Reviewer’s report

**Title:** Examining the efficacy of a support algorithm for commencing patients with type 2 diabetes on a basal/prandial insulin regimen in the primary care setting with retrospective continuous glucose monitoring as an adjunct: INITIATION STUDY PROTOCOL

**Version:** 3  
**Date:** 20 March 2014

**Reviewer:** Susan Smith

**Reviewer’s report:**

Thank you for asking me to review this protocol for the INITIATION study. This is a study examining insulin initiation in Australian GP settings. It is an important topic and there is strong evidence of the need to address delays in insulin initiation, particularly in primary care settings. The study team is very strong and the study is well thought through. My comments relate to how it is being presented which I think needs to be clarified:

**Major revision:**

1. Please clarify the design in the title and abstract. I presumed on reading the title and abstract that this would be an RCT of an insulin initiation intervention and the sub-study randomizing patients into two different monitoring groups adds to this lack of clarity. Essentially the study is either a controlled before and after study of an insulin initiation intervention with an embedded sub-study regarding the impact of different supportive glucose monitoring strategies or it could be described as an RCT of glucose monitoring strategies to enhance insulin initiation and titration in GP settings. If it is the former, the design needs to be clear in the title and abstract. However, if it is the latter this also needs to be clearer including a research question that is focused on the actual intervention being randomized. There is a contemporaneous control from the specialist setting which is a great way to compare two different settings but I don’t think this would count as a controlled before and after study as there is a different patient group attending specialist settings for insulin initiation as the authors refer to in their background. Overall, the authors may prefer to call it an exploratory trial of a complex intervention which fits within the MRC Framework for complex intervention though I recognize they have already undertaken pilot work but a larger exploratory trial with a focus on feasibility would be reasonable.

**Minor discretionary revisions/comments**

2. The authors say they couldn’t ethically justify withholding insulin and therefore can’t randomize the insulin initiation element but they could do a cluster trial comparing their new insulin initiation system with usual care

3. It would be useful if the authors presented a flow sheet of the process which will indicate how they plan to address selection bias of patients – they describe identifying all patients with HbA1c >7.5 and inviting them for a screening review
to check eligibility. One of the really interesting findings will be how many patients are actually suitable for insulin given likely multimorbidity in older patients. A cut-point of 7.5 seems quite low particularly in the over 70 group, given the concerns now about excessively tight control in older patients with type 2 diabetes.

4. The focus on glycaemic control alone is not entirely consistent with the evidence that macrovascular complications that are the major cause of mortality in type 2 diabetes depend as much on BP management. It would be interesting to see if BP control is good in this group but at the least it should be observed because an unintended consequence of the intervention could be that the focus on glycaemia switches attention away from BP management.

5. Page 6 intervention description, para 2. The authors state assessments and visits “will be arranged” – by who? Needs to be clear if practices are going to coordinate all this activity as has implications for sustainability.

6. The authors acknowledge the potential for the control monitoring arm to be contaminated by GP and PN knowledge of the continuous monitoring system – how will they monitor any contamination activity?

7. The trial safety monitoring committee seems to be the same specialist support team – should at least one member be independent?

8. The authors use the term efficacy and pragmatic which is not really consistent – pragmatism matches effectiveness and in any case the design as it stands does not address efficacy or effectiveness in a robust way in relation to insulin initiation without a control group.

**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 declare that I have no competing interests