Circulation: Cardiovascular Quality and Outcomes

CORRECTION

Correction to: 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

In the article by Heidenreich 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," which published ahead of print on June 27, 2016, and appeared in the July 2016 issue of the journal (*Circ Cardiovasc Qual Outcomes.* 2016;9:443–488. DOI: 10.1161/HCQ.0000000000000018), several corrections were needed.

1. In response to new data that resulted in changes in the US Food and Drug Administration 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. They appeared in Appendix A and are:
   - "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" on page 472.
   - "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" on page 482.

   They are shown below.
2. On page 444, the 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.
3. On page 444, in Table 1, the entry for QM-6 has the following changes:
   - In the "Measure Title" column, "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" has been replaced with "Deleted in response to new data in 2018."
   - In the "Care Setting" column, "Inpatient" has been deleted.
   - In the "Measure Domain" column, "Patient Safety" has been deleted.
4. On page 444, in Table 1, the entry for QM-15 has the following changes:
   - In the "Measure Title" column, "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" has been replaced with "Deleted in response to new data in 2018."

- In the "Care Setting" column, "Outpatient" has been deleted.
- In the "Measure Domain" column, "Patient Safety" has been deleted.

5. On pages 451 and 452, in Table 5, the entries for QM-6 and QM-15 have the following changes:
   - In the "Care Setting" column, the word "Inpatient" has been deleted for QM-6 and "Outpatient" for QM-15.
   - In the "Measure Title" column, "Inappropriate Prescription of a Direct Thrombin and Factor Xa Inhibitor (Rivaroxaban or Edoxaban) in Patients With Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" has been replaced with "Deleted in response to new data in 2018."
   - In the "Rationale for Creating New Measure" column, the following text, which applied to QM-6 and QM-15, has been deleted: "The 2014 AHA/ACC/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."
   - In the "Rationale for Designating as a Quality Measure as Opposed to a Performance Measure (if Applicable)" column, the following text, which applied to QM-6 and QM-15, has been deleted: "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 patient 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."
6. On page 483, 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 (eg, WATCHMAN device)."

These corrections have been made to the current online version of the article, which is available at http://circoutcomes.ahajournals.org/lookup/doi/10.1161/HCQ.0000000000000018.

REFERENCE

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.

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 y, with AF who also have end-stage kidney disease (CrCl <15 mL/min) or are on dialysis and who were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban) prior to discharge.	
Numerator	Patients with a diagnosis of AF who do not have normal kidney function that and were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban) prior to discharge
Denominator	All patients with AF 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 (eg, 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 because 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.

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 y, with AF who also have end-stage kidney disease (CrCl <15 mL/min) or are on dialysis and who were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban).	
Numerator	Patients with a diagnosis of AF who do not have normal kidney function that were prescribed a direct thrombin or factor Xa inhibitor (rivaroxaban or edoxaban)
Denominator	All patients with AF 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	Reporting year
Sources of data	Medical record or other database (eg, 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 because 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]	
1. The direct thrombin inhibitor dabigatran and the factor Xa inhibitor rivaroxaban are not recommended in patients with AF and end-stage chronic kidney disease or on dialysis because of the lack of evidence from clinical trials with regard to 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.

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