - You may wish to avoid initiating statin therapy in high-risk groups found not to benefit (higher grades of heart failure and hemodialysis)

* 10-year ASVD: Risk of first nonfatal myocardial infarction, coronary heart disease death, nonfatal or fatal stroke

Primary Prevention
Statin Therapy

- Thresholds for initiating statin therapy derived from 3 exclusively primary prevention RCTs
- Before initiating statin therapy, clinicians and patients engage in a discussion of the potential for ASCVD risk reduction benefits, potential for adverse effects, drug-drug interactions, and patient preferences

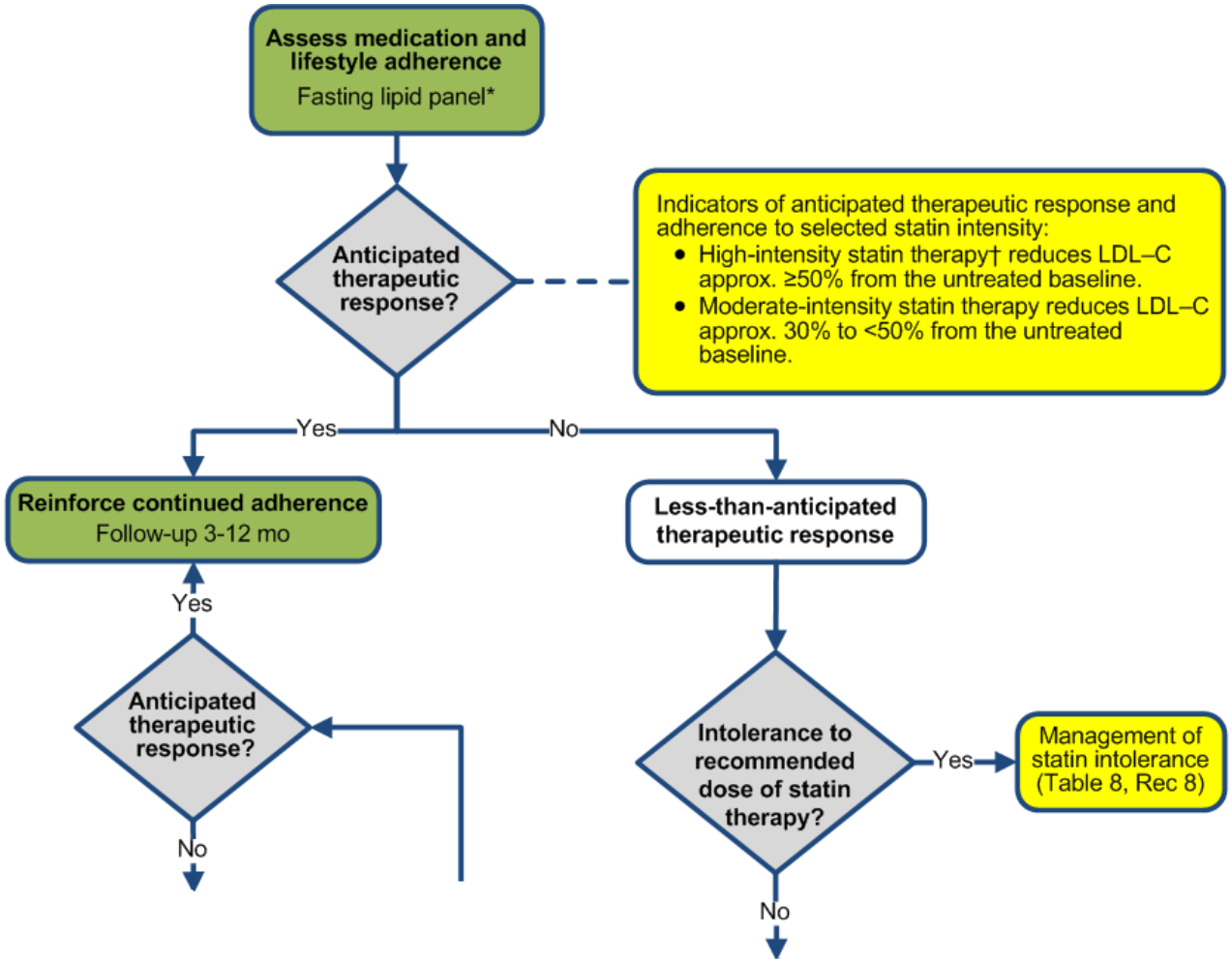
Individuals Not in a Statin Benefit Group

- In those not clearly in 1 of 4 statin benefit groups, additional factors may inform treatment decision-making:
  - *Family history of premature ASCVD*
  - *Elevated lifetime risk of ASCVD*
  - *LDL–C ≥160 mg/dL*
  - *hs-CRP ≥2.0 mg/L*
  - *Subclinical atherosclerosis*
    - *CAC score ≥300 or ABI<0.9*
- Discussion of potential for ASCVD risk reduction benefit, potential for adverse effects, drug-drug interactions, and patient preferences

Safety

- RCTs & meta-analyses of RCTs used to identify important safety considerations
- Allow estimation of **net benefit** from statin therapy
    - ASCVD risk reduction versus adverse effects
- Expert guidance on management of statin-associated adverse effects, including muscle symptoms
- Advise use of additional information including pharmacists, manufacturers prescribing information, & drug information centers for complex cases

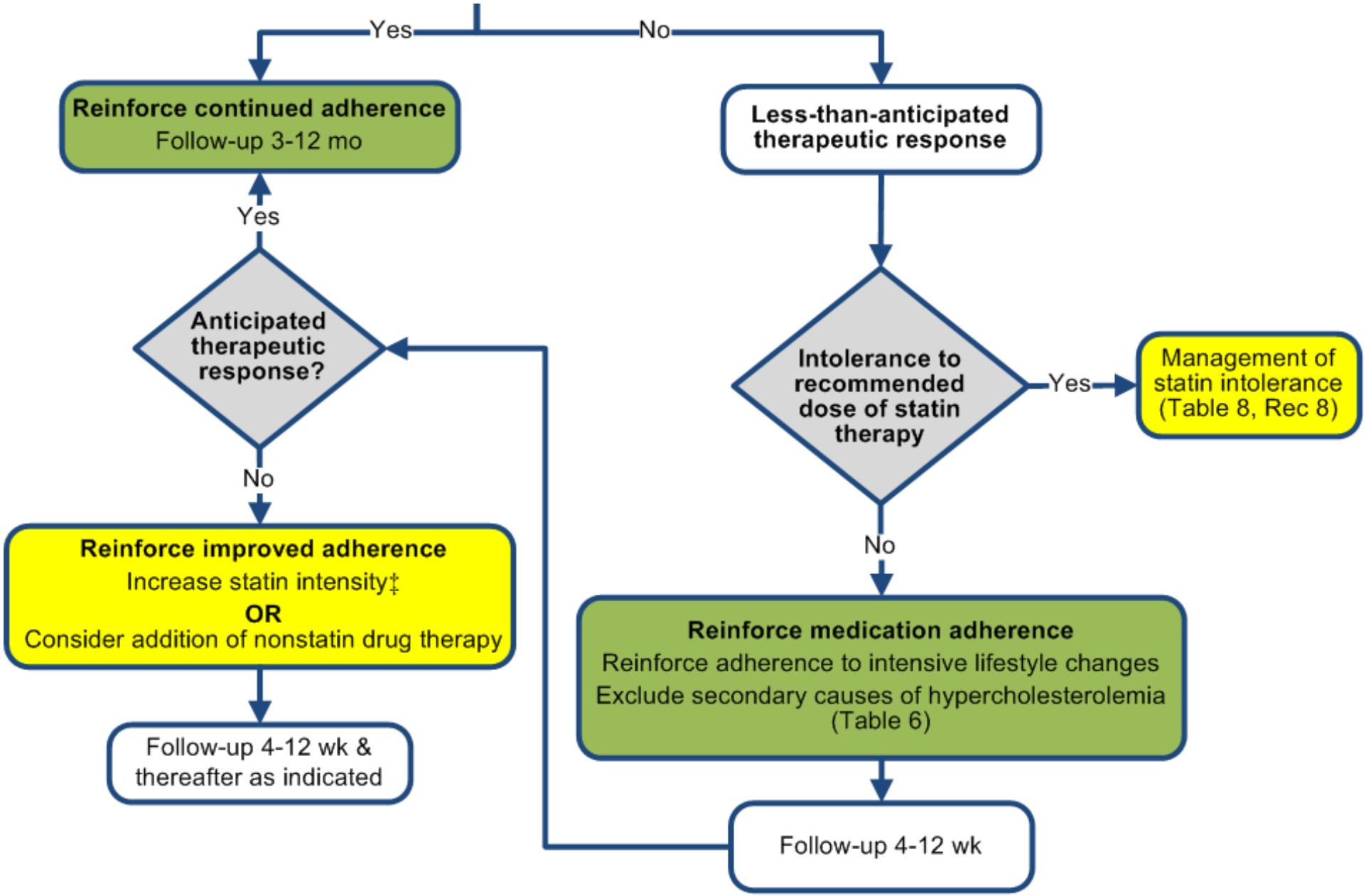
Statin Therapy: Monitoring Response and Adherence



*Fasting lipid panel preferred. In a nonfasting individual, a nonfasting non-HDL–C >220 mg/dL may indicate genetic hypercholesterolemia that requires further evaluation or a secondary etiology. If nonfasting triglycerides are >500 mg/dL, a fasting lipid panel is required.

†In those already on a statin, in whom baseline LDL–C is unknown, an LDL–C <100 mg/dL was observed in most individuals receiving high-intensity statin therapy in RCTs.

‡See guideline text



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Management of Muscle Symptoms on Statin Therapy

- It is reasonable to evaluate and treat muscle symptoms including pain, cramping, weakness, or fatigue in statin-treated patients according to the management algorithm
- To avoid unnecessary discontinuation of statins, obtain a history of prior or current muscle symptoms to establish a baseline before initiating statin therapy

Management of Muscle Symptoms on Statin Therapy (con't)

If unexplained severe muscle symptoms or fatigue develop during statin therapy:

- Promptly discontinue the statin
- Address possibility of rhabdomyolysis with:
  - CK
  - Creatinine
  - urine analysis for myoglobinuria

Management of Muscle Symptoms on Statin Therapy (con't)

If mild-to-moderate muscle symptoms develop during statin therapy:

- Discontinue the statin until the symptoms are evaluated
- Evaluate the patient for other conditions* that might increase the risk for muscle symptoms
- If after 2 months without statin Rx, muscle symptoms or elevated CK levels do not resolve completely, consider other causes of muscle symptoms

*Hypothyroidism, reduced renal or hepatic function, rheumatologic disorders such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency or primary muscle diseases

Statin-Treated Individuals
Nonstatin Therapy Considerations

- Use the maximum tolerated intensity of statin
- Consider addition of a nonstatin cholesterol-lowering drug(s)
  - If a less-than-anticipated therapeutic response persists
  - Only if ASCVD risk-reduction benefits outweigh the potential for adverse effects in higher-risk persons:
    - *Clinical* ASCVD <75 years of age
    - Baseline LDL–C ≥190 mg/dL
    - Diabetes mellitus 40 to 75 years of age
- Nonstatin cholesterol-lowering drugs shown to reduce ASCVD events in RCTs are preferred

Lessons From the Vignettes

ASCVD risk calculation NOT needed: JR6

- **Case 1: ASCVD** JR7
  - JR8 High-intensity statin therapy for optimal risk reduction in those ≤75 years who tolerate it
  - Moderate intensity may be initiated or continued if >75 yo or if high-intensity Rx not safe or not tolerated JR9
- **Case 2: LDL–C ≥190 mg/dL;** 2°causes ruled out JR10
  - Evidence supports high-intensity statin therapy
  - LDL–C levels may still remain very high, even after the intensity of statin therapy has been achieved; addition of a nonstatin drug may be considered to further lower LDL–C

Lessons From the Vignettes

ASCVD risk calculator useful:

- **Case 3: Diabetes; 40-75 yo; LDL–C 70-189 mg/dL** JR5
  - Moderate-intensity statin to be initiated or continued
  - High-intensity statin reasonable if estimated 10-year ASCVD risk calculated to be ≥7.5% JR11 JR12
- **Cases 4 & 5: Primary prevention; 40-75 yo; LDL–C 70-189 mg/dL**
  - Use Pooled Cohort Equations (risk calculator) to estimate 10-year ASCVD risk for African American and white individuals to guide initiation of statin therapy JR13
  - Clinician-patient discussion before treatment is initiated JR14
  - Moderate or high intensity statin when ≥7.5% 10-year ASCVD risk
  - Moderate intensity statin therapy reasonable when ≥5% 10-year ASCVD risk or when other characteristics that increase ASCVD risk are present JR3

Lessons From the Vignettes: Primary prevention - Not in statin benefit group

- **In selected individuals with LDL–C <190 mg/dL who are considered for primary prevention therapies:**
  - Not otherwise identified in a statin benefit group

    OR
  - After quantitative risk assessment, a risk-based treatment decision is uncertain

- **Moderate intensity statin therapy reasonable when 5 to <7.5% 10-yr ASCVD risk**
- **Additional factors that increase risk may be considered**
  - LDL ≥160 mg/dl, Family history of premature ASCVD, Lifetime risk of ASCVD, hs-CRP ≥2.0 mg/L, CAC score ≥300, or ABI ≤0.90

Lessons From the Vignettes: Primary prevention - Not in statin benefit group JR16

- **In selected individuals with LDL–C <190 mg/dL who are considered for primary prevention statin therapy:**
  - *Statin therapy may be considered* JR15 after evaluating the potential for ASCVD risk reduction benefits, adverse effects, drug-drug interactions, and discussion of patient preferences
  - Example of where guidelines inform clinical judgment but do not replace it

Slide 34

JR15 deleted repitittious wording
Jennifer G Robinson, 11/27/2013

JR16 there is not vignette for this example to confusing. changed header to refleft content
Jennifer G Robinson, 11/27/2013

Three Principles

- Do not focus on LDL-C or non-HDL-C levels as treatment goals
  - Although continue to to use LDL-C to monitor adherence
- Use medications proven to reduce ASCVD risk
- Drug treatment decisions in primary prevention based on *What Will Most Benefit the Patient*
  - Clinician-patient discussion needed in primary prevention

Future Updates to the Blood Cholesterol Guideline

- This is a comprehensive guideline for the evidence-based treatment of blood cholesterol to ***reduce ASCVD risk***
- These guidelines represent a change from previous guidelines
- For primary prevention, they are “patient-centered”
- Guidelines will change in the future as high-quality data will improve future cholesterol treatment guidelines