**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0964

**Measure Title**: Aspirin prescribed at discharge

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

**Date of Submission**: 11/8/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Aspirin prescribed at discharge for PCI patients

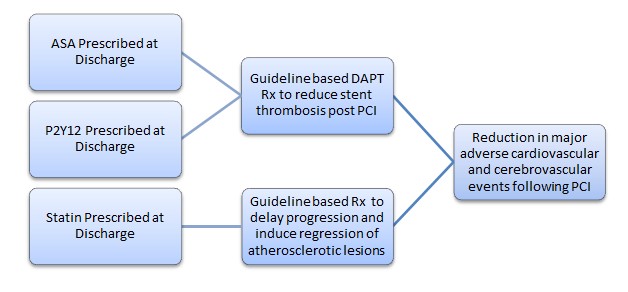
Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) and to reduce the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time. While acute stent thrombosis is relatively uncommon, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor inhibitors) markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is strongly endorsed by national consensus practice guidelines to reduce adverse events or death following PCI.



**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

X☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

X☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007.  URL for guideline: <http://content.onlinejacc.org/article.aspx?articleid=1147816> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Page 41 of 79; e84. Section 6.1 Postprocedural Antiplatelet Therapy: Recommendations CLASS I  #1. After PCI, use of aspirin should be continued indefinitely. (Level of Evidence: A)  #3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist. (Level of Evidence: C)    CLASS IIa  #1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses). (Level of Evidence: B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The weight of the evidence in support of most of the ACCF/AHA/SCAI recommendations included are rated as Level A, Level C and Level B respectively as noted parenthetically. Level A evidence refers to “Data derived from multiple randomized clinical trials or meta-analyses.” The weight of the evidence in support of additional recommendations is rated as Level B and C. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies” while Level C evidence refers to “Only consensus opinion of experts, case studies, or standard-of-care.” |
| Provide all other grades and definitions from the evidence grading system | See question above and next two questions below for more information. |
| Grade assigned to the **recommendation** with definition of the grade | ACCF/AHA/SCAI recommendations included have been assigned a Class I and Class IIa recommendation. Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.” Class IIa recommendations refer to “Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. Weight of evidence/opinion is in favor of usefulness/efficacy.” |
| Provide all other grades and definitions from the recommendation grading system | ACCF/AHA guideline methodology categorizes indications as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:  Classification Types  Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.  Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.   * + IIa: Weight of evidence/opinion is in favor of usefulness/efficacy   + IIb: Usefulness/efficacy is less well established by evidence/opinion.   Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful.   * + No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit   + Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful   Additional detail regarding the classification of recommendation and level of evidence is provided in the following table.  Table 1: |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Two meta-analyses were evaluated (one collaborative meta-analysis reviewing 287 studies involving 135,000 patients in comparisons of antiplatelet therapy versus control and 77,000 in comparisons of different antiplatelet regimens and one meta- analysis of risk of bleeding complications after different doses of aspirin in 192,036 patients enrolled in 31 randomized controlled trials); one observational analysis from a double-blind, placebo-controlled, randomized trial 15,595 patients; two scientific advisory groups were consulted (the 2008 American College of Chest Physicians Evidence-Based Clinical Practice Guidelines and the 2007 Science Advisory Statement from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians); and two clinical trials were included in this body of evidence.  Information regarding the overall quality of evidence across studies is not available. |
| Estimates of benefit and consistency across studies | Quantitative estimates of benefit of Aspirin therapy across this body of evidence are not reported. |
| What harms were identified? | The guidelines document addresses a post hoc analysis of the PLATO study, specifically that the based on the results in the U.S. patient cohort, a black box warning was developed stating that maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor, a P2Y12 Inhibitor, and should be avoided. After any initial dose, ticagrelor should be used with aspirin 75 mg to 100 mg per day.  Ticagrelor has not been studied in elective PCI or in patients who received fibrinolytic therapy; thus, no recommendations about its use in these clinical settings can be made. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | The ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention was most recently updated in 2011 with respect to these specific therapies as cited above. |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Brilakis ES, Patel VG, Banerjee S. Medical management after coronary stent implantation: a review.  *JAMA.* 2013;310(2):189-198. doi:10.1001/jama.2013.7086  <http://jama.jamanetwork.com/article.aspx?articleid=1710463> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | The review focused on medical therapy after percutaneous coronary intervention (PCI). |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The authors of the systematic review did not assign a grade to the overall quality of the evidence. |
| Provide all other grades and definitions from the evidence grading system | The methodology for evidence review is included in the methods section of the review cited. The authors of the systematic review did not assign a grade to the overall quality of the evidence. |
| Grade assigned to the **recommendation** with definition of the grade | NA |
| Provide all other grades and definitions from the recommendation grading system | NA |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The systematic review included 91 publications, with priority given to data from large randomized- controlled trials, systematic reviews, and meta-analyses.  The authors of the review did not provide an assessment of the overall quality of evidence across studies. |
| Estimates of benefit and consistency across studies | Quantitative estimates of benefit of aspirin therapy across this body of evidence are not reported. |
| What harms were identified? | The 2013 JAMA review considered issues surrounding appropriate dose and duration of anti-platelet drugs, drug allergies, method of administration, surgery following stent implantation, oral anticoagulation, and risk of bleeding. After consideration of the risks and benefits of therapy, the authors concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the appropriate medical therapy for optimizing outcomes following PCI |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | The body of evidence is current and no additional, relevant studies have been identified. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

**1a.4.2 What process was used to identify the evidence?**

The authors do no provide an overall grade for the evidence.

**1a.4.3.** **Provide the citation(s) for the evidence.**

**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0964

**Measure Title**: P2Y12 inhibitor prescribed at discharge

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

**Date of Submission**: 11/8/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.** 1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: P2Y12 inhibitors prescribed at discharge for PCI patients/prescribing optimal medical therapy at discharge for patients undergoing PCI

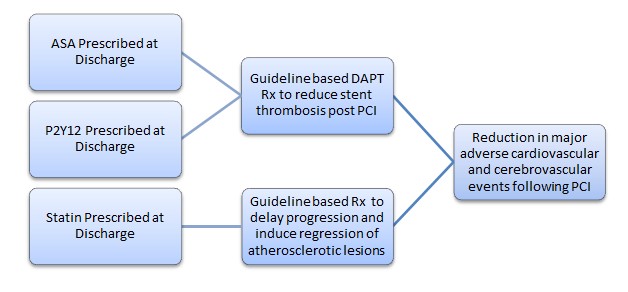
Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) and to reduce the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time. While acute stent thrombosis is relatively uncommon, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor inhibitors) markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is strongly endorsed by national consensus practice guidelines to reduce adverse events or death following PCI.



**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

X☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

X☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007.  URL for guideline: <http://content.onlinejacc.org/article.aspx?articleid=1147816> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Page 41 of 79; e84. Section 6.1. Postprocedural Antiplatelet Therapy: Recommendations  1) The duration of P2Y12 inhibitor therapy after stent implantation should generally be as follows:    a) In patients receiving a stent (BMS or DES) during PCI for ACS, P2Y12 inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily(570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). (Class I, Level of Evidence: B)  b) In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding (208,212,571). (Class I, Level of Evidence: B)  c) In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (572). (Class I, Level of Evidence: B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The weight of the evidence in support of the various ACCF/AHA/SCAI recommendations included in section 1a.4.2 is rated as Level B, as noted parenthetically. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies.” |
| Provide all other grades and definitions from the evidence grading system | See question above and next two questions below for more information. |
| Grade assigned to the **recommendation** with definition of the grade | All ACCF/AHA/SCAI recommendations have been assigned a Class I recommendation. Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.” |
| Provide all other grades and definitions from the recommendation grading system | ACCF/AHA guideline methodology categorizes indications as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:  Classification Types  Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.  Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.   * + IIa: Weight of evidence/opinion is in favor of usefulness/efficacy   + IIb: Usefulness/efficacy is less well established by evidence/opinion.   Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful.   * + No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit   + Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful   Additional detail regarding the classification of recommendation and level of evidence is provided in Table 1 below.  Table 1: |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 4 randomized controlled trials, 1 observational study, and 1 science advisory statement are cited in support of the recommendation provided. The science advisory statement cites an additional 5 randomized controlled trials.  Science advisory statement citation: Grines CL, Bonow RO, Casey DE Jr., et al. Prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents: a science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians. J Am Coll Cardiol. 2007;49:734 –9.  Information regarding the overall quality of evidence across studies is not available. |
| Estimates of benefit and consistency across studies | The science advisory statement includes the following summary table which includes the percentage of reported major adverse cardiovascular events in patients treated with dual antiplatelet therapy (ie, aspirin and a P2Y12 inhibitor) compared to aspirin alone or the use of aspirin and warfarin. |
| What harms were identified? | The guidelines refer to the potential risk of morbidity from P2Y12 inhibitor therapy after stent implantation and that this may prompt the reasonable earlier discontinuation (e.g., < 12 months) of P2Y12 inhibitor therapy in some patients.  The science advisory statement includes the following regarding the risk of dual antiplatelet therapy: Dual antiplatelet therapy is not without risk. Like all antithrombotic agents, both aspirin and clopidogrel increase the risk of bleeding compared with placebo. When compared with aspirin, clopidogrel may be associated with lower risk of GI bleeding. However, when clopidogrel was combined with aspirin and administered for prolonged duration (up to 28 months), randomized trials demonstrated an absolute increase (ranging from 0.4% to 1.0%) in major bleeding, compared with aspirin alone |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | The ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention has not been updated since the 2011 document referenced in the citations above PCI. |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Brilakis ES, Patel VG, Banerjee S. Medical management after coronary stent implantation: a revew.  *JAMA.* 2013;310(2):189-198. doi:10.1001/jama.2013.7086  <http://jama.jamanetwork.com/article.aspx?articleid=1710463> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | The review focused on medical therapy after percutaneous coronary intervention (PCI). |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The authors of the systematic review did not assign a grade to the overall quality of the evidence |
| Provide all other grades and definitions from the evidence grading system | The methodology for evidence review is included in the methods section of the review cited. The authors of the systematic review did not assign a grade to the overall quality of the evidence |
| Grade assigned to the **recommendation** with definition of the grade | NA |
| Provide all other grades and definitions from the recommendation grading system | NA |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The systematic review included 91 publications, with priority given to data from large randomized- controlled trials, systematic reviews, and meta-analyses.  The authors of the review did not provide an assessment of the overall quality of evidence across studies. |
| Estimates of benefit and consistency across studies | The authors of the review did The 2013 JAMA review includes the following summary table of pivotal trials of P2Y12 inhibitors following PCI which includes the event rate, point estimate, and p-value found in each trial. |
| What harms were identified? | The 2013 JAMA review considered issues surrounding appropriate dose and duration of anti-platelet drugs, drug allergies, method of administration, surgery following stent implantation, oral anticoagulation, and risk of bleeding. After consideration of the risks and benefitts, the authors concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the appropriate medical therapy for optimizing outcomes following PCI. The authors emphasized the importance of tailoring the P2Y12 treatment regimen to the patient’s unique clinical profile to ensure that the drug, dose, and duration are appropriate for the individual patient’s needs. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | The body of evidence is current, and no additional, relevant studies have been identified. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

**1a.4.2 What process was used to identify the evidence?**

The authors do no provide an overall grade for the evidence.

**1a.4.3.** **Provide the citation(s) for the evidence.**

**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0964

**Measure Title**: Statin prescribed at discharge

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

**Date of Submission**: 11/8/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.** 1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Statins prescribed at discharge for PCI patients

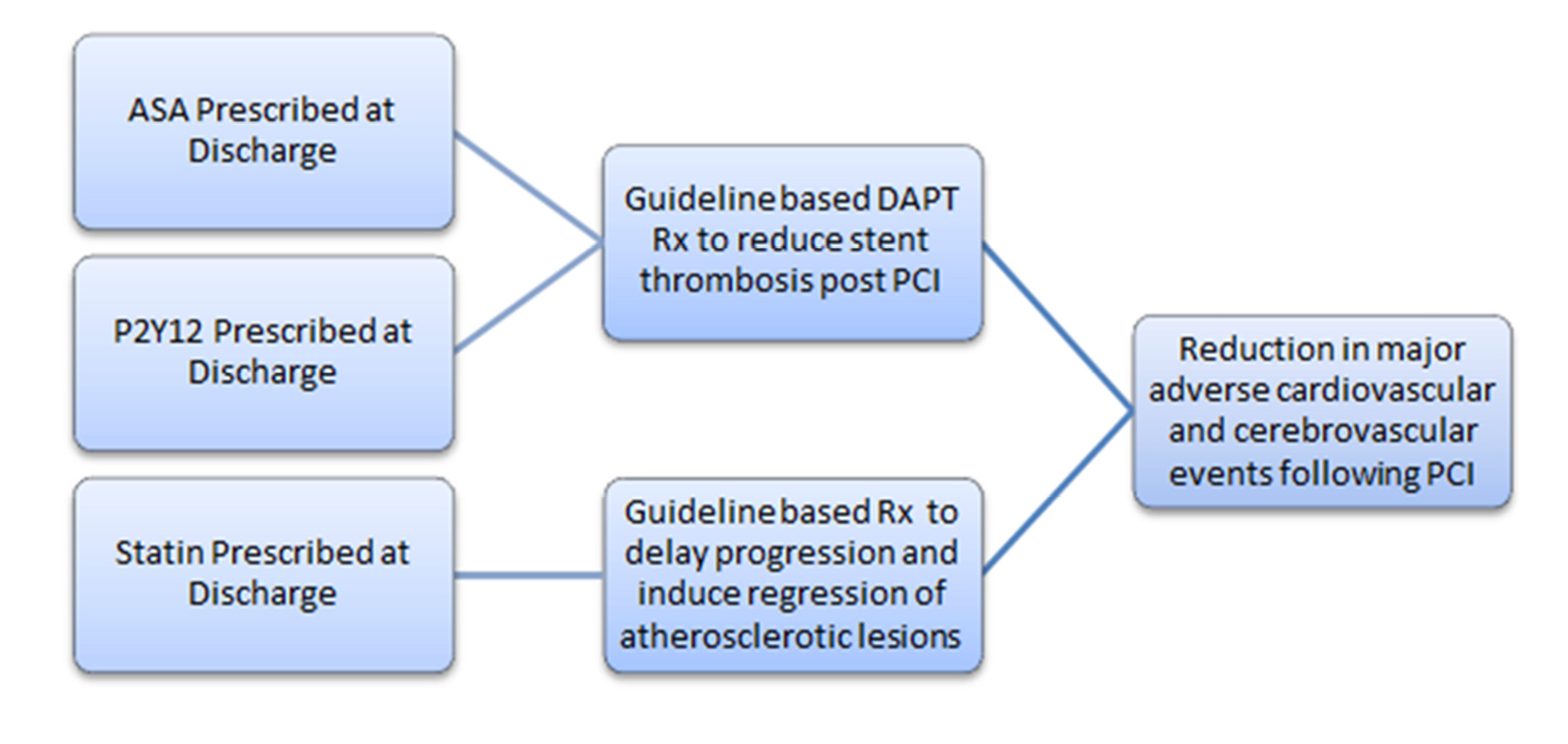
Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are deployed used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) soon after the procedure, as well as to reduce reducing the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time compared the prevalence of repeat PCI for patients undergoing only balloon angioplasty. However, stent restenosis and stent thrombosis are potential complications of coronary artery stenting. While acute stent thrombosis is a relatively uncommon complication, it often presents as death and is almost always accompanied by MI, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor inhibitors) significantly markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression and induce the regression of atherosclerotic lesion in this patient population of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is guideline driven strongly endorsed by national consensus practice guidelines to reduce and guideline supported in order to reduce the adverse events or mortality death following PCI.



**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

X☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

X☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;():. doi:10.1016/j.jacc.2013.11.002.  URL: <http://content.onlinejacc.org/article.aspx?articleid=1770217> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Secondary Prevention Recommendations - Page 23  Recommendation 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 atherosclerotic cardiovascular disease (ASCVD\*), unless contraindicated. (NHLBI Grade A, Strong; ACC/AHA Class I Level A)    Recommendation 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 statin should be used as the second option if tolerated). (NHLBI Grade A, Strong; ACC/AHA Class I Level A)  \*ASCVD (defined from the RCT inclusion criteria as acute coronary syndromes; history of MI, stable or unstable angina, coronary revascularization, stroke, or TIA presumed to be of atherosclerotic origin, and peripheral arterial disease or revascularization)  The NHLBI initiated these guidelines by sponsoring systematic evidence reviews and collaborating with the ACC and AHA to complete and publish the guideline. Recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality, and were not formulated when sufficient evidence was not available. Each recommendation has been mapped from the NHLBI grading format to the ACC/AHA Class of Recommendation/Level of Evidence (COR/LOE) construct and is expressed in both formats.  The evidence review focused on LDL–C and non-HDL–C goals for the secondary and  primary prevention of atherosclerotic cardiovascular disease (ASCVD) with cholesterol-lowering drug therapy. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Recommendations 1 and 2   * ACC/AHA: Level A Evidence |
| Provide all other grades and definitions from the evidence grading system | **ACC/AHA**  The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect.  Level B: Limited populations evaluated; Data derived from a single randomized trial or nonrandomized studies  Level C: Very limited populations evaluated; only consensus opinion of experts, case studies or standard of care  Specific LOE definitions are included in Table 1 below. |
| Grade assigned to the **recommendation** with definition of the grade | Recommendations 1 and 2   * + NHLBI: Grade A, Strong Recommendation (There is high certainty based on evidence that the net benefit is substantial   + ACC/AHA Class I: Procedure/Treatment should be performed/administered |
| Provide all other grades and definitions from the recommendation grading system | **NHLBI Grading the Strength of Recommendations**  Grade 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.  Grade C: Weak recommendation: There is at least moderate certainty based on evidence that there is a small net benefit.  Grade D: Recommendation against. There is at least moderate certainty based on evidence that it has no benefit or that risks/harms outweigh benefits.  Grade E: Expert opinion: There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group 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 Work Group thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.  Grade 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 Work Group thought no recommendation should be made. Further research is recommended in this area  ACC/AHA:  Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm.  Class IIa: It is reasonable to perform procedure/administer treatment Class IIb: Procedure/Treatment may be considered  Class III: No benefit (Not helpful or No proven benefit)  Class III: Harm (Excess cost w/o benefit or Harmful to patients) Specific COR definitions are included in Table 1 below.  ACC/AHA Table 1. Applying Classification of Recommendation and Level of Evidence  Additional detail regarding the classification of recommendation and level of evidence is provided in the following table. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 19 Randomized Control Trials (RCT)  1 Meta-analysis – 201 Cholesterol Treatment Trialsist (CTT)  The 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults does not make any qualifying statements about the overall quality of evidence across studies. The guideline states that the recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality, and were not formulated when sufficient evidence was not available. |
| Estimates of benefit and consistency across studies | The guideline Expert Panel reviewed 19 RCTs to determine the LDL–C and non-HDL–C goals for the secondary and primary prevention of atherosclerotic cardiovascular disease (ASCVD) with cholesterol- lowering drug therapy. According to the guideline, the majority of studies confirmed the  efficacy of cholesterol reduction in improving clinical outcomes in patients with clinical ASCVD using a single fixed-dose statin therapy to lower LDL–C levels.  The meta-analysis conducted by the Cholesterol Treatment Trialists (CTT) in 2010 includes percent reductions in LDL–C for a specific statin and dose calculated for the RCTs included in which statin therapy reduced ASCVD events. The CTT meta-analysis provided the following results:   |  |  |  | | --- | --- | --- | | **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% |   The guideline defines High- Moderate- and Low-Intensity Statin Therapy in Table 5 on page 26 of the guideline. |
| What harms were identified? | The guideline states that women and men with clinical ASCVD are at increased risk for recurrent ASCVD and ASCVD death. Evidence demonstrates that high-intensity statin therapy reduces ASCVD events more than moderate-intensity statin therapy in individuals with clinical ASCVD.    Furthermore, the guideline states that in order to optimize the safety of statins, selection of the appropriate statin and dose 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 alanine transaminase elevations >3 times Upper Limits of Normal * Patient characteristics or concomitant use of drugs affecting statin metabolism. * >75 years of age.   Statins modestly increase the excess risk of type-2 diabetes in individuals with risk factors for diabetes. The potential for an ASCVD risk reduction benefit outweighs the excess risk of diabetes in all but the lowest risk individuals. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | A Cochrane review was carried out to assess the effects, both harms and benefits, of statins used for primary prevention in people with no history of cardiovascular disease. Reductions in all-cause mortality, major vascular events and revascularizations were found with no excess of adverse events among people without evidence of CVD treated with statins. Although this measure focuses on secondary prevention, the Cochrane review provides further evidence that statins reduce total mortality, and adverse events.  Taylor F, Huffman MD, Macedo AF et al. Statins for the primary prevention of cardiovascular disease. The Cochrane database of systematic reviews 2013; Issue 1. Art. No.: CD004816. DOI: 10.1002/14651858.CD004816.pub5.  A meta-analysis included individual participant data from 22 trials of statin versus control and five trials of more versus less statin. The analysis concluded that statins reduce LDL cholesterol and prevent vascular events in individuals at low risk of vascular events.  Cholesterol Treatment Trialists Collaboration. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet* 2012;380:581–90 |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

**1a.4.2 What process was used to identify the evidence?**

The authors do no provide an overall grade for the evidence.

**1a.4.3.** **Provide the citation(s) for the evidence.**