Dear Dr. Abraham:

Manuscript ID BMJ.2014.023104.R2 entitled "Comparative risk of gastrointestinal bleeding with dabigatran, rivaroxaban and warfarin" which you submitted to BMJ,

Many thanks for your revision, which has addressed the concerns raised by our statistician. I would be pleased to accept the paper after one small edit. The sentence "Both dabigatran and rivaroxaban demonstrated non-inferiority to warfarin for the prevention of stroke (see table A4 in appendix)" has been added to the paper. Since non-inferiority means something specific, and that was not the goal of this analysis, it might be better just to say that the event rates were not statistically significantly different or something to that effect. I understand it's a small change but we don't have a better mechanism for making this edit. Once this is done, I'll be please to accept the paper.

I also wanted to include the rationale for the decision to place this analysis in an appendix, so that we have a formal record of it (no changes needed on your part here). I'll just copy what I wrote to you in the email, in response to your query about how to proceed with incorporating an analysis of efficacy:

Dr. Perera noted in an email to me about this question that "Effect/harms are two sides of the same coin. It is not scientifically sound to choose different data to analyse each separately so as their argument is that this shows safety on the "real world", the same argument would need to be made about effect." That being said, we understand that if we had wanted the paper to be fully revised, we should have asked earlier. At this point, I and a senior editor have discussed this and feel that a happy medium might be to perform the analyses and place them in an appendix. A mention of the appendix could be put in the paper in the appropriate places, and the paper would not have to be revised much further than that with regard to this question.

Yours sincerely,

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