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CORRECTIONS

Heidenreich PA, Solis P, Estes NAM 3rd, Fonarow GC, Jurgens CY, Marine JE, McManus DD, McNamara RL.

2016 ACC/AHA Clinical Performance and Quality Measures for Adults With Atrial Fibrillation or Atrial Flutter: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures

J Am Coll Cardiol 2016;68:525–68.

1. In response to new data that resulted in changes in the Food and Drug Administration (FDA) labeling regarding the use of one of the Factor Xa inhibitors in patients with end-stage kidney disease or on dialysis (1), the Task Force on Performance Measures has removed 2 quality measures ("QM-6: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa inhibitor (Rivaroxaban or Edoxaban) Prior to Discharge in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" and "QM-15: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor (Rivaroxaban or Edoxaban) in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis") from Appendix A of the "2016 ACC/AHA Clinical Performance and Quality Measures for Adults With Atrial Fibrillation or Atrial Flutter" measure set (2) shown below.
2. In quality measure set QM-16, "Atrial Fibrillation: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease," patient protocol for the use of the WATCHMAN device for hospitals performing left atrial appendage occlusion procedures requires that patients be discharged on warfarin and aspirin. Because this is considered to be appropriate for the patient, this quality measure has been modified to exclude these patients so that they can be removed from the denominator of the measure. The following was added to the Denominator Exclusions criteria: "Patients undergoing procedures using certain devices where they are appropriately prescribed both an antiplatelet and an oral anticoagulant (e.g., WATCHMAN device)." This change to QM 16 is shown below.
3. Table of contents entries for "QM-6: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa inhibitor (Rivaroxaban or Edoxaban) Prior to Discharge in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" and "QM-15: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor (Rivaroxaban or Edoxaban) in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" have been deleted.
4. Table 1, "2016 ACC/AHA Atrial Fibrillation Clinical Performance and Quality Measures", entry for QM-6. In the column headed "Measure Title", the measure title has been replaced with the phrase "Deleted in response to new data in 2018." In the column headed "Care Setting", the word "Inpatient" has been deleted. In the column headed "Measure Domain", the words "Patient Safety" have been deleted.
5. Table 1, entry for QM-15. In the column headed "Measure Title", the measure title has been replaced with the phrase "Deleted in response to new data in 2018." In the column headed "Care Setting", the word "Outpatient" has been deleted. In the column headed "Measure Domain", the words "Patient Safety" have been deleted.
6. Table 5, "New Atrial Fibrillation Measures", entry for QM-6. In the "Care Setting" column, the word "Inpatient" has been deleted. In the "Measure Title" column, the measure title has been replaced with the phrase "Deleted in response to new data in 2018." The column headed "Rationale for Creating New Measure" previously contained the following text, which applied to both QM-6 and QM-15: "The 2014 ACC/AHA/HRS Guidelines for Management of Patients With Atrial Fibrillation recommend that patients with AF and end-stage kidney disease or on dialysis not be prescribed the direct thrombin inhibitor dabigatran and the factor Xa inhibitor rivaroxaban because of the lack of evidence from clinical trials with regard to the balance of risks and benefits. The writing committee, in developing this measure, expanded it to include edoxaban because it was approved for use in patients with AF after the 2014 AHA/ACC/HRS Guidelines for Management of Patients With Atrial Fibrillation had been released." This text been deleted. The column headed "Rationale for Designating as a Quality Measure as Opposed to a Performance Measure (if Applicable)"

previously contained the following text, which applied to both QM-6 and QM-15: "In developing this quality measure the writing committee did consider existing studies that relate to anticoagulation in patients with kidney disease (31). Based on additional studies that may be published or changes to future ACC/AHA recommendations, the writing committee may re-evaluate the construct of this measure. At this time the measure is designated as a quality measure. Additional data are required prior to making this measure a performance measure. The ability to elevate these measures to a performance measure will depend on the quality of data obtained once the measures are implemented. If it is found that patients are being provided with medications that can have a negative impact on patient safety, the writing committee may determine that the measure should be elevated to the status of a performance measure. However at this time we do not whether there is evidence to support elevation to a performance measure." This text has been deleted.

7. Table 5, "New Atrial Fibrillation Measures", entry for QM-15. In the "Care Setting" column, the word "Outpatient" has been deleted. In the "Measure Title" column, the measure title has been replaced with the phrase "Deleted in response to new data in 2018." Text in the columns headed "Rationale for Creating New Measure" and "Rationale for Designating as a Quality Measure as Opposed to a Performance Measure (if Applicable)" has been deleted as detailed above.

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APPENDIX A 2016 ACC/AHA ATRIAL FIBRILLATION CLINICAL PERFORMANCE AND QUALITY MEASURES

Short Title: QM-6: Inappropriate Prescription of a Direct Thrombin or Factor Xa inhibitor (Rivaroxaban or Edoxaban) Prior to Discharge	
QM-6: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa inhibitor (Rivaroxaban or Edoxaban) Prior to Discharge in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis	
Measure Description: Percentage of patients, age 18 and older, with atrial fibrillation that also have end stage kidney disease (CrCl <15 mL/min) or are on dialysis, who were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban) prior to discharge.	
Numerator	Patients with a diagnosis of atrial fibrillation who do not have normal kidney function that were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban) prior to discharge
Denominator	All patients with atrial fibrillation who also have end stage kidney disease (CrCl <15 mL/min) or are on dialysis
Denominator Exclusions	Patients age < 18 y
Denominator Exceptions	None
Measurement Period	Encounter
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care Setting	Inpatient
Rationale	
2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23) For patients with chronic kidney disease, dose modifications of the new agents are available (Table 8); however, for those with severe or end-stage kidney disease, warfarin remains the anticoagulant of choice, as there are no or very limited data for these patients. Among patients on hemodialysis, warfarin has been used with acceptable risks of hemorrhage (108).	
Clinical Recommendation(s)	
2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23) 1. The direct thrombin inhibitor dabigatran and the factor Xa inhibitor rivaroxaban are not recommended in patients with AF and end-stage CKD or on dialysis because of the lack of evidence from clinical trials regarding the balance of risks and benefits (52–54,111–113). (Class III, Level of Evidence: C)	

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CrCl, creatinine clearance; HRS, Heart Rhythm Society; and QM, quality measure.

APPENDIX A 2016 ACC/AHA ATRIAL FIBRILLATION CLINICAL PERFORMANCE AND QUALITY MEASURES

Short Title: QM-15: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor (Rivaroxaban or Edoxaban)

QM-15: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor (Rivaroxaban or Edoxaban) in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis

Measure Description: Percentage of patients, age 18 and older, with atrial fibrillation that also have end stage kidney disease (CrCl <15 mL/min) or are on dialysis, who were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban).

Numerator	Patients with a diagnosis of atrial fibrillation who do not have normal kidney function that were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban)
Denominator	All patients with atrial fibrillation that also have and end stage kidney disease (CrCl <15 mL/min or are on dialysis
Denominator Exclusions	Patients age <18 y
Denominator Exceptions	None
Measurement Period	Reporting Year
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or provider level.
Care Setting	Outpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

For patients with chronic kidney disease, dose modifications of the new agents are available (Table 8); however, for those with severe or end-stage kidney disease, warfarin remains the anticoagulant of choice, as there are no or very limited data for these patients. Among patients on hemodialysis, warfarin has been used with acceptable risks of hemorrhage (115).

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

The direct thrombin inhibitor dabigatran and the factor Xa inhibitor rivaroxaban are not recommended in patients with AF and end-stage CKD or on dialysis because of the lack of evidence from clinical trials regarding the balance of risks and benefits (52–54,111–113). (Class III, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CrCl, creatinine clearance; HRS, Heart Rhythm Society; and QM, quality measure.

APPENDIX A 2016 ACC/AHA ATRIAL FIBRILLATION CLINICAL PERFORMANCE AND QUALITY MEASURES

Short Title: QM-16: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy

QM-16: Atrial Fibrillation: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease

Measure Description: Percentage of patients, age 18 and older, with atrial fibrillation who do not currently have coronary artery disease and/or vascular disease that were inappropriately prescribed both an antiplatelet and an oral anticoagulant.

Numerator	Patients with a diagnosis of atrial fibrillation who do not have coronary artery disease and/or vascular disease that were inappropriately prescribed both an antiplatelet and an oral anticoagulant.
Denominator	All patients with atrial fibrillation who do not currently have coronary artery disease and/or vascular disease.
Denominator Exclusions	• Patients less than 18 years of age • Patients with mechanical heart valves • Patients undergoing procedures using certain devices where they are appropriately prescribed both an antiplatelet and an oral anticoagulant (e.g., WATCHMAN device)
Denominator Exceptions	None
Measurement Period	Reporting Year
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry).
Attribution	Measure reportable at the facility or provider level.
Care Setting	Outpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Stroke prevention trials compared warfarin or aspirin with placebo and compared aspirin with warfarin or clopidogrel and aspirin. Warfarin was also compared with dual antiplatelet agents (clopidogrel and aspirin). Trials have also compared direct thrombin inhibitors and factor Xa inhibitors with warfarin and, in 1 case, with aspirin. Both primary and secondary stroke prevention have been evaluated. The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clopidogrel plus aspirin was evaluated for stroke prevention in the ACTIVE (Atrial Fibrillation Clopidogrel Trial With Irbesartan for Prevention of Vascular ACTIVE-W found a 40% RR reduction (95% CI: 18% to 56%; $p<0.001$) for stroke with warfarin compared with the dual antiplatelet regimen. ACTIVE-A compared clopidogrel Events)-W trial (114). The combination of clopidogrel and aspirin resulted in a 28% RR reduction (95% CI: 17% to 38%; $p<0.0002$) in all strokes compared with aspirin alone. Major bleeding was significantly greater with the combination and increased by 57% (95% CI: 29% to 92%; $p<0.001$).

Clinical Recommendation(s)

No clinical recommendation currently exists for this measure.

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CI, confidence interval; HRS, Heart Rhythm Society; INR, International Normalized Ratio; QM, quality measure; and RR, relative risk.

REFERENCES

1. Dias C, Moore KT, Murphy J, et al. Pharmacokinetics, pharmacodynamics, and safety of single-dose rivaroxaban in chronic hemodialysis. Am J Nephrol 2016;43:229–36.

2. Heidenreich PA, Solis P, Estes NA 3rd, et al. 2016 ACC/AHA clinical performance and quality measures for adults with atrial fibrillation or atrial flutter: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2016;68:525–68.

Pilote L, Raparelli V

Participation of Women in Clinical Trials: Not Yet Time to Rest on Our Laurels

J Am Coll Cardiol 2018;71:1970-2.

On page 1970, second column, second paragraph, third sentence, the following sentence read:

During this period, the mean percentage of women participants was 34%, ranging from 22% to 81% across different cardiovascular areas.

But should have read:

During this period, the overall percentage of women participants in the trials analyzed was 34% and the proportion per trial ranged from 22% to 81% (mean per trial = 46%) across different cardiovascular areas.

The authors apologize for this error.

The online version of the article has been corrected to reflect this change.

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