Additionally, considering the change in FDA recommendations for both apixaban and rivaroxaban (US package inserts have nearly identical recommendations for patients diagnosed with ESRD on hemodialysis and atrial fibrillation), Figure 8 “Suggested algorithm for the decision-making process in prescribing oral anticoagulant therapy in patients with various degrees of renal function impairment” on page 135 fails to include the recommended rivaroxaban dose for patients with creatinine clearance < 15 mL/min or ESRD on renal replacement therapy.1

Although I am not advocating the use of novel oral anticoagulants in this population, it is important to provide some clarity and balance to better inform physicians of these guidelines and the current rivaroxaban US label.

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References

Response
To the Editor:
We thank Dr Moore for the comment on the 2018 CHEST guidelines.1 We agree that the US Food and Drug Administration has now harmonized the labels for both rivaroxaban and apixaban for end-stage renal disease (ESRD) on hemodialysis, so they are essentially the same.

Basically, the labels for both apixaban and rivaroxaban now say that based on pharmacokinetic and pharmacodynamic data these agents can be used in ESRD on hemodialysis, but does mention that there are no clinical outcome data from large randomized trials. At the time of writing that particular section and the 2018 CHEST guidelines, only apixaban had this description in its label, but the revised rivaroxaban label now has similar text. This is not an error as implied by Moore, because guidelines are based on what evidence was reviewed at a particular evidence search time point in a (very) rapidly evolving field.

Of note, the 2019 focused update atrial fibrillation management guidelines from the American Heart Association/American College of Cardiology/Heart Rhythm Society recommend only apixaban for ESRD.2 Ultimately, the bottom line is that stroke prevention is pivotal for the management of patients with atrial fibrillation, and the debate has shifted from “do we treat” to “how we treat.”3

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References