Reviewer’s report

Title: DreamTel; Diabetes Risk Evaluation and Management Tele-monitoring Study

Version: 4 Date: 22 December 2008

Reviewer: Dereck Hunt

Reviewer’s report:

Major Compulsory Revisions:

Abstract:
The abstract has been improved significantly compared with the initial abstract. The authors may wish to amend sentence three of the second paragraph to indicate the duration of Phases 2 and 3.

Page 3 – paragraph 1:
The authors should change the first occurrence of the word “is” to the word “indicates” in line 7. In line 10, the authors may wish to remove the capital letters used in the term “people with diabetes”. In line 13, the authors should add a comma after reference 3. In line 14, the authors may wish to add the word “optimal” after the word “the”. In line 15, the authors suggest that the ADVANCE study demonstrated a reduction in macrovascular events with normalization of the HbA1c below 7.0%. In fact, the ADVANCE study did not demonstrate any reduction in macrovascular events.

Page 3 – paragraph 2:
The first sentence in this paragraph is an important topic. It does not, however, relate to the material that follows subsequently in this paragraph. It is in fact an isolated concept. In line 4 of this paragraph, the authors should add a comma after the phrase “for those who develop diabetes”. A period needs to be added after the initial reference to reference 7. Further down in the same paragraph, the authors may wish to indicate the actual distance that separates the diabetes education centre in Edmonton from individuals living in northern Saskatchewan.

Page 4 – paragraph 1:
In line 12 of paragraph 1, the word “the” should be changed to the words “use of”.

Page 5 – paragraph 2:
The paragraph addressing the pathophysiologic consequences of diabetes is in fact somewhat repetitive as many of these issues have in fact been addressed earlier in the paper.

Page 5 – paragraph 3:
The material related to the definition of a severe hypoglycemic episode, currently
in lines 14 and 15, should be moved to earlier in the sentence.

Page 6 – paragraph 1:
The comma can be removed from the first line in the sentence after the word “services”. In line 8 of the paragraph, a comma should be inserted after the word Cree.

Page 6 – paragraph 3:
The authors may wish to number the items in the list highlighting the ways in which the home care program has been augmented over the last three years. In line 11 of the paragraph, the word “refer” should be changed to referred, to indicate the past tense. Similarly, the word “advocate” should be changed to “advocated”. Line 21 represents a very new concept, and I would suggest that it would be appropriate to begin a new paragraph at this stage.

Page 7 – paragraph 1:
In line 12, the authors may wish to reword the sentence so that it reads “Blue tooth enabled glucose meters facilitate the downloading of the results to a secure electronic format…”.

Page 7 – paragraph 3:
Throughout this paragraph, the past tense has been used. This suggests that in fact the various activities of phase 1, 2 and 3 have in fact already been completed. Should this paragraph not be reworded using the future tense?

Page 7- paragraph 4:
In the first line of the paragraph discussing the experimental design, the past tense is used. Should this not be changed to the future tense?

Page 8 – paragraph 1:
Once again in this paragraph, and in the paragraphs that follow on this page, the past tense has been used. This makes it difficult to be certain as to which activities have in fact already been completed and which activities are planned as part of the current protocol.

Page 8 – paragraph 3:
In line 5, the authors may wish to change the word “developed” to the word “delivered”. In line 6, the authors may wish to change the word “response” to the word “impression”. In line 7, the initial use of the word “the” should be removed. With respect to the same sentence, are there any details regarding the questionnaires that were used to assess participants’ impressions of the teleprompt system? In line 8 of the paragraph, the authors note that the frequency of the patients’ response to the questionnaires was recorded. It is unclear as to whether the authors are referring to the questionnaires or to the actual teleprompts themselves.

Page 8 – paragraph 4:
In the first line, the authors may wish to begin the sentence with the words “another objective for” instead of the words “the plan for”. In line 2, there should be a comma before the word “noting”. In this paragraph overall, it is unclear exactly which results are going to be compared, given the fact that there will be results in the patients’ meter memory, as well as results in the patients’ logbooks, and results on the central server. Additionally, it is unclear who will be completing this activity. Will this be completed by the home care nurse?

Page 9 – paragraph 1:

In the last sentence the authors note that the frequency of participants’ ability to generate a result will be calculated. Are they referring to the participants’ ability to complete a glucose measurement and download this to the server?

Page 9 – paragraph 2:

In the title for Phase 2, the authors include the terms “and implementation”. Should these words in fact be removed as the implementation is in fact part of Phase 3.

For the discussion of Phase 2 in general, it is unclear as to how much of the work described has in fact already been completed, and how much of the work is in fact part of the current protocol. For example, it would appear that the algorithm for medication introduction and adjustment has already been developed, but still needs to be reviewed with local practitioners and experts.

Page 9 – paragraph 2:

In the first paragraph under Phase 2, the authors note that thiazolidinediones will be added if sulfonylureas have failed. Would it be correct to say that the primary care practitioners will be responsible for assessing contraindications to the thiazolidinediones?

Page 9 – paragraph 3:

Once again, there is a range of verb tenses used in this paragraph, making it unclear as to which activities have been completed and which will be completed in the future. The final sentence should be rewritten as it is somewhat unclear at present and lacks necessary punctuation.

Page 9 – paragraph 4:

The verb tense in the first line should be the future tense.

Page 9 – paragraph 5:

The first four sentences in this paragraph in fact refer to Phase 1 of the study and are currently out of place. The balance of the paragraph appears to relate to activities that form part of Phase 3 of the study protocol. In line 7, the verb tense should be the future tense. In line 8, the authors indicate that at the intake into the study, clinic patients willing to participate will receive a physical examination and an assessment of their current diabetes status. The protocol does not indicate, however, as to whether this will occur at the beginning of Phase 1 or
Phase 3.

Page 10—paragraph 2:
In the first line, the authors make reference to Appendix B. It is interesting that no reference was made earlier in the manuscript to Appendix A. At the end of line 1, I would also suggest that a colon be used instead of a period. In line 5 of the paragraph, the authors should be explicit as to which Phase they are referring to. I take it that they are in fact referring to enrolment into Phase 3 of the study. With respect to the entire paragraph, my sense is that it would be helpful to move the paragraph so that it is located after the first paragraph in the discussion of Phase 2. In line 14 of the paragraph, a comma should be inserted after the first clause.

Page 10—paragraph 3:
In line 2, the word “include” should be changed to the future tense. In addition, the word “rational” should be changed to “rationale”.

Page 10—paragraph 4:
Once again there is the issue of the verb tense. It is unclear as to whether the home care referrals have in fact already been developed or if they will be developed as part of Phase 2. In line 4 of the paragraph, the authors refer to following those patients whose family physicians do not wish to be part of the study in an intent to treat manner. Would it not be better to refer to this group as a control group? With regard to these control patients, will information regarding diabetes clinic referrals be collected? Will these patients be allowed to use their blue tooth enabled glucose meters, and if so, will the downloaded values be forwarded to the primary care providers?

With regard to Phase 2 in general, it is unclear as to how long Phase 2 is envisioned to last, or if this is somewhat open-ended based on the rate at which its goals are achieved?

Page 11—paragraph 2:
The rationale provided in the first paragraph under Phase 3 is in fact the rationale for the entire DreamTel project, rather than the rationale for Phase 3 specifically. The material in this paragraph should be blended into the first paragraph of the background on page 3. In the current paragraph, the authors appropriately indicate that the UKPDS study suggested a 25% reduction in the risk of myocardial infarction for every 1% reduction in HbA1c. In the subsequent sentence, however, the authors state that this finding is consistent with the ADVANCE study. This is not the case as the ADVANCE trial did not demonstrate any reduction in macrovascular events with improvement in glucose levels.

It would be appropriate for the authors to provide a paragraph describing the overall rationale and purpose for Phase 3 of the study.

Page 11—paragraph 4:
In the first line of paragraph 4, the authors note that Phase 3 is designed as a pilot study involving 50 subjects. If significantly fewer than 50 individuals
successfully complete Phase 1 of the study, will the plan be to recruit additional individuals into Phase 1 so that 50 subjects will be included in the pilot study? If so, this should be indicated in the protocol.

Page 11 – paragraph 4:
In line 1 of paragraph 4, the word “Phase” has been misspelled as “hase”. In line 2, the word “will” should be added in before the word “have”. In the final line of the paragraph, the words “are drawn” should be changed to “will be drawn”.

Page 11 – paragraph 5:
The future tense should be used in this paragraph.

Page 12 – paragraph 4:
In the first line, the authors note that the inclusion criteria for Phase 3 will include individuals with HbA1c > 7.0%. Have the authors intentionally set a different HbA1c cutoff for Phase 3 in contrast to Phase 1? For Phase 1, the HbA1c cutoff was noted to be 7.4% (see page 8, line 1).

Page 12 – paragraph 5:
The authors should put a comma after the word “compare” in line 2. Further in the same paragraph, the authors note that another goal will be to determine the ability of individuals to maintain an 80% adherence rate to the recommended glucose self-monitoring frequency. Is this a goal of Phase 3 as well as being a goal of Phase 1?

Page 12 – paragraph 7:
In this paragraph, the authors note that patients will be asked to note any adverse events. The protocol does not, however, specify which events will be included. It does imply that hypoglycemic evidence will be included. It is not clear, however, whether other events such as hospitalizations or myocardial infarctions, etc., will be included.

Page 13 – paragraph 1:
In the first line, the word “severe” should be inserted before the word “hypoglycemia”.

Will other medication use during Phase 3 of the study also be tracked (for example: ACE inhibitor use, statin use, etc.)? Will physician visits be tracked?

Page 13 – paragraph 4:
The authors note that participants will be followed for 18 months from the study entry. The authors should be explicit as to whether they are referring to study entry into Phase 1 or Phase 3.

Page 22:
The authors may wish to make reference to Appendix A in the body of the text.
Page 28:
In the second paragraph, reference is made to Appendix A. Clearly, however, the Appendix A being referred to on page 28 is in fact not the same Appendix A currently in the manuscript.

Page 30:
Reference is made to Appendix B (a sample consultation sheet), and to Appendix C (a sample order sheet). These appendices have not been included with the manuscript.

**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.