Reviewer's report

Title: Update on the Transfusion in Gastrointestinal Bleeding (TRIGGER) trial: statistical analysis plan for a cluster-randomised feasibility trial

Version: 3 Date: 17 May 2013

Reviewer: Graeme MacLennan

Reviewer's report:

Thank you for the opportunity to review this submission to Trials. This statistical analysis plan (SAP) requires minor suggested revisions that may improve clarity, but other than that this it is fine.

1) Restructure the abstract into two sections: Background section (perhaps the first sentence only in the current background) and then Methods and Design section, giving a brief outline of the trial (starting with second sentence in current background section).

2) Suggest adding "statistical analysis plan" to the keywords

3) In the second paragraph on the main text perhaps make it explicit here that there are three hospitals in each arm, a 1:1 ratio was used.

4) The protocol focuses on the feasibility outcomes over the clinical outcomes, but the SAP is the opposite. Is there a reason for this? If not, I think that protocol and SAP would dovetail more closely if the SAP was restructured to shift emphasis to the feasibility outcomes. This is more appropriate given the aims of the trial. (Or justify this shift of focus in SAP)

5) The protocol mentions using the data from TRIGGER and observational data to estimate an ICC to include in design of a potential phase III trial at a later date, might the SAP be a suitable place to outline the strategy for estimating the ICC?

6) You might want out add the randomisation method from protocol to the SAP.

7) Add that interaction will be reported with its 95% confidence interval.