Reviewer’s report

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

Version: 2 Date: 1 October 2008

Reviewer: Dereck Hunt

Reviewer’s report:

COMPULSORY REVISIONS:

Abstract:
The methods paragraph needs to be rewritten as there are significant grammatical issues. In addition, the conclusions do not flow from the comments in the methods.

Page 4 – Paragraph 1:
Many individuals would dispute the last sentence, given the significant health benefits of blood pressure and lipid control in individuals with diabetes, and also in view of the recently published findings from the ACCORD and ADVANCE clinical trials.

Page 4 – Paragraph 2:
The authors should include a reference for the first sentence. For sentence two, as already noted, blood pressure and lipid control are also critical for the prevention of long-term complications. The authors may wish to change the word “practices” to “recommendations”.

Page 5 – Paragraph 1:
The authors should break this paragraph into two separate paragraphs as it does in fact address two distinct concepts. The authors may wish to rewrite the third last sentence as there are grammatical issues with this sentence. The authors may also wish to define the term “homecare” as I am concerned as to how well recognized this term is internationally.

Page 6 – Paragraph 1:
The authors should provide a reference after they introduce the concept of a chronic disease management program with its four distinct elements.

Page 6 – Paragraph 2:
The authors should provide a reference for the first sentence. The second sentence is a run-on sentence and should be broken down to two or three smaller sentences.

Page 7:
The first sentence of the first complete paragraph needs to be rewritten.

Page 9 – Paragraph 1:
The sentence regarding the glycemic targets in the STENO-2 trial should be divided into two sentences, as the current sentence is a run-on sentence. In the subsequent sentence, the authors refer to five episodes versus twelve episodes of hypoglycemia. The authors need to indicate these as percentages of the individuals participating in each arm of the study so that the reader will be able to assess the true frequency of hypoglycemia.

Page 9 – Paragraph 2:
I am uncertain as to whether it is essential for the names of the chiefs to be listed. In the same paragraph, it is unclear in the paper as it currently stands the range of individuals who contribute to form the health portfolio councilors.

Page 10 – Paragraph 2:
I am uncertain as to whether the term “certified diabetes educators” is an internationally recognized term.

Page 11 – Paragraph 2:
The authors may wish to add the term “on insulin” to the end of the first sentence of paragraph 2, as the role of glucose self-monitoring remains controversial in individuals who are solely on oral hypoglycemic agents.

Page 12 – Paragraph 1:
The term dysglycemia has been misspelled.

Page 12 – Paragraph 2:
In the first statement the authors write “the ultimate goal of the DreamTel project was community development”. It is unclear exactly what is meant by the term “community development”.

Page 13 – Paragraph 2:
The verb tense in this paragraph is the future tense, whereas the verb tense in the preceding paragraphs had been the past tense. In the same paragraph, it is noted that fifty subjects will be targeted for the pilot study. It is not indicated how these subjects will be identified or recruited. The protocol is not clear as to whether these individuals will already be enrolled in a diabetes program or will be followed by their family doctors alone. It is not specified whether these individuals will be randomly selected or whether they will be a convenience sample. In the same paragraph, it is noted that the Lifestat device will be installed into the homes of people who consent to the study. It will be important to describe this device. In the preceding sentence, the authors also note that participants will be trained on the blue tooth technology. The authors have not, however, previously described the blue tooth technology to which they are referring.

Page 14 – Paragraph 1:
The authors refer to data being forwarded to a web server. It is unclear where the web server will be located. It is also unclear who will receive printed copies of the glucose profiles. The protocol also indicates that consenting subjects will be asked to review the use of the new device with their primary care physicians. The timing of this review, however, is not indicated. In addition, the protocol does not note whether primary care physicians will receive prior training and information packages regarding the new technology.

Page 14 – Paragraph 2:
In this paragraph, the authors note that patient satisfaction will be assessed by using a questionnaire and interviews. The authors do not, however, note any details regarding this questionnaire. The questionnaire is not described. There is no indication as to whether the questionnaire has been validated. There is no evidence provided regarding the validity of the questionnaire when used in translation. The protocol does not state who will administer the questionnaire either. The authors may also wish to consider breaking the current paragraph down into two paragraphs, as there is a rather sudden change in concepts when the paragraph progresses from evaluation of patient and homecare team satisfaction with the system over to the concept of the mechanics of using the system.

Page 14 – Paragraph 2:
In terms of the patient satisfaction questionnaires, the authors also do not indicate the exact timing of the administration of these surveys. The planned analysis of the questionnaires is also not described.

Page 15 – Paragraph 2:
It may be appropriate to consider changing the term “diabetes intensification” over to “blood glucose control intensification” in the title for phase 2. The authors should provide a reference for the first statement in paragraph 2. The authors should also provide references for the statements regarding Gliclazide and Rosiglitazone.

Page 15 – Paragraph 3:
I would suggest finding a different word to use rather than the word “thing” in the first sentence of paragraph 3. The authors indicate in the protocol that the primary care physician will be kept in the loop. The paper does not, however, indicate how the family physician will be informed of developments. The protocol also does not indicate who will be responsible for keeping the primary care physicians informed. In the final sentence of the paragraph, the authors refer to a system of graded alerts and medical backup. It is unclear who will be responsible for developing these alerts and backup systems. It is also unclear who will be responsible for activating the provincial emergency health hotline.

Page 16 – Paragraph 1:
The authors describe creating a change of practice to improve diabetes management that is lasting. It is unclear which individuals will be driving this
phase of the study. It is also unclear who will be developing these systems to integrate the primary care physicians and the homecare team. The authors note that patients who require diabetes intensification will be identified by physicians, nurses, or possibly patients themselves. The protocol does not specify, however, on what grounds the decision will be made that a specific patient requires diabetes intensification. Will this be based on the most recent HbA1c or will it also look at glucose variability or recurrent hypoglycemia or established complications? The authors indicate that a signed homecare referral form will initiate a home visit. They do not, however, indicate exactly which individuals will make the visit to the home. Will this be limited to the homecare nurse or will other study participants also be involved in the home visit? The protocol does not specify who will be involved with the installation and teaching of the new blue tooth enabled technology. Will this be completed by the homecare nurse, or will company representatives involved with the specific technology be involved? The authors note that participants will receive questionnaires and lab testing at the initiation of the device and three months later. The protocol does not state, however, the focus of these questionnaires and laboratory testing. Later in the paragraph, the authors note that individuals’ educational needs will be assessed. The protocol does not state, however, how the educational needs will be evaluated. The authors also describe a medication algorithm. Will the authors be attaching an appendix with the medication algorithm clearly described?

Page 17 – Paragraph 1:
The authors describe a standardized homecare order set. Have the primary care physicians been involved with the development of these orders? Has there been “buy in” from the primary care physicians in the region?

Page 17 – Paragraph 2:
The last word in line two should be changed to “include”. Will the authors be highlighting the other topics addressed during the educational sessions for the primary care physicians? The final sentence in this paragraph also requires rewording to make it flow properly.

Page 17 – Paragraph 3:
The second sentence in the paragraph is unclear. The range of options available to the primary care physicians has not clearly been stated. It is also unclear in the current protocol how the study will handle situations when the primary care physician does not agree with intensification.

Page 18 – Paragraph 1:
The protocol does not state how hospital and emergency visits will be tracked.

Page 18 – Paragraph 2:
The protocol refers to designated registered nurses. Are these designated nurses part of the pre-existing homecare team? The authors also indicate that the diabetes educators will be participating in a learning module. The authors do not indicate, however, the primary focus of the learning module. It is also unclear
who will be the exact focus of the teaching sessions. Will the diabetes educators be providing support to patients with diabetes and their primary care practitioners?

Page 18 – Final Paragraph:
Remove the word “have” from the first line.

Page 19 – Paragraph 1:
The authors should also make reference to the recently published ACCORD and ADVANCE trials which failed to demonstrate significant macrovascular benefits from normalizing glucose levels in patients with longstanding diabetes.

Page 19 – Paragraph 2:
As previously noted, the authors should include an appendix describing the diabetes management intensification protocol algorithm.

Page 19 – Paragraph 4:
The authors note that all patient information specific to diabetes management from each visit will be forwarded to their primary care physician. The protocol does not, however, specify the visit schedule. The protocol notes that follow-up with the primary care physician will be arranged to ensure that the physicians are aware of the patients new treatment status. Will the patients be responsible for informing their physicians of their new medications and treatment plan, or will this be communicated to the physicians by the homecare nurses or other study personnel? How will the study handle situations where the physician disagrees with the treatment algorithm in terms of treatment goals for a specific patient? The statement is made that contact with participants will be maintained so that the results of the study can be communicated. The protocol does not indicate, however, who will be responsible for ensuring ongoing contact with the participants. Will this be the responsibility of the homecare nurses or will central study personnel be responsible for this activity?

Page 20 – Paragraph 1:
The protocol mentions the participants will be provided with snacks and meals as required as well as health promotion materials. Are these activities part of the current protocol, or are they part of current and preexisting health promotional activities?

Page 21 – Paragraph 1:
The authors may wish to consider moving the details of the sample size calculation for the subsequent randomized control trial to an appendix.

Page 23 – Paragraph 3:
The authors note that the primary outcome of the study will be HbA1c after six months. Is there a plan to collect HbA1c information and analyze the results at the eighteen month point as well?
The authors note that a cost effective analysis will be completed. Will the authors be including measures of physician cost and patient time in their cost effectiveness analysis? Has a healthcare economist been involved in the development of the cost effectiveness analysis?

Other Comments:
It is unclear as to whether the protocol has undergone formal ethics review. With regard to the randomized control trial, the authors do not comment on the potential implications of contamination, given that the primary care physicians will be following patients in the active arm as well as the control arm of the study.

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

**Quality of written English:** Needs some language corrections before being published

**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.