ICSI has endorsed with qualifications recommendations from two guidelines:

1. 2016 United States Preventive Services Task Force (USPSTF) recommendations on:
   a. Primary prevention for adults age 40-75

2. 2013 American College of Cardiology (ACC) / American Heart Association (AHA) recommendations on:
   a. Treatment targets
   b. Secondary prevention,
   c. Primary prevention for adults ≥ 21 years old with LDL ≥ 190 mg/dL
   d. Statin Safety
   e. Optimizing Statin Therapy
   f. Monitoring Statin Therapy
   g. Insufficient Response to Statin Therapy

ACC/AHA full citation:

USPSTF full citation:

The American College of Cardiology (ACC), the American Heart Association (AHA), and the United States Preventive Services Task Force (USPSTF) are not sponsors of, affiliated with, nor do they endorse ICSI or the ICSI Lipids Management in Adults work group. ACC, AHA, and the USPSTF have not reviewed ICSI’s process for endorsement of guidelines. The following ICSI endorsement and conclusions are solely the consensus of the ICSI Lipid Management in Adults work group using the ICSI endorsement process.

Using the ICSI endorsement process, this document has been reviewed by the ICSI Lipid Management in Adults work group: Canoniero M, Kottke T, Baechler C, Fabian K, Kofron P, Leslie S, O’Connor P, Stewart S, Zerr B.

Please note, the previous ICSI Lipid Management in Adults guideline from November 2013 is being retired.
# Health Care Guideline:
Lipid Management in Adults

## Table of Contents

**Foreword** ................................................................. 2-3
- Introduction ........................................................................ 2-3
- Methodology ....................................................................... 3
**Glossary** ......................................................................... 4
**Endorsement Summary Table** ........................................... 5-12
- ICSI Work Group Comments on Statins and New Onset Diabetes .................................................................................. 13
- ICSI Work Group Comments on Pooled Cohort Equation and Risk Assessment ................................................................. 13
- ICSI Work Group Comments on Non-Statin Therapies .............................................................................................................. 13-15
**Quality Improvement Support** ........................................... 16-20
- Aims and Measures ............................................................ 17
  - Measurement Specifications ................................................. 18-20
**Supporting Evidence** ....................................................... 21-30
- References ......................................................................... 22-24
- Appendix A – ICSI Shared Decision-Making Model .................. 25-30
**Disclosure of Potential Conflicts of Interest** .......................... 31-33
**Acknowledgements** ........................................................ 34
**Document History and Development** ................................. 35-36
- Document History ............................................................... 35
- ICSI Document Development and Revision Process ................. 36

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Foreword

The American College of Cardiology (ACC), the American Heart Association (AHA) and the United States Preventive Services Task Force (USPSTF) are not sponsors of, affiliated with, nor do they endorse ICSI or the ICSI Lipid Management in Adults work group. The ACC, AHA and the USPSTF have not reviewed ICSI’s process for endorsement of guidelines. The following ICSI endorsement and conclusions are solely the consensus of the ICSI Lipid Management in Adults work group using the ICSI endorsement process.

Introduction

According to the Centers for Disease Control and Prevention (CDC), approximately 71 million Americans have high LDL cholesterol and only one out of three of those with high LDL has the condition under control (CDC Fact Sheet). Fewer than 50% of adults with elevated LDL get treatment (CDC Fact Sheet). High cholesterol is a key risk factor for heart disease. Given the prevalence of hyperlipidemia and heart disease, the impact on patients and caregivers, and the health care resources they demand, clinical guidelines are critical to standardizing and improving care throughout health care systems.

It is important to note that there are several major guidelines regarding lipid management in adults, including those produced by the American College of Cardiology/American Heart Association (2013), the United States Preventive Services Task Force (2016), the European Society of Cardiology and European Atherosclerosis (2016), the Canadian Cardiovascular Society (2013), and the UK National Institute for Health and Care Excellence (2014) (Greenland, 2017).

We encourage health care systems and clinicians to understand the similarities and differences in these major guidelines and the guidelines’ approach to lipid management.

For this endorsement, the ICSI Lipid Management in Adults work group is endorsing with qualifications recommendations in two different guidelines:

- 2016 USPSTF recommendations on:
  - Primary prevention for adults age 40-75
- 2013 ACC/AHA recommendations on:
  - Treatment targets
  - Secondary prevention
  - Primary prevention for adults ≥ 21 years old with LDL ≥ 190mg/dL
  - Statin safety
  - Optimizing statin therapy
  - Monitoring statin therapy
  - Insufficient response to statin therapy

Conflict of Interest Considerations

The ICSI Lipid Management in Adults work group reviewed and discussed the conflict of interest disclosures by the authors for both ACC/AHA and USPSTF.
For the ACC/AHA guideline, conflict of interest disclosures by the authors and expert reviewers are on pages 2919-2922.

For the USPSTF, conflict of interest disclosures are found here: https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures.

Citations

**ACC/AHA full citation:**


**USPSTF full citation:**


*Return to Table of Contents*

**Methodology**

ACC/AHA and the USPSTF use their own system for classifying recommendations and evaluating the levels of evidence. In addition, because the ACC/AHA guideline was a collaboration with NHLBI, the NHLBI grading is provided as well. For the ACC/AHA guideline, the methodology is explained on pages 2890-2895. ICSI has provided the ACC/AHA grading in our endorsement document; for NHLBI grading, please refer to the original document. The USPSTF grading system is detailed here: https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions.

The ICSI work group conducted a literature search on the following terms: risk calculator and cholesterol, risk calculator and lipids, American College of Cardiology Risk Calculator, risk calculator and cardiovascular disease, risk calculator and heart disease, pooled cohort equations, pooled cohort equations and lipids, pooled cohort equations and cholesterol, ASCVD Risk Estimator and American College of Cardiology, non-statin therapy, non-statin drug, fibrates, ezetimibe, bile acid sequestrants, PCSK9 inhibitors, statin and hemodialysis, statin and chronic kidney disease, statin and heart failure, statin and creatine kinase, statin and liver function measurement, statin and hepatic transaminase levels, statin and diabetes, statin and breastfeeding, statin and lactation, statin and pregnancy, niacin, omega-3 fatty acids, omega-3, plant sterols and plant stenols.

The literature search included systematic reviews, meta-analysis, randomized controlled trials and observational trials from the dates of November 1, 2009, through August 1, 2016. There were no age constraints. In addition, work group members provided several articles not found in the literature search.

In instances where new literature was available to support the qualification/comment, that literature was cited. If there was no new literature on the topic, and the recommendation was still valid based on the existing practice and previous literature, no literature was cited.

*Return to Table of Contents*
Glossary

ALT: alanine aminotransferase

ASCVD: atherosclerotic cardiovascular disease. For the ACC/AHA guideline, ASCVD includes coronary heart disease, stroke, and peripheral artery disease – all of presumed atherosclerotic origin.

Clinical ASCVD: For the ACC/AHA guideline, this includes acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease presumed to be of atherosclerotic origin.

CK: creatine kinase

CVD: cardiovascular disease, i.e., symptomatic coronary artery disease or stroke

HDL-C: high-density lipoprotein cholesterol

LDL-C: low-density lipoprotein cholesterol

NYHA: New York Heart Association

ULN: upper limit normal

Please see ACC/AHA guideline, Table 5 on page 2902 (Stone, 2013) for a list of high-, moderate- and low-intensity statin therapy used in the RCTs reviewed by their expert panel.

Return to Table of Contents
## Endorsement Summary Table

### Treatment Targets

1. The expert panel makes no recommendation for or against specific LDL-C or non-HDL-C targets for the primary or secondary prevention of ASCVD.  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: ---

### Secondary Prevention

1. High-intensity statin therapy should be initiated or continued as first-line therapy in women and men ≤ 75 years of age who have clinical ASCVD, unless contraindicated. *(Class I; Level of Evidence A)*  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: Class I: Benefit>>Risk  
   - **Procedure/treatment** SHOULD be performed/administered.

2. In individuals with clinical ASCVD in whom high-intensity statin therapy would otherwise be used, when high-intensity statin therapy is contraindicated or when characteristics predisposing to statin-associated adverse effects are present, moderate-intensity stain should be used as the second option if tolerated. *(Class I; Level of Evidence A)*  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: Class I: Benefit>>Risk  
   - **Procedure/treatment** SHOULD be performed/administered.

3. In individuals with ASCVD > 75 years of age, it is reasonable to evaluate the potential for ASCVD risk-reduction benefits and for adverse effects and drug-drug interactions and to consider patient preferences when initiating a moderate- or high-intensity statin. It is reasonable to continue statin therapy in those who are tolerating it. *(Class IIa; Level of Evidence B)*  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: Class IIa: Benefit >> Risk  
   - **IT IS REASONABLE** to perform procedure/administer treatment.

### Primary Prevention in Individuals ≥ 21 Years of Age with LDL-C > 190 mg/Dl

1. Individuals with LDL-C ≥ 190 mg/dL or triglycerides ≥ 500 mg/dL should be evaluated for secondary causes of hyperlipidemia. *(Class I; Level of Evidence B)*  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: Class I: Benefit >> Risk  
   - **Procedure/treatment** SHOULD be performed/administered.

2. Adults ≥ 21 years of age with primary LDL-C ≥ 190 mg/dL should be treated with statin therapy (10-year ASCVD risk estimation is not required):  
   - Use high-intensity statin therapy unless contraindicated  
   - For individuals unable to tolerate high-intensity statin therapy, use the maximum tolerated statin therapy. *(Class I; Level of Evidence B)*  
   - **Original Author** of Recommendation: ACC/AHA  
   - **Grading Classification** of Recommendation: Class I: Benefit >> Risk  
   - **Procedure/treatment** SHOULD be performed/administered.  
   - The FDA recommends against the use of statins in pregnant and nursing women *(Food and Drug Administration, 2014)*. The ICSI work group advises clinical judgment be used in women of childbearing age not actively taking birth control.
<table>
<thead>
<tr>
<th>Recommendation (Grading Classification)</th>
<th>Original Author of Recommendation</th>
<th>Grading Classification of Recommendation</th>
<th>ICSI Lipids Work Group Qualification Statement/Comment</th>
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<tr>
<td>3. For individuals ≥ 21 years of age with an untreated LDL-C ≥ 190 mg/dL, it is reasonable to intensify statin therapy to achieve at least a 50% LDL-C reduction. <em>(Class IIa; Level of Evidence B)</em></td>
<td>ACC/AHA</td>
<td>Class IIa: Benefit &gt;&gt; Risk</td>
<td>The FDA recommends against the use of statins in pregnant and nursing women <em>(Food and Drug Administration, 2014)</em>. The ICSI work group advises clinical judgment be used in women of childbearing age not actively taking birth control.</td>
</tr>
<tr>
<td>4. For individuals ≥ 21 years of age with an untreated LDL-C ≥ 190 mg/dL, after the maximum intensity of statin therapy has been achieved, the addition of a non-statin drug may be considered to further lower LDL-C. Evaluate the potential for ASCVD risk-reduction benefits, adverse effects and drug-drug interactions, and consider patient preferences. <em>(Class IIb; Level of Evidence C)</em></td>
<td>ACC/AHA</td>
<td>Class IIb: Benefit ≥ Risk</td>
<td>Procedure/treatment MAY BE CONSIDERED.</td>
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</table>

**Primary Prevention in Individuals Aged 40 to 75**

1. Initiate use of low- to moderate-dose statins in adults aged 40 to 75 years without a history of CVD who have 1 or more risk factors (dyslipidemia*, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 10% or greater. *(B recommendation)*

   *Dyslipidemia: LDL-C >130 or a HDL < 40

   USPSTF | B recommendation: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | It is the consensus of the ICSI work group that a moderate-dose statin should be initiated, rather than low-dose, unless there is a contraindication. |

2. Clinicians selectively offer low- to moderate-dose statins to adults aged 40 to 75 years without a history of CVD who have 1 or more CVD risk factors (dyslipidemia, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 7.5% to 10%. *(C recommendation)*

   USPSTF | C recommendation: The USPSTF recommends selectively offering to provide this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | It is the consensus of the ICSI work group that a moderate-dose statin should be initiated, rather than low-dose, unless there is a contraindication. |
<table>
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<tr>
<th>Recommendation (Grading Classification)</th>
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<th>ICSI Lipids Work Group Qualification Statement/Comment</th>
</tr>
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<tbody>
<tr>
<td>3. Current evidence is insufficient to assess the balance of benefit and harms of initiating statin use in adults 76 years and older. (I recommendation)</td>
<td>USPSTF</td>
<td>I recommendation: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.</td>
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</table>

**Heart Failure and Hemodialysis**

<table>
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<th>Recommendation (Grading Classification)</th>
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<th>ICSI Lipids Work Group Qualification Statement/Comment</th>
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<tbody>
<tr>
<td>1. The expert panel makes no recommendation regarding the initiation or discontinuation of statins in patients with NYHA class II-IV ischemic systolic heart failure or in patients on maintenance hemodialysis.</td>
<td>ACC/AHA</td>
<td>---</td>
<td>Statin use in mild to moderate chronic kidney disease (eGFR greater than 30 ml/min) does reduce risk of major vascular events, but as renal function decreases, the reduction in risk of major vascular events from statin use decreases. There is limited evidence of benefit in patients already undergoing hemodialysis (<em>Cholesterol Treatment Trialists’ Collaboration</em>, 2016). In the CORONA trial, there was no evidence that rosuvastatin reduced the number of deaths from any cause in older patients with ejection fraction less than 40% (<em>Rogers</em>, 2014).</td>
</tr>
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*Return to Table of Contents*
### Statin Safety

1. To maximize the safety of statins, selection of the appropriate statin and dose in men and non-pregnant/non-nursing women should be based on patient characteristics, level of ASCVD risk and potential for adverse effects. Moderate-intensity statin therapy should be used in individuals in whom high-intensity statin therapy would otherwise be recommended when characteristics predisposing them to statin-associated adverse effects are present.

Characteristics predisposing individuals to statin adverse effects include but are not limited to:

- Multiple or serious comorbidities, including impaired renal or hepatic function
- History of previous statin intolerance or muscle disorders
- Unexplained ALT elevations ≥ 3 times ULN
- Patient characteristics or concomitant use of drugs affecting statin metabolism
- Age >75 years

Additional characteristics that could modify the decision to use higher statin intensities might include but are not limited to:

- History of hemorrhagic stroke
- Asian ancestry  

**(Class I; Level of Evidence B)**

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<tr>
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<tbody>
<tr>
<td>ACC/AHA</td>
<td>Class I:</td>
<td>Benefit &gt;&gt;&gt; Risk</td>
<td>Procedure/treatment SHOULD be performed/administered.</td>
</tr>
</tbody>
</table>

2a. CK should not be routinely measured in individuals receiving statin therapy.  

**(Class III; Level of Evidence A)**

2b. Baseline measurement of CK is reasonable for individuals believed to be at increased risk for adverse muscle events because of a personal or family history of statin intolerance or muscle disease, clinical presentation or concomitant drug therapy that might increase the risk of myopathy.  

**Class IIa: Benefit >> Risk**  

**IT IS REASONABLE to perform procedure/administer treatment.**

2c. During statin therapy, it is reasonable to measure CK in individuals with muscle symptoms, including pain, tenderness, stiffness, cramping, weakness or generalized fatigue.  

**Class IIa: Benefit >> Risk**  

**IT IS REASONABLE to perform procedure/administer treatment.**  

If CK values are greater than 10 times the upper limit of normal (unrelated to secondary causes such as unusual or excessive exercise), statin therapy should be stopped, at least temporarily  

**Medical Letter, The, 2016.**

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Return to Table of Contents
### Endorsement Summary Table

<table>
<thead>
<tr>
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<tr>
<td><strong>Statin Safety</strong></td>
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<tr>
<td>3a. Baseline measurement of hepatic transaminase levels (ALT) should be performed before initiation of statin therapy. <em>(Class I; Level of Evidence B)</em></td>
<td>ACC/AHA</td>
<td>Class I: Benefit &gt;&gt;&gt; Risk Procedure/Treatment SHOULD be performed/administered.</td>
<td></td>
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<tr>
<td>3b. During statin therapy, it is reasonable to measure hepatic function if symptoms suggesting hepatotoxicity arise (e.g., unusual fatigue or weakness, loss of appetite, abdominal pain, dark-colored urine or yellowing of the skin or sclera). <em>(Class IIa; Level of Evidence C)</em></td>
<td>ACC/AHA</td>
<td>Class IIa: Benefit &gt;&gt; Risk IT IS REASONABLE to perform procedure/administer treatment.</td>
<td></td>
</tr>
<tr>
<td>4. Decreasing the statin dose may be considered when two consecutive values of LDL-C levels are &lt; 40 mg/dL. <em>(Class IIb; Level of Evidence C)</em></td>
<td>ACC/AHA</td>
<td>Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.</td>
<td></td>
</tr>
<tr>
<td>5. It may be harmful to initiate simvastatin at 80 mg daily or increase the dose of simvastatin to 80 mg daily. <em>(Class III; Level of Evidence A)</em></td>
<td>ACC/AHA</td>
<td>Class III: Harm</td>
<td>Please see the ICSI Lipid Management for Adults work group “Comments on Statin and New Onset Diabetes” for a more detailed discussion.</td>
</tr>
<tr>
<td>6. Individuals receiving statin therapy should be evaluated for new-onset diabetes according to the current diabetes screening guidelines (American Diabetes Association). Those who develop diabetes during statin therapy should be encouraged to adhere to a heart-healthy dietary pattern, engage in physical activity, achieve and maintain a healthy body weight, cease tobacco use and continue statin therapy to reduce their risk of ASCVD events. <em>(Class I; Level of Evidence B)</em></td>
<td>ACC/AHA</td>
<td>Class I: Benefit &gt;&gt;&gt; Risk Procedure/Treatment SHOULD be performed/administered.</td>
<td></td>
</tr>
<tr>
<td>7. For individuals taking any dose of statins, it is reasonable to use caution in individuals &gt; 75 years of age, as well as in individuals who are taking concomitant medications that alter drug metabolism, taking multiple drugs or taking drugs for conditions that require complex medication regimens (e.g., those who have undergone solid organ transplantation or are receiving treatment for HIV). A review of the manufacturer’s prescribing information may be useful before initiation of any cholesterol-lowering drug. <em>(Class IIa; Level of Evidence C)</em></td>
<td>ACC/AHA</td>
<td>Class IIa: Benefit &gt;&gt; Risk IT IS REASONABLE to perform procedure/administer treatment.</td>
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*Return to Table of Contents*
8. It is reasonable to evaluate and treat muscle symptoms – including pain, tenderness, stiffness, cramping, weakness or fatigue – in statin-treated patients according to the following management algorithm:

- To avoid unnecessary discontinuation of statins, obtain a history of prior or current muscle symptoms to establish a baseline before initiation of statin therapy.
- If unexplained severe muscle symptoms or fatigue develop during statin therapy, promptly discontinue the statin and address the possibility of rhabdomyolysis by evaluating CK and creatinine, and performing urinalysis for myoglobinuria.
- If mild to moderate muscle symptoms develop during statin therapy:
  - Discontinue the statin until the symptoms can be evaluated.
  - Evaluate the patient for other conditions that might increase the risk for muscle symptoms (e.g., hypothyroidism, reduced renal or hepatic function, rheumatologic disorders such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle diseases).
  - If muscle symptoms resolve, and if no contraindication exists, give the patient the original or a lower dose of the same statin to establish a causal relationship between the muscle symptoms and statin therapy.
  - If a causal relationship exists, discontinue the original statin. Once muscle symptoms resolve, use a low dose of a different statin.
  - Once a low dose of a statin is tolerated, gradually increase the dose as tolerated.
  - If, after 2 months without statin treatment, muscle symptoms or elevated CK levels do not resolve completely, consider other causes of muscle symptoms listed above.
  - If persistent muscle symptoms are determined to arise from a condition unrelated to statin therapy, or if the predisposing condition has been treated, resume statin therapy at the original dose.

(Class IIa; Level of Evidence B)
### Lipid Management in Adults

Endorsement Summary Table

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>9. For individuals presenting with a confusional state or memory impairment while on statin therapy, it may be reasonable to evaluate the patient for non-statin causes, such as exposure to other drugs, as well as for systemic and neuropsychiatric causes, in addition to the possibility of adverse effects associated with statin drug therapy. (Class IIb; Level of Evidence C)</td>
<td>ACC/AHA</td>
<td>Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.</td>
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</tbody>
</table>

### Monitoring Statin Safety

1. Adherence to medication and lifestyle, therapeutic response to statin therapy, and safety should be regularly assessed. This should also include a fasting lipid panel performed within 4-12 weeks after initiation or dose adjustment and every 3-12 months thereafter. Other safety measurements should be measured as clinically indicated. (Class I; Level of Evidence A) | ACC/AHA | Class I: Benefit >>> Risk Procedure/Treatment SHOULD be performed/administered. | The work group agrees that a fasting lipid panel should be performed within 4-12 weeks after initiation or dose adjustment. However, because evidence is lacking regarding a specific testing interval, the timing of follow-up lipid testing should be done at the discretion of the clinician. |

### Optimizing Statin Safety

1. The maximum tolerated intensity of statin should be used in individuals for whom a high- or moderate-intensity statin is recommended but not tolerated. (Class I; Level of Evidence B) | ACC/AHA | Class I: Benefit >>> Risk Procedure/Treatment SHOULD be performed/administered. |  |

### Insufficient Response to Statin Therapy

1. In individuals who have a less-than-anticipated therapeutic response or are intolerant of the recommended intensity of statin therapy, the following should be performed:
   - Reinforce medication adherence.
   - Reinforce adherence to intensive lifestyle changes.
   - Exclude secondary causes of hyperlipidemia. (Class I; Level of Evidence A) | ACC/AHA | Class I: Benefit >>> Risk Procedure/Treatment SHOULD be performed/administered. |  |
2. It is reasonable to use the following as indicators of anticipated therapeutic response to the recommended intensity of statin therapy. Focus is on the intensity of the statin therapy. As an aid to monitoring:
- High-intensity statin therapy generally results in an average LDL-C reduction of $\geq 50\%$ from the untreated baseline.
- Moderate-intensity statin therapy generally results in an average LDL-C reduction of 30% to < 50% from the untreated baseline.
- LDL-C levels and percents reduction are to be used only to assess response to therapy and adherence. They are not to be used as performance standards.

*(Class IIa; Level of Evidence B)*

3. In individuals at higher ASCVD risk receiving the maximum tolerated intensity of statin therapy who continue to have a less-than-anticipated therapeutic response, addition of non-statin cholesterol-lowering drug(s) may be considered if the ASCVD risk-reduction benefits outweigh the potential for adverse effects. Higher-risk individuals include:
- Individuals with clinical ASCVD < 75 years of age
- Individuals with baseline LDL-C $\geq 190$ mg/dL
- Individuals 40-75 years of age with diabetes

Preference should be given to nonstatin cholesterol-lowering drugs shown to reduce ASCVD events in RCTs.

*(Class IIb; Level of Evidence C)*

4. In individuals who are candidates for statin treatment but are completely statin intolerant, it is reasonable to use non-statin cholesterol-lowering drugs that have been shown to reduce ASCVD events in RCTs if the ASCVD risk-reduction benefits outweigh the potential for adverse effects.

*(Class IIa; Level of Evidence B)*
Comments on Statins and New Onset Diabetes

Meta-analyses have demonstrated that statins increase the risk for new-onset diabetes in a dose-dependent fashion, at 9% for moderate intensity compared with placebo and 12% for high-intensity compared with moderate-intensity (Priess, 2011; Sattar, 2010). It is important to weigh this increase in diabetes risk with the benefit of statins in reducing atherosclerotic cardiovascular events, which according to the Cholesterol Treatment Trialists’ has been shown to be 21% for moderate-intensity statins and 15% with high-intensity statins (Cholesterol Treatment Trialists’ Collaboration, 2010; Cholesterol Treatment Trialists’ Collaboration, 2005). In absolute terms, with moderate-intensity statins there are five fewer ASCVD events for every one additional case of diabetes, and with high-intensity statins there are three fewer ASCVD events for every one additional case of diabetes (Priess, 2011; Sattar, 2010). These differences should be included in a risk-benefit discussion when considering initiation of statin therapy.

In post-hoc analyses of several randomized clinical trials, it has been shown that the increased risk for diabetes is limited to patients who have risk factors for diabetes at baseline (impaired fasting glucose, elevated triglycerides, elevated BMI, elevated blood pressure). In the JUPITER trial, there were no cases of diabetes diagnosed in the patients who had no risk factors at the time of study enrollment. Additionally, 86 total ASCVD events were prevented (Ridker, 2012). Likewise, in the TNT and IDEAL trials the risk for new-onset diabetes was increased with high-intensity statins in patients with 2-4 risk factors but not with 0-1 risk factors for diabetes at baseline (Waters, 2013).

For patients with diabetes risk factors at baseline, statins should be used in accordance with the 2013 ACC/AHA guidelines for the treatment of blood cholesterol after a risk-benefit discussion. Emphasis should also be placed on lifestyle modifications shown to effectively prevent the development of diabetes, namely at least 150 minutes of physical activity per week and a 7.5% weight loss (Bray, 2002). Appropriate monitoring should be conducted to measure plasma glucose concentrations.

Comments on Pooled Cohort Equation and Risk Assessment

The pooled cohort equation calculator is a way to initiate a conversation about treatment using shared decision-making. Although not included in the pooled cohort equation, family history of atherosclerotic cardiovascular disease with onset < 55 years of age in first-degree male relative or < 65 years of age in a first-degree female relative may also be considered. Additional risk factors that also may be considered by the clinician include primary LDL-C ≥ 160mg/dL or other evidence of genetic hyperlipidemia; high-sensitivity C-reactive protein ≥ 2mg/L; coronary artery calcium (CAC) score ≥ 300 Agatston units or ≥ 75th percentile for age, sex and ethnicity; ankle-brachial index (ABI) < 0.9; or lifetime risk of ASCVD (ACC/AHA, 2013).

Comments on Non-Statin Therapy

Ezetimibe

For patients with stable ASCVD who have not achieved their goal reduction in LDL-C on maximum tolerated statin dose, ezetimibe can be considered. Although clinical endpoint trials of statin plus ezetimibe have not been conducted for patients without a clinical diagnosis of ASCVD, the ICSI work group believes that it is appropriate to consider prescribing ezetimibe for patients who have not achieved their LDL-C goals on maximally tolerated dose of statin alone.

Fibrates

In 2016, the FDA withdrew its approval of the indications related to the co-administration with a statin for fenofibric acid delayed-release capsules (Food and Drug Administration, 2016). While the FDA has concluded that the benefit of adding fenofibrate to a statin does not outweigh the risk for most patients, the
ACCORD trial has found, in post-hoc analysis, that the combination is associated with lower mortality in diabetic patients with triglycerides > 204 mg/dl and an HDL level < 34 mg/dl (Elam, 2017). Therefore, the ICSI work group recommends that the combination be used in this sub-population. Renal status (creatinine and eGFR) should be assessed before initiating fenofibrate and periodically thereafter, and dosing should be adjusted for renal function (ACC/AHA, 2013). Addition of fenofibrate to a statin may be considered in patients with and without diabetes who have triglycerides ≥ 500 mg/dL (ACC/AHA, 2013).

The ICSI work group agrees with the ACC/AHA recommendation that due to concerns for muscle symptoms and rhabdomyolysis, gemfibrozil should be not initiated in patients on statin therapy (ACC/AHA, 2013).

PCSK-9 Inhibitors

The proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors alirocumab and evolocumab have been studied in a variety of patient populations including:

- Patients with heterozygous (Raal, 2015; Raal, 2012; Stein, 2012a; Stein, 2012b) and homozygous (Raal, 2015) familial hypercholesterolemia (FH) on maximally-tolerated statin
- Patients at high cardiovascular risk on maximally tolerated statin dose not achieving LDL-C targets of < 70 mg/dL or < 100 mg/dL (Cannon, 2015; Kereiakes, 2015; Robinson, 2015; Hirayama, 2014; Robinson, 2014)
- Patients at varied cardiovascular risk on maximally tolerated statin not achieving LDL-C targets of < 70 mg/dL or < 100 mg/dL (Robinson, 2014; Giugliano, 2012; McKenney, 2012; Roth, 2012)
- Patients at varied cardiovascular risk unable to take a statin due to intolerance (Nissen, 2016; Moriyarty, 2015; Stroes, 2015; Sullivan, 2012)

A recent systematic review of the randomized controlled trials with alirocumab and evolocumab found low-to-high-strength evidence of moderate- to large-magnitude of reduction in LDL-C when added to maximally tolerated statin therapy in both patients with familial hypercholesterolemia or at high risk for cardiovascular disease events. Alirocumab 75 mg to 150 mg subcutaneously every two weeks and evolocumab 120 mg subcutaneously every two weeks to 420 mg every four weeks resulted in LDL-C reductions of 8-67% and 32-71% respectively. The evidence is stronger for alirocumab in patients at high cardiovascular risk not at LDL-C target, and the evidence is stronger for evolocumab in patients with heterozygous familial hypercholesterolemia and patients with varied cardiovascular risk not at LDL-C target (McDonagh, 2016). Evidence is strongest for patients with heterozygous familial hypercholesterolemia. Evidence for use in statin-intolerant patients is stronger with evolocumab than alirocumab. The current evidence for cardiovascular events is limited as the available randomized controlled trials adjudicated them as secondary outcomes and were not sufficiently designed for proper assessment (Cannon, 2015; Kereiakes, 2015; Robinson, 2015; Sabatine, 2015; Hirayama, 2014). Large randomized controlled trials powered to detect cardiovascular outcomes are underway and results are expected sometime in 2017.

At this time it is difficult to interpret the benefit of incremental reductions in LDL-C beyond that achieved with a statin for several reasons, including recent guidelines suggesting that lipid-lowering therapy be directed at absolute risk not LDL-C targets, lack of maximization of statin therapy in the control group, and the lack of good-quality evidence on cardiovascular outcomes with the PCSK9 inhibitors. Thus, while PCSK9 inhibitors provide significant LDL-C lowering, the currently available evidence on the benefits and harms of the PCSK9 inhibitors is insufficient to make conclusions on their place in therapy. Alirocumab and evolocumab should currently be used according to their FDA-approved labeling.

There is a signal toward adverse cognitive effects in the larger studies of the PCSK9 inhibitors with longer follow-up. A recent meta-analysis of 11 studies (nine smaller early-phase and two larger outcome trials) suggested a statistically significant increased incidence of neurocognitive adverse effects. However, the
overall incidence of these effects was low (<1% in both groups), they were self-reported by the study participants, and no baseline cognitive assessment was obtained (Khan, 2017). The ongoing large-scale randomized controlled outcomes trials of the PCSK9 inhibitors as well as specifically designed trials to assess cognitive function will provide more definitive results on the incidence and severity of these neurocognitive effects and help identify susceptible subgroups (Sabatine, 2016; Schwartz, 2014).

**Niacin**

According to a 2016 summary in the Medical Letter, a meta-analysis of 11 randomized controlled trials found that use of niacin had a beneficial effect for secondary prevention of cardiovascular events, but the included trials varied in size and quality (Medical Letter, The, 2016). By contrast, in the HPS2-THRIVE study, the addition of niacin and laropipant to statin therapy for patients with atherosclerotic cardiovascular disease did not reduce the incidence of major vascular events but did increase the risk of serious adverse events (HPS2-THRIVE Collaborative Group, 2014). Likewise, in the AIM-HIGH study, patients with atherosclerotic cardiovascular disease and LDL-C less than 70 mg/dL, there was no incremental clinical benefit of the addition of niacin to a statin despite improvements in HDL and triglyceride levels (AIM-HIGH Investigators, 2011). In 2016, the FDA withdrew its approval of the indications related to the co-administration with a statin for niacin extended-release (Food and Drug Administration, 2016).

Because of safety concerns and lack of efficacy, niacin is not recommended for use in combination with a statin. Use of niacin as monotherapy may be considered in specific circumstances best left to the discretion of the clinician.

**Bile acid sequestrants**

It is the consensus of the ICSI Lipid Management in Adults work group that bile acid sequestrants should be considered only after other therapies have been tried.

**Omega-3 fatty acids**

According to a 2016 summary by the Medical Letter, the results of clinical trials do not offer convincing evidence that fish oil supplements prevent cardiovascular disease or improve outcomes in patients with cardiovascular disease (Medical Letter, The, 2016).

**Plant stanols**

Plant stanols and plant stanol esters have been found to reduce LDL cholesterol by up to 17% if consumed in doses that exceed 2 grams per day (Musa-Veloso, 2011). While one systematic review and meta-analysis concluded that the LDL cholesterol-lowering effect of plant stanols and plant stanol esters is significantly greater than that of plant sterols and plant sterol esters, at least one other systematic review and meta-analysis has concluded that they are equally effective (Talati, 2010).
The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivision of this section is:

- Aims and Measures
Aims and Measures

1. Increase the percentage of patients with or at high risk for atherosclerotic disease that are on statin therapy.

Measures for accomplishing this aim:

a. Percentage of patients ≤ 75 years of age who have clinical ASCVD and are prescribed statin therapy.
   Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

b. Percentage of patients ≥ 21 years of age with primary LDL-C ≥ 190 mg/dL who are prescribed statin therapy.
   Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

c. Percentage of patients ages 40 to 75 years without a history of CVD who have one or more risk factors (e.g., dyslipidemia, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 10% or greater and are prescribed statin therapy.
   Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Return to Table of Contents
Measurement Specifications

Measurement #1a
Percentage of patients ≤ 75 years of age who have clinical ASCVD and are prescribed statin therapy.

Population Definition
Patients ≤ 75 years of age who have clinical ASCVD. Exclusion: Patients for which there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Data of Interest

\[
\text{\# of patients prescribed statin therapy} \quad \text{\# of patients \leq 75 years of age who have clinical ASCVD}
\]

Numerator/Denominator Definitions
Numerator: Number of patients who are prescribed statin therapy. See ACC/AHA definitions for statin definitions.

Denominator: Number of patients ≤ 75 years of age who have clinical ASCVD.
Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Method/Source of Data Collection
Review EHR for patients meeting criteria in the denominator and determine the number of patients meeting the numerator criteria.

Time Frame Pertaining to Data Collection
Monthly.

Notes
This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents
Measurement #1b
Percentage of patients ≥ 21 years of age with primary LDL-C ≥ 190 mg/dL who are prescribed statin therapy.

Population Definition
Patients ≥ 21 years of age with primary LDL-C ≥ 190 mg/dL.
Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Data of Interest
\[
\frac{\text{# of patients prescribed statin therapy}}{\text{# of patients} \geq 21 \text{ years of age with primary LDL-C} \geq 190 \text{ mg/dL}}
\]

Numerator/Denominator Definitions
Numerator: Number of patients who are prescribed statin therapy. See ACC/AHA definitions for statin definitions.
Denominator: Number of patients ≥ 21 years of age with primary LDL-C ≥ 190 mg/dL.
Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Method/Source of Data Collection
Review EHR for patients meeting criteria in the denominator and determine the number of patients meeting the numerator criteria.

Time Frame Pertaining to Data Collection
Monthly.

Notes
This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents
Measurement #1c

Percentage of patients ages 40 to 75 years without a history of CVD who have one or more risk factors (e.g., dyslipidemia, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 10% or greater and are prescribed statin therapy.

Population Definition

Patients ages 40 to 75 years without a history of CVD who have one or more risk factors (e.g., dyslipidemia, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 10% or greater.

Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Data of Interest

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Numerator/Denominator Definitions

Numerator: Number of patients who are prescribed statin therapy.

Denominator: Number of patients aged 40 to 75 years without a history of CVD who have one or more risk factors (dyslipidemia, diabetes, hypertension, smoking) and a calculated 10-year CVD event risk of 10% or greater.

Exclusion: Patients for whom there is documentation that statin therapy is contraindicated or not tolerated, including those who are pregnant or at risk for pregnancy.

Method/Source of Data Collection

Review EHR for patients meeting criteria in the denominator and determine the number of patients meeting the numerator criteria.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents
The subdivisions of this section are:

- References
- Appendices
References


*Return to Table of Contents*


Appendix A – ICSI Shared Decision-Making Model

The Collaborative Conversation™ Shared Decision-Making and the Translation of Evidence into Practice

A consistent finding from clinical and health services research is the failure to translate research into practice. The translation of evidence into practice can be advanced through the use of shared decision-making since shared decision-making results in evidence being incorporated into patient and clinician consultations.

Shared decision-making (SDM) is a process in which patient and clinicians collaborate to clarify all acceptable options, ensure that the patient is well-informed and chose a course of care consistent with patient values and preferences and the best available medical evidence. (Minnesota Shared Decision-Making Collaborative [MSDMC], 2011).

Evidence-based guidelines may recommend the use of shared decision-making for decisions in instances where the evidence is equivocal, when patient action or inaction (such as medication adherence or lifestyle changes) can impact the potential outcome, or when the evidence does not indicate a single best recommendation.

SDM is a patient-centered approach that involves a conversation between the patient and the clinician. It is ideal to involve caregivers and family members in these conversations as well. Family members and caregivers can participate in discussions, ask questions, hear content the patient may miss and provide invaluable support in decision follow-through. Although only patients and clinicians are specifically mentioned throughout this document for brevity purposes, this does not diminish the importance of caregivers and families in patient-centered care.

Both the patient and the clinician bring expertise to the shared decision-making conversation. Clinicians' expertise includes disease etiology, prognosis, options for treatment including the burden and benefit to the patient, and outcome probabilities. Patients' expertise lies in their knowledge of their risk tolerance, body, priorities, family and financial issues, as well as their daily experience with the condition (adapted from Making Shared Decision-Making a Reality. No decision about me, without me. Coulter, A., Collins, A., The King's Fund 2011).

Treatment options vary in their burden on a patient. SDM offers an opportunity to help the patient select a treatment to which they can adhere. When conversations discussing options occurs, patients and clinicians are actively engaged while considering the attributes and issues of the available options. This empathic approach results in the clinician and patient co-creating a decision and a plan of care (adapted from Montori, V., the Mayo Clinic KER UNIT, April 2015). Decision aids can be supportive of this conversation when they communicate the best available evidence to inform the patient and clinician discussion.

Without a conversation, clinicians may make assumptions about what the patient prefers. This creates the potential for discrepancies between what clinicians assume and what patients want, resulting in a "preference misdiagnosis" (adapted from Health Policy Publishing, LLC, May 2013).

Difficulty in initiating a conversation is cited by patients and clinicians as one of the barriers to shared decision-making. To address this impediment, ICSI worked with patients, practicing clinicians, and other stakeholders to develop the Collaborative Conversation™ model for use across the care continuum.

*Return to Table of Contents*
Collaborative Conversation™

A collaborative approach towards decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an interprofessional approach that nurtures relationships; enhances patients' knowledge, skills and confidence as vital participants in their health; and encourages them to manage their health care. Within a Collaborative Conversation™, the perspective is that the patient, rather than the clinician, knows which course of action is most consistent with the patient's values and preferences.

Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care clinician and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness is one example of such a circumstance.

The overall objective for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences, along with the best available evidence. A rote script, completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects of the person involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the collaborative conversation approach. These skills include (Adapted from O'Connor, Jacobsen Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting their Health [2007], and Bunn H, O'Connor AM, Jacobsen MJ Analyzing decision support and related communication [1998, 2003])

1. **Listening skills**
   - **Encourage** patient to talk by providing prompts to continue such as *go on, and then? and uh huh* or by repeating the last thing a person said, *It's confusing.*
   - **Paraphrase content of messages shared by patient** to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The clinician should use their own words rather than just parroting what they heard.
   - **Reflection of feelings** usually can be done effectively once trust has been established. Until the clinician feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the clinician understands the patient's feelings and may work as a catalyst for further problem solving. For example, the clinician identifies what the person is feeling and responds back in his or her own words like this: *"So, you're unsure which choice is the best for you."*
   - **Summarize the person's key comments** and reflect them back to the patient. The clinician should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situation rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is *"You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks."*
   - **Perception checks** ensure that the clinician accurately understands a patient or family member perspective, and may be used as a summary or reflection. They are used to verify that the clinician is interpreting the message correctly. The clinician can say, *"So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?"*
2. Questioning Skills

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be, "What else would influence you to choose this?" Closed questions are appropriate if specific information is required, such as "Does your daughter support your decision?"

Other skills such as summarizing, paraphrasing, and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the clinician saying, "You mentioned earlier…"

3. Information-Giving Skills

Providing information and providing feedback are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a clinician to supplement his or her knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the clinician.

Providing information can be sharing facts or responding to questions. An example is "If we look at the evidence, the risk is…” Providing feedback gives the patient the clinician's view of the patient's reaction. For instance, the clinician can say, "You seem to understand the facts and value your daughter's advice."

When to Initiate a Collaborative Conversation™

Certain seminal events occur along the care continuum, creating especially opportune times for collaborative conversations. More than one of these opportunities may present at a time, and they will occur in no specific order.
Cues for the Care Team to Initiate a Collaborative Conversation™:

- Life goal changes: Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.

- Diagnosis/prognosis changes: Additional diagnoses, improved or worsening prognosis.

- Change or decline in health status: Improving or worsening symptoms, change in performance status or psychological distress.

- Change or lack of support: Increase or decrease in caregiver support, change in caregiver, change in caregiver status, change in financial standing, difference between patient and family wishes.

- Disease progression: Change in physical or psychological status as a result of the disease progression.

- Clinician/caregiver contact: Each contact between the clinician/caregiver presents an opportunity to reaffirm with the patient that the care plan and the care he or she is receiving are consistent with his or her values.

Patient and Family Needs within a Collaborative Conversation™

- Request for support and information: Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values, or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When patient expresses a need for information regarding options and their potential outcomes, the patient should understand the key facts about the options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.

- Advance Care Planning: With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis of a life-limiting illness.

- Consideration of Values: The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize his or her preferences, value clarification can be achieved through the use of decision aids, detailing the benefits and harms of potential outcomes in terms of how they will directly affect the patient, and through collaborative conversations with the clinician.

- Trust: The patient must feel confident that his or her preferences will be communicated to and respected by all caregivers.

- Care Coordination: Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Further, the care delivery system must be capable of delivering coordinated care throughout the continuum of care.

- Responsive Care System: The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he or she receives throughout the care continuum.

Return to Table of Contents
The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation Map™ can be used as a stand-alone tool that is equally applicable to clinicians and patients, as shown in Table 2. Clinicians use the map as a clinical workflow. It helps get the shared decision-making process initiated and provides navigation for the process. Care teams can use the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.

### Table 2

*Return to Table of Contents*
Evaluating Shared Decision-Making

It has proven challenging to assess shared decision-making. Measuring shared decision-making remains important for continued adoption of shared decision-making as a mechanism for translating evidence into practice; promoting patient-centered care; and understanding the impact of shared decision-making on patient experience, outcomes and revenues. Many assessments exist, but they are often proxy measures.

Two suggested methods for measuring shared decision-making are the CollaboRATE tool and the SURE Test. These two tools measure different aspects of shared decision-making, as described below.

The CollaboRATE tool measures the level of shared decision-making in the clinical encounter from the patient's perspective. It is a brief patient-reported measure of shared decision-making. The tools and guidance on their use can be found at http://www.collaboratescore.org/.

The SURE Test is a brief screening questionnaire the patient uses to access his or her readiness and capacity to make a decision or to determine whether he or she is comfortable with the choice that was made. In other words, it provides information on how likely a patient may be experiencing decisional conflict. If the SURE Test indicates decisional conflict may exist, the Decisional Conflict Scale should be completed in order to assess clinically significant decisional conflict.

Shared decision-making is a useful mechanism for translating evidence into practice. While research on the impacts of shared decision-making continues to grow, there is mounting evidence that both patients and clinicians benefit from SDM. Shared decision-making offers the opportunity to bring evidence and the patient's values into the patient/clinician discussion of health choices.

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Disclosure of Potential Conflicts of Interest:
Lipid Management in Adults

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Return to Table of Contents
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Return to Table of Contents
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Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Return to Table of Contents
ICSI seeks review from members and the public during the revision process.

**Member Review**

All ICSI documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations, and implementation. Members are also welcome to participate in the public comment period (see below).

*This endorsement was not a variable for feedback in the pre-revision review.*

**Public Comment**

ICSI makes a draft of the guideline available to the public on the ICSI website. The public is invited to comment in an effort to get feedback prior to its finalization. All comments will be reviewed by the ICSI facilitator and work group members when needed. ICSI work group may or may not make changes to the guideline based on public comment responses.

*ICSI endorsement documents are not available for public comment.*

**Invited Reviews**

For some guidelines, ICSI will invite experts in the community to comment on a guideline draft prior to finalization. This is done during the public comment period.

*No invited review was done for the Lipid Management in Adults guideline.*

**ICSI Patient Advisory Council (PAC)**

The ICSI Patient Advisory Council responds to any guideline review requests put forth by ICSI facilitators and work groups. The PAC members may be involved at the beginning, middle, and/or end of the revision process. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document.

*The ICSI Patient Advisory Council did not review the Lipid Management in Adults guideline.*

*Return to Table of Contents*
Document History and Development:
Lipid Management in Adults

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<td><strong>HealthPartners</strong></td>
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<td>Marietta Booth, CEBS</td>
<td><strong>Ramsey Medical Center</strong></td>
<td>Jeff Sikkink, MD</td>
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<td><strong>Lakeview Clinic</strong></td>
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<td><em>Land O’Lakes</em></td>
<td><em>Patrick O’Connor, MD</em></td>
<td>Duke Trence, MD</td>
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<td>Denise Dupras, MD</td>
<td><em>Measurement Advisor</em></td>
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<td><strong>Mayo Clinic</strong></td>
<td><em>Julie Persoon, RN</em></td>
<td>Tony Woolley, MD</td>
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<td>Gary Freeman, MD</td>
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<td>Susan Hanson, RD</td>
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<td><strong>Institute for Research and Education HealthSystem Minnesota</strong></td>
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The next revision will be no later than March 2022.

### Document History

In this revision, the work group endorsed content from two guidelines:

- American College of Cardiology/American Heart Association (2013)
- United States Preventive Services Task Force (2016)

*Return to Table of Contents*

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ICSI Document Development and Revision Process

Overview
Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use
The information contained in this ICSI health care guideline is intended primarily for health professionals and other expert audiences.

This ICSI health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI health care guideline and applying it in their individual case.

This ICSI health care guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process
The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI’s Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Endorsement Process
External guidelines endorsed by ICSI work groups undergo an extensive vetting process, first by ICSI staff and then by the ICSI work group. Careful consideration is given to scope, date of publication, usability, and authors’ conflict of interests. Each work group can decide whether to endorse the guideline as is, not endorse, or endorse with qualifications. The ICSI work group conducts additional literature searches to 1) find articles published outside the external guideline’s literature search period or 2) provide information on a topic not included in the guideline. Final review and approval of the endorsement document is done by ICSI’s Committee on Evidence-Based Practice.

Implementation Recommendations and Measures
These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle
Scientific documents are revised as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals for any pertinent evidence that would affect a particular guideline and recommendation.

Return to Table of Contents