Author's response to reviews

Title: Anticoagulated patient's perception of their illness, their beliefs about the anticoagulant therapy prescribed and the relationship with adherence: impact of novel oral anticoagulant therapy - The Switching Study

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Version: 3
Date: 24 November 2015

Author's response to reviews: see over
Dr Peter O’Donovan  
Editor  
BMC Haematology

Dear Dr O’Donovan,

Re: MS: 7491772681446721  
Anticoagulated patient’s perception of their illness, their beliefs about the anticoagulant therapy prescribed and the relationship with adherence: impact of novel oral anticoagulant therapy – The Switching Study

Many thanks for the opportunity to revise our manuscript in light of the reviewer’s additional comments made, following our first revision made at the beginning of this year.

In the table below are the additional comments made by the reviewers, along with our author responses to these. Where changes have been made to the manuscript, these have been highlighted as track changes in the revised submitted manuscript. We have kept the original track changes in this document from the first revision, for completeness.

We look forward to hearing the outcome of your review.

On behalf of the manuscript authors,

Yours sincerely,

Vivian Auyeung, PhD  
Lecturer in Medicines Use and Health Psychologist  
King’s College London

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<th>Comments</th>
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<td>Authors’ comments “the majority of patients prescribed chronic anticoagulant therapy are prescribed VKA. Evaluating the quality of life issues, beliefs about medication and illness perceptions for patients prescribed heparin will be different”.</td>
<td>As you described it in your answer, you should introduce the statement that the majority of patients prescribed chronic anticoagulant therapy are prescribed VKA in the introduction and give references. This has been included in the introduction now – please see revision.</td>
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New oral anticoagulants can also be a source of drug-drug and drug-food interactions. If you say “the aforementioned disadvantages has (have!) led to the development of new classes of oral anticoagulants...” and “these agents hold many advantages over VKA” the reader will understand that new anticoagulants aren't source of drug-drug and drug-food interactions and this is wrong. You described the pro’s of NOACs in the introduction (l. 72-74); you should also describe their risks (CYP P450 interactions for example).

This has been clarified in the introduction, and the risks associated with NOACs are now included – please see revision.

| Please complete the text with the explanations you provided to us. The reviewer 1 said “authors must somehow justify the choice of such a TTR threshold” but I didn’t find any corrections in the text. | We have added a section in the method section of the manuscript, justifying the TTR cut-off points for this study, which informed the two groups. |
| I am afraid that quality of answers to questionnaires in study 1 will differ because administration of those questionnaires varies (at home vs. at visit 1). Timing of administration of questionnaire seems also different. Method should be more standardized. Or limitations described in the discussion. | There is a section in the text, which states that patients seen in clinic are given the option of completing the questionnaire in clinic or at home. Our experience to date with recruitment is, that most patients (99%) complete the questionnaire at home. This observation will of course be discussed in papers which are published for the Switching study reporting results. We did not feel it was appropriate to discuss limitations in a methods paper, as convention is to discuss limitations in a results paper, where readers have results to consider. |

Study II: reasons for not switching should be collected and described.

This has now been clarified in the text.

Study outcomes: Timing for measuring study outcomes should be described. How can ‘a treatment pathway’ be a quantitative outcome?

Timing of study outcomes has been clarified in the text, under the outcome sections. The treatment pathway was an outcome from the completion of the study III. However, we can see this might be confusing, and have therefore removed this from the text.

The control group should include all consecutive patients with a TTR >75%. Please specify.

This has now been specified in the text.

How the socio-demographic data will be collected? By survey or from medical file? Please clarify.

This information will be collected from the medical notes and has been clarified in the table of information to be collected.

The manuscript still lacks the information on how persistence will be measured.

Persistence measure at visit 4 will be evaluated through the GP summary care records which will provide prescription issue data from the patients GP and allow anticoagulation coverage days to be calculated. This has been described in the text.

You said that you used the MMAS questionnaire. Please add it to the text. Add also information about questions

The MMAS-8 will be used at visit 4 as the adherence screener and this detail has been
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<td>used by Clifford et al 2008.</td>
<td>added to the text. There is no reference to Clifford et al in the text - we are unsure what the comment relates to and so have not responded to this.</td>
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<td>Please specify that the primary purpose of the intervention is to support patients during the first two months.</td>
<td>The primary purpose of the intervention is to support patient’s prescribed chronic anticoagulant therapy. The evaluation made during the first two months in study 3, will be compared to those patients from study 2.</td>
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<td>Will the results of group 2a (study II - NOAC) and group 3 (study III - NOAC) be compared? You said that the results will be compared. Please add it in the text.</td>
<td>Yes, they will be compared. This has been added.</td>
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<td>As a general and important comment, I am afraid that the NAOCs adherence measurement methods are pretty weak and not well documented (References for questionnaires are old; all adherence questions are not made available; question to evaluate persistence is not described).</td>
<td>We disagree. Adherence is being measured through patient self-report and pill counts, following the switch and then longer term adherence is being assessed at 1 year through patient self-report, the 8-item Morisky Medication Adherence scale and utilisation of the GP summary care record.</td>
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<td>The list of abbreviations is not complete (the abbreviations used in the table 1 don’t appear in the list) The list is still uncompleted.</td>
<td>This list has been updated and ordered into alphabetical order.</td>
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