Reviewer’s report

Title: Development of a computerised decision aid for thrombolysis in acute stroke care

Version: 2

Date: 3 September 2014

Reviewer: Richard Lindley

Reviewer’s report:

This is an important piece of work. The authors report a staged development of a computerised decision support system for acute stroke thrombolysis. Much of the controversy regarding this intervention is about the risk – and those who have had bad experiences have probably led the ongoing campaign against this treatment (e.g. those in the discipline of Emergency Medicine in Australia). The recent letter by Roger Shinton in the Lancet is further evidence that this conflict has not been resolved. The decision support system has clear face validity and this work describes the acceptability and early utility of the support tool by clinicians and patients and relatives.

1) Is the question posed by the authors well defined?

Yes.

This work is important as the explanation of risks and benefits are not straightforward, ischaemic stroke is common and often fatal or disabling, and the balance of risks and benefits remain controversial, even amongst clinicians. A simple, validated clinician support tool would be an important advance in emergency medicine.

2) Are the methods appropriate and well described?

The mixed methodology is appropriate for the work described. I note that the lead author performed the qualitative interviews and was the only researcher to analyse the transcripts. This could lead to bias as it is usual to have two independent analyses of transcripts for qualitative work. This potential weakness should be discussed. The authors should carefully review the content of the “Methods” section and consider how much content could be moved to the Results section without losing the “story” of the development. I note that a lot of the Methods section is actually your results.

3) Are the data sound?

Please see above.

Minor essential revision: Given the clear expertise of the authors in software development you should state the qualifications of the computer programmer and provide some details in the results section (for example, a computer sciences graduate with x years programming experience wrote the software, spending approximately y hours programming time on the project). It is good to have
sufficient detail in your paper to allow replication and we need to know what your resources were in any replication.

4) Does the manuscript adhere to the relevant standards for reporting and data deposition?
   Please see above.

5) Are the discussion and conclusions well balanced and adequately supported by the data?
   There are areas where this can be improved, see section 6.

6) Are the limitations of the work clearly stated?
   Minor essential revision: The authors discuss the small numbers. They should also acknowledge that the analysis of the interviews was performed by a single analyst, who may have introduced some biases, given the nature of the project. The need for ongoing adjustment of the support tool was discussed. This is very relevant as new data (Emberson et al Lancet 2014) will change the underlying assumptions in the tool.

7) Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
   Yes.

8) Do the title and abstract accurately convey what has been found?
   The abstract would benefit from major revision:

   Minor essential revisions:

   Page 2, line 8: you should add “by clinicians to patients/relatives”
   Line 9, “using mixed methods we developed a computerised decision tool in a iterative staged process. We then tested the tool in simulated situations with final testing in real life stroke thrombolysis decisions in hospitals”.

   I would recommend moving the text: “COMPASS 13 expresses predicted outcomes (bleeding complications, death, and extent of disability) with 14 and without thrombolysis, presented numerically (percentages and natural frequencies) and
   15 graphically (pictographs, bar graphs and flowcharts)” currently in the Methods section of the abstract to the Results section.

   Remove the duplicated sentence: No adverse effects of use of COMPASS were reported.

   In Conclusions, I suggest deleting the text: “A mixed-methods feasibility study provided evidence that COMPASS may support clinicians to assess the value of treating individual stroke patients with thrombolysis, and may enhance patients’
and their relatives' understanding of clinical outcome probabilities on benefits/risks of thrombolysis.", and merely state that “Our structured development process led to the development of a gamma prototype computerized decision support tool. Initial evaluation has demonstrated reasonable acceptability amongst patients, relatives and clinicians. The impact of COMPASS on clinical outcomes requires wider prospective evaluation in clinical settings.”

9) Is the writing acceptable?

Minor essential revision: I think the Method section could be shortened, with more “results” placed in the results section. Overall, more succinct writing could reduce the length of the manuscript.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I have received honoraria for work as Chair of a Scientific Meeting for a conference organised by Boehringer Ingelheim. I have recently been paid honoraria for two lectures for Covidien.

I have previously worked with Gary Ford and Helen Rodgers (> 11 years ago).

I was Co-Principal Investigator of the Third International Stroke Trial (IST-3) of stroke thrombolysis and also author of the recent individual patient meta-analysis of alteplase trials.