Reviewer's report

Title: AUtomated Risk Assessment for Stroke in Atrial Fibrillation: cluster randomised controlled trial of an automated software system electronic reminder intervention to promote anticoagulation and reduce stroke risk (AURAS-AF)

Version: 2 Date: 17 June 2013

Reviewer: Timothy Kenealy

Reviewer’s report:

General comments
The protocol has received ethical approval and funding, and is thus not likely to be changed. The key questions asked of the reviewer are:

1. Will the study design adequately test the hypothesis? My answer - yes
2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing? My answer – yes with minor comments
3. Is the planned statistical analysis appropriate? My answer - yes
4. Is the writing acceptable? My answer – the writing is clear but the organisation needs to be re-worked.

Major compulsory revisions

1. The Journal requests that protocols be reported in line with the CONSORT statement and then sets out a long list of sections to include. The CONSORT statement is not referenced, the journal order is largely ignored and, for the purposes of this Journal, the document is both repetitive and wordy. As an example, the Journal refers to a list of “Tips for preparing your manuscript” which suggests two paragraphs on “why you started” http://www.biomedcentral.com/authors/report. The submitted document contains 16 paragraphs under background and rationale. Similarly, I think the 24 paragraphs on ethical issues could be dramatically reduced. The authors might want to rephrase the suggestion that an ethical risk of the trial is “reducing patient autonomy”. Patient autonomy can only be properly exercised in knowledge of benefits and risks - not offering therapy to patients is not a way to protect patient autonomy.

Minor essential revisions

2. The document repeatedly refers to “eligible” patients with AF but we are not told that the NICE criteria will be used until section 7.2 and not told what the NICE criteria are until Box 1 under section 7.3.2.

3. Overall I think potential harms of oral anticoagulation are not sufficiently mentioned. For example, in Background, the comment about “concern over the QOF’s current stance” and related text in the same and the following paragraph
seem to imply that the authors consider that all patients with AF should be on warfarin (dabigatran is probably not sufficiently mentioned in this document). Similarly, the authors seem much more concerned about inappropriate under-prescribing than they are about inappropriate over-prescribing.

4. It would be helpful to list the clinical codes (Read or alternative) that will be used to automatically extract data on eligibility and outcomes. Similarly, it would be helpful to confirm which of the NICE eligibility criteria will be coded in the GP notes – I would not expect NYHA class, LVEF and falls risk to be well coded. This may raise issues over the accuracy of the denominator for calculation of percentage of appropriate prescribing.

5. It would be useful to concisely give more detail on the qualitative data collection. It would be useful and interesting to know what the investigators suspect or expect the results to be, and why, as these prior assumptions will shape the questions asked, the spontaneous additional questions used as probes, and the interpretation of the interviews. They have already conducted a systematic review and no doubt will already have clear ideas on what to expect. Similarly I suggest identifying criteria for purposive selection of patients and staff – this should probably be for maximum variability across age/gender/medical condition/ethnicity/deprivation for patient, and age/gender/practice size/locality amongst GPs. Having providers nominate patients is not ideal, although asking providers to veto the list (e.g. to eliminate dying people) is essential. It would be appropriate to nominate a specific qualitative methodology (perhaps general inductive theory or qualitative description). And it would be helpful to see the interview guides.

Discretionary revisions

6. The authors distinguish between “systematic” and “opportunistic” screening, where the first refers to sending out invite letters based on a list, and the second refers to screening in response to a reminder generated in real time when the patient attends the practice. As a suggestion, I think the that “opportunistic” is best applied to non-systematic care provided if-or-when the provider thinks of it, and what the authors describe here is more accurately termed “systematic opportunistic” screening i.e. the opportunity has been systematically planned or created.

7. 7.2.1.IIc As well as planning to record stroke rates after 1y, it would be also be useful to repeat remote collection of % appropriate oral anticoagulant therapy because even if the reminders are effective the literature suggests that when they are removed at 6 months the rates are likely to return to baseline.

8. Are the enrolled GPs likely to have a known track record of good response to research projects, or will they receive incentives or training? If not, I wish the researchers luck in getting the GP participants to complete an audit pro forma.

9. The Control group will be given the option to use software at end of trial (presuming it is successful), but the reminders to the Intervention group are being turned off at this stage. I would have thought it reasonable to leave the intervention running for both groups.

10. I am unsure what role, if any, practice nurses play in the intervention. The
authors repeatedly refer to “clinicians” – does this mean GPs and nurses?

11. I presume the real-time reminders will pop up for all users, unless this is controlled by who is logged-in to the computer. I think GPs are the primary target of the reminders but if all users will see them it may be useful to describe the intervention as including all parties; reminders to receptionists, nurses and others are likely to reinforce the effects of reminders to GPs.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests