

Diabetes Information Technology & WebWatch

Questionnaires for a Randomized Controlled Trial Methodology to Evaluate the Teaching Utility of Diabetes Simulation Programs

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ABSTRACT

AIDA is an interactive educational diabetes simulator which has been made available without charge on the Internet. Since its launch on the World Wide Web in 1996 over 87,000 people have visited the AIDA Website—<http://www.2aida.org>—and over 22,000 copies of the program have been downloaded from there free-of-charge. The AIDA software is believed to be of use in recreating clinically realistic diabetes situations for interactive simulation. However, despite its widespread application, its actual utility for supporting the education of patients with type 1 diabetes mellitus remains to be objectively demonstrated in a clinical randomised controlled trial (RCT) setting. The current “Diabetes Information Technology & WebWatch” column overviews a prospective RCT methodology for formally evaluating the educational utility of an interactive diabetes simulator, like AIDA. The protocol makes use of two study arms—each receiving different educational interventions. During lessons, arm A of the study will be exposed to the AIDA simulator (the active intervention), while arm B (the control group) will benefit from conventional educational methods using standard presentations with slides and transparencies. Six lessons will be held for each study arm (one per week). At the beginning and end of the study self-monitoring blood glucose (SMBG) data will be collected, details of any hypoglycemic episodes recorded, and assessments made of glycosylated hemoglobin (HbA_{1c}) levels. Participants will also be required to complete a detailed questionnaire to assess their self-confidence, quality of life and metabolic control, attitudes towards SMBG, and knowledge about insulin dosage calculation. Comparisons will be made between arm A and arm B using unpaired statistical analyses. A partial cross-over study design is also proposed whereby subsequently the control group will be exposed to the AIDA simulator during a further 6-week course of lessons. This will ensure that the maximum number of subjects will eventually receive the active intervention, and will also allow further within group paired analyses to be applied (with greater statistical power). This current “Diabetes Information Technology & WebWatch” column documents two of the questionnaires which are intended to be used for this RCT approach.

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PROTOCOL AND SUBJECTS

THE PROTOCOL has been described in detail elsewhere.¹ Briefly, outcome measures which this protocol is intended to evaluate are set out in Table 1. To demonstrate an improvement in these we have proposed a randomized controlled trial (RCT) methodology consisting of conventional education sessions versus computer-simulation sessions, with a partial cross-over design to maximise the numbers of subjects exposed to the diabetes simulator. Using such an approach, both between group and within group comparisons and statistical analyses will be possible. Figures 1 and 2 summarize the overall study design.

Inclusion and exclusion criteria for the study have been summarized elsewhere.¹ For the initial evaluation study, we are planning to enroll adult subjects with insulin-dependent (type 1) diabetes, and randomly assign them to one of the two study arms (arm A: simulator; arm B: conventional education [control group]). However, for later studies, we may also involve patients with insulin-treated type 2 diabetes mellitus, as well as possibly diabetic adolescents/teenagers.

PRE-RANDOMIZATION (BASELINE) PHASE OF STUDY

The pre-randomization (baseline) phase of the study is summarised in Figure 1. Upon recruit-

TABLE 1. MAIN (AND SECONDARY) OUTCOME MEASURES OF STUDY

<i>Main outcome measures:</i>	
1.	Improve knowledge of how to tailor the insulin dose to the specific needs of the subject.
2.	Improve morning and postprandial self-monitoring blood glucose (SMBG) data.
3.	Improve forward thinking (ability to answer "what-if" type questions).
4.	Improve well being and self-confidence.
5.	Reduce the number of hypoglycemic episodes.
6.	Improve HbA _{1c} .
7.	Achieve subject feeling of "empowerment."
<i>Secondary outcome measures:</i>	
8.	Increase social behavior and interpersonal cooperation about diabetes.
9.	Help to increase confidence with a computer.
10.	Increase physiological knowledge.
11.	Establish sample sizes required for a possible future larger-scale, multicenter study.

(From Tatti & Lehmann¹).

ment, all subjects will be asked to keep a log of any symptomatic hypoglycemic episodes, and collect their self-monitoring blood glucose (SMBG) data for 1 week before breakfast (fasting) and 2 h after lunch and dinner. Subjects will only be included in the study if they have collected at least 75% of the SMBG data requested. The patients' logbook entries can be cross-verified with the memory from their reflectance meter, as required.

After this, subjects will be randomly assigned to either arm A or arm B of the study, using a process of stratified randomization that takes into account hypoglycemia/low blood glucose risk and the glycosylated hemoglobin (HbA_{1c}) level. The purpose of the stratification is to ensure that arm A and arm B of the study have similar numbers of subjects in relation to key variables that might influence outcome. Therefore subjects will be stratified into four groups according to (1) low HbA_{1c} level, low "hypo" risk; (2) high HbA_{1c} level, low "hypo" risk; (3) low HbA_{1c} level, high "hypo" risk; and (4) high HbA_{1c} level, high "hypo" risk (Fig. 1).

For the purpose of stratification each subject's individual HbA_{1c} level will be assessed as the average (arithmetic mean) of their previous 12 months' HbA_{1c} data; a low HbA_{1c} being defined as less than the median (50th percentile) HbA_{1c} level for the whole cohort, while a high HbA_{1c} is defined as greater than or equal to the median HbA_{1c} level of the cohort.

"Hypo" risk is categorized based on the 1 weeks' SMBG data collection; high "hypo" risk being defined as any symptomatic hypoglycemic events or recorded SMBG data less than 70 mg/dL (3.9 mmol/L) during that week. For the purpose of this study, low "hypo" risk is defined as no symptomatic hypoglycemic episodes and recorded SMBG data greater than 70 mg/dL (3.9 mmol/L) during that week.

Method of randomization

In order to ensure complete separation of subject recruitment and study execution from the randomization process, an external randomization service has been set up via the AIDA Website (at <http://www.2aida.org/random>). This allows subject details (patient name, hospital/study number, gender, age, number of symptomatic "hypos" and average HbA_{1c}

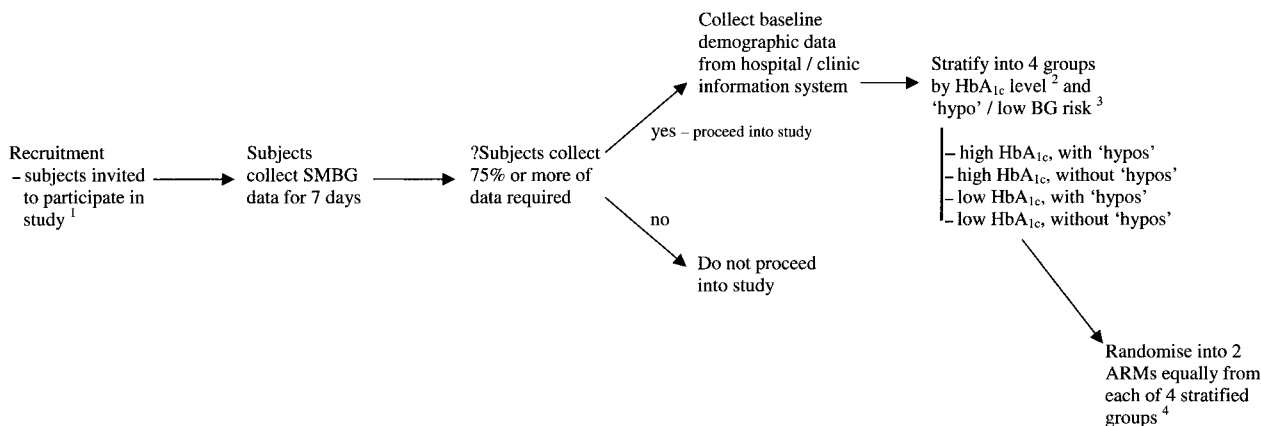


FIG. 1. Pre-randomization (baseline) phase of study. (1) Initial invitations/recruitment based on study inclusion/exclusion criteria. (2) HbA_{1c} level based on average (arithmetic mean) of glycosylated haemoglobin levels recorded during the preceding 12 months. (3) “Hypo”/low BG risk determined from initial 7 days’ self-monitoring blood glucose (SMBG) data collection. (4) Stratification ensures that equal numbers from each of the four groups end up in each of the two study arms (arm A or arm B). (Modified from Tatti and Lehmann.¹)

level) to be entered for each study participant. It is intended that entries should be made by the physician or nurse who recruited the subjects, categorised according to low/high “hypo” risk and low/high HbA_{1c} levels, as outlined above. Data entered in this way can then be automatically submitted across the Internet, via electronic mail (email), to a co-investigator (E.D.L.) in London, England. Using dedicated software written specifically for this purpose

(incorporating a random number generator) it will be possible for this co-investigator to independently randomize participants either to the AIDA or control groups; randomization codes being returned to the referring physician/nurse by email.

In this way, there should be a complete division between the recruitment, enrollment, and teaching of subjects, and their initial randomization to either arm A or arm B of the study.

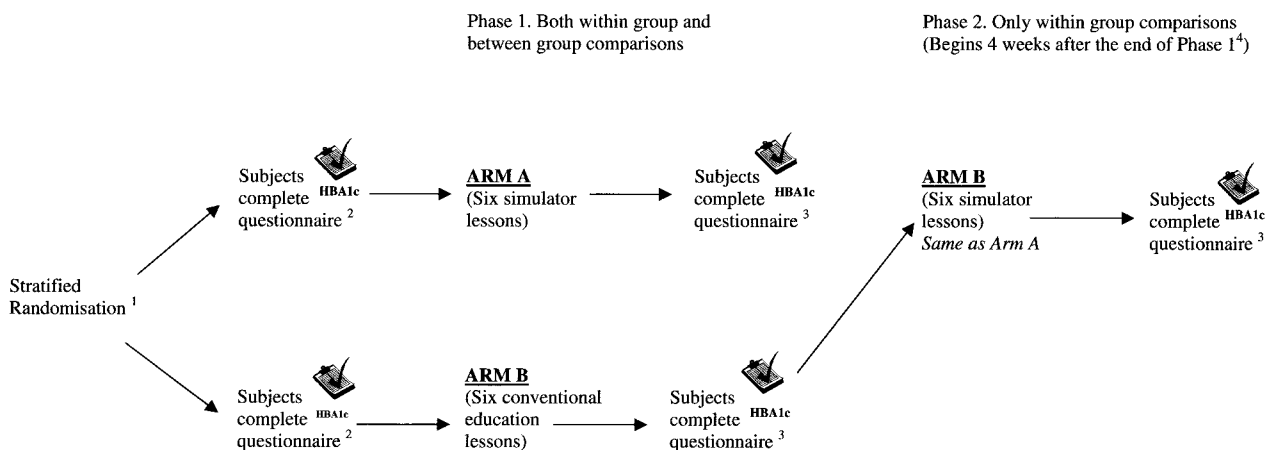


FIG. 2. Main phase of study. (1) Stratification will be according to the glycosylated hemoglobin (HbA_{1c}) level and “hypo”/low blood glucose risk of the subjects. (2) The questionnaire aims to determine the main outcome measures (see Appendix 1). (3) In addition to completing the questionnaire, the subjects will also be requested to complete a diary with fasting, preprandial, and 2-h postprandial blood glucose data. HbA_{1c} will be sampled prior to the start of phase 1 and 1 month after the end of the last lesson. Furthermore HbA_{1c} will be measured 1 month after the end of phase 2 for the subjects in arm B. (4) The delay will allow resampling of HbA_{1c} levels in the cross-over subjects and also reduce any “carry-over” effect on blood glucose levels—from the conventional lessons (phase 1) to the simulator-based lessons (phase 2). The final HbA_{1c} for arm B will be sampled 1 month after the end of phase 2, about 20 weeks after the first sample. (Modified from Tatti and Lehmann.¹)

MAIN PHASE OF STUDY

The main phase of the study is summarized in Figure 2. Just before entering this phase, the enrolled subjects will have their baseline HbA_{1c} measured, and they will fill in a study questionnaire. This questionnaire is documented in Appendix 1.

Interventions

The two arms of the study will receive different interventions. Arm A will use the AIDA simulator as described below, while arm B will benefit from conventional (standard) educational methods (verbal communication with slides and transparencies). The aims of the lessons provided to the two study arms will be identical, as outlined in Table 2.

The study subjects will be randomized into groups of six subjects each (with multiple groups planned). All the study subjects will be asked not to use the AIDA simulator on their own to avoid the possibility that one “over-performer” can lead the group—or that the results can be biased in any way—for instance by someone in the control group (arm B) accessing the simulator at home.

Before the start of the main phase of the study, all subjects will be asked to bring with them to lessons their own SMBG data, insulin regimen, and carbohydrate intake details—for possible use during classes. At the end of each lesson, subjects will be given a short, separate generic one-page questionnaire (documented in Appendix 2) to complete regarding their thoughts on the lesson, and whether they felt that they benefited from it.

TABLE 2. AIMS OF THE SIX STUDY LESSONS

Lesson I: learn how to match insulin and food intake.
Lesson II: learn about regulation of blood glucose (BG) levels overnight
Lesson III: learn about role of the renal threshold of glucose and role of exercise
Lesson IV: learn about the avoidance and treatment of hypoglycemia.
Lesson V: learn about behavior in case of shift work or travel abroad.
Lesson VI: learn how to manage BG control in unforeseen circumstances.

(From Tatti & Lehmann¹).

All subjects will go through six lessons, one each week. In the description of the two study arms which follow, more detail is given about the simulator arm (arm A) simply because this is the novel intervention being tested. However, it is intended that the duration of the lessons should be the same for both study arms (approximately 65–70 min).

ARM A (SIMULATOR ARM): PHASE 1

The participants will not interact directly with the computer—rather the teaching experts will serve as “wizards” or facilitators undertaking all interactions with the computer. This will circumvent any problems if the participants are not computer-literate or confident to use a computer themselves. Also this approach should help to avoid any “learning curve” effect where it takes the study participants a number of lessons to become fully familiar with the program’s functions.

For all simulation lessons, two computer screens will be made available—linked to the same PC—ensuring that all study participants will have a good view of the computer displays. At the end of each lesson, the number of simulations run during that lesson will be recorded. The topics to be covered during each lesson are summarized in Table 2.

ARM B (CONTROL ARM— CONVENTIONAL EDUCATION): PHASE 1

For this group, the content of a standard textbook will be used as a reference.² The principles are the same as described above for arm A and the topics will be the same as set out in Table 2, but this group will not use the AIDA simulator.

The general scheme of these lessons will involve conventional (standard) education sessions on a given topic, using slides and transparencies—followed by discussion and questions—and then a recap. As for arm A, at the end of each lesson participants will be given a short, generic one-page questionnaire to complete regarding their thoughts about the lesson.

CROSS-OVER PHASE: PHASE 2

At the end of the control arm (arm B—phase 1) there will be a gap, once phase 1 is complete, of 4 weeks, following which the subjects will complete the study questionnaire, have their HbA_{1c} re-measured, and then enter the cross-over phase of the study. This will entail a further cycle of 6 lessons, exactly the same as arm A (with the simulator).

The purpose of this partial cross-over phase is to expose the control (standard education) group to the simulator—and therefore increase the final sample size actually receiving the active intervention. In addition to allowing between group analyses—this approach will also allow further comparisons to be made within groups of the same subjects—and therefore allow more paired statistical analyses to be used, with their associated greater statistical power.

FINAL OUTCOME MEASURES

At the end of the study, after the interventions (both of phase 1 and phase 2), the participants will be required to:

1. Collect SMBG data for 1 week, before breakfast (fasting), and 2 h after lunch and dinner.
2. Have their HbA_{1c} measured (1 month after the end of the intervention).
3. Provide a record of any symptomatic hypoglycemic episodes during the course of the study.
4. Complete the main study questionnaire (see Appendix 1)—to assess their self-confidence, and well-being (rated on a scale), together with their knowledge of “what-if” type problem solving in diabetes care. An additional page of feedback comments will be sought from the participants in the simulator arm (arm A) concerning what they thought about the AIDA simulation software.³

The recording of symptomatic hypoglycemic episodes will be differentiated from biochemical “hypos” (recorded low BG levels less than 70 mg/dL [3.9 mmol/L]).

STUDY LOGISTICS

It is well recognized in education that the smaller the class size the greater the educational opportunity that can be offered to participants. For this study, class sizes also need to be kept small in order to allow each of the subjects to present their own data during one of the six simulation lessons. For this reason the class size will be limited to six subjects per class for both arm A and arm B. It is intended for subjects to have one lesson per week—so it will take 6 weeks to run a complete course of 6 lessons.

Due to local time constraints and the availability of teachers, it may be necessary to run only one lesson for arm A—and one lesson for arm B—each week. This means that more than one 6-week course of lessons will be required to get all the recruited subjects through the lessons.

DISCUSSION

To evaluate the impact of education sessions with an interactive diabetes simulator on the well-being and short-term and intermediate metabolic control of patients with type 1 diabetes, we have designed a study protocol using a rigorous and transparent methodology.

The approach overviewed above, and described in detail elsewhere¹ combines a prospective, randomized controlled trial with a partial cross-over design to maximise the number of subjects exposed to the simulator. The biggest limitation of this approach is likely to be the availability of teachers and the time required to actually run the lessons. Subjects will also need to be motivated as they will need to commit to 6–12 weeks of lessons. However they do benefit from useful education sessions with conventional lessons and/or a simulator, so that should hopefully be enough to motivate them.

It should be self-evident that interactive simulations such as those highlighted here only provide one aspect of the education required by patients with diabetes. It is quite possible to envisage a study—which incorporates components of the randomized controlled trial described above—as part of the assessment of more standard educational diabetes interventions. In this respect, it will be important not to

restrict this protocol to use just with a teacher and 1-h clinic lessons.

For instance, it is well recognized that there are not enough resources (trained diabetes educators, money, facilities, etc.) available for patients to be seen in clinic as often as might be regarded as ideal. For example, in the Diabetes Control and Complications Trial (DCCT),⁴ patients in the intervention group were seen fortnightly and often contacted by telephone weekly.⁵ One issue appears to be whether information technology tools might be able to assist in bridging part of the gap between what was available in the DCCT versus what is usually available routinely in day-to-day clinical practice.

Therefore, other questions that we might wish to address in future evaluation studies include the following—does allowing a patient access to an interactive educational simulation program in between formal visits to a diabetes educator or clinic improve knowledge, confidence, self-management skills, or glycemic control? To be able to judge whether such software can help in this role requires a rigorous evaluation methodology.¹

Initially, we are trialling the approach described above in a hospital clinic setting. However, longer term, it is not difficult to envisage that the basic methodology of the questionnaire approach—combined where necessary with appropriate recording of clinical (biochemical) data—could be equally applicable for patients with diabetes using the simulator on their own at home,⁶ between clinic visits, or even possibly for health-care student evaluation (e.g., with medical, nursing, pharmacy, or diabetes educator students) who make use of the simulations for their own education.

APPENDICES

Three questionnaires have been adopted for this randomized controlled study.

Appendix 1 provides the main study questionnaire which is divided into seven sections—covering baseline questions, plus questions about (1) patient self-confidence, (2) quality of life and metabolic control, (3) social and emotional impact of diabetes on lifestyle, (4) attitudes towards SMBG, (5) prior knowledge about diabetes, and (6) “what-if” type questions and knowledge about insulin dosage calculation. This questionnaire is based in part on questions from the Diabetes Care Profile, from the Michigan Diabetes Research and Training Center.⁷

Appendix 2 gives a second generic one-page questionnaire that has been developed for use at the end of each lesson. This is intended to establish if the participants felt more confident with the information provided during the lessons, and to get them to rank the information provided on a Likert scale from “*not at all useful*” through to “*very useful*.” Participants are also asked what areas they felt were not adequately covered by the lessons—allowing them to offer feedback.

The third questionnaire—intended for completion by participants at the end of arm A of the study—after they have been exposed to the AIDA simulator has been documented in the previous “Diabetes Information Technology & WebWatch” column.³ This contains 11 questions to establish what the participants thought of the simulator, and to identify ways in which they see the simulations being applied more widely in routine practice.

APPENDIX 1: DIABETES EDUCATION—EVALUATION QUESTIONNAIRE

Date_____/_____/_____

Study no.____ RND_____

BASELINE QUESTIONS

1. How would you describe your computer skills:
 - Beginner
 - Intermediate
 - Expert
2. Do you personally have e-mail access at home / work? YES NO
3. Do you have online Internet / World Wide Web access at home / work? YES NO
4. Which level (grade) did you reach at school? _____
5. Do you have a job? YES NO
- 5.a —If yes, which job? _____

SECTION I—Self-confidence

Qu. 6. Please rate how confident you are that you can do the following things at present

(0 = not at all confident 6 = totally confident)

- | | | | | | | | |
|--|---|---|---|---|---|---|---|
| 6.a I can manage my diabetes | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.b I can deal with hypoglycemic episodes | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.c I can test my blood sugar correctly | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.d I can have a trip abroad | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.e I can do my usual physical activity | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.f I can work out what to eat at home | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.g I can eat out at a restaurant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.h I can control my weight | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.i I can cope with my diabetes when I am sick | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6.j I can inject my insulin correctly | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

Qu. 7. Please circle a number which indicates your answer

(0 = not at all 6 = extremely)

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| 7.a How concerned are you about your diabetes | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 7.b How satisfied are you with your blood sugar control | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

SECTION II—Quality of life and metabolic control

- 8.a How many times in the last month have you had a low blood sugar reaction with sweating, weakness, anxiety, trembling, hunger, or headache (hypoglycemia)?
- 0 1-3 4-6 7-12 12+
-
- 8.b How many times in the last year have you had severe hypoglycemia with loss of consciousness or need for help?
- 0 1-3 4-6 7-12 12+
-
- 8.c How many days in the last month have you had high blood sugar with thirst, dry mouth and skin, nausea or fatigue?
- 0 1-3 4-6 7-12 12+
-
- 8.d Have you ever been hospitalized for the treatment of diabetes?
- YES NO
- 8.e —If yes, how many times in the past year? _____
- 8.f How often does your diabetes prevent you from doing your normal daily activities? (0 = almost never; 6 = almost always)
- 0 1 2 3 4 5 6
-

SECTION III—Social and emotional impact of diabetes on lifestyle

Qu. 9. My diabetes and its treatment prevent me from:

(0 = strongly disagree; 1 = disagree; 3 = neutral; 5 = agree; 6 = strongly agree)

- 9.a Having enough money
- 0 1 2 3 4 5 6
-
- 9.b Meeting work responsibilities
- 0 1 2 3 4 5 6
-
- 9.c Going out or travelling
- 0 1 2 3 4 5 6
-
- 9.d Being as active as I would like
- 0 1 2 3 4 5 6
-
- 9.e Eating foods that I like
- 0 1 2 3 4 5 6
-
- 9.f Having a good relationship with people
- 0 1 2 3 4 5 6
-
- 9.g Going to sleep late
- 0 1 2 3 4 5 6
-
- 9.h Having diabetes makes my life difficult
- 0 1 2 3 4 5 6
-
- 9.i I am afraid of my diabetes
- 0 1 2 3 4 5 6
-
- 9.j I find it hard to believe that I really have diabetes
- 0 1 2 3 4 5 6
-
- 9.k I feel depressed because of my diabetes
- 0 1 2 3 4 5 6
-
- 9.l I have no difficulty taking care of my diabetes
- 0 1 2 3 4 5 6
-
- 9.m I feel inferior to others because of my diabetes
- 0 1 2 3 4 5 6
-
- 9.n I find it hard to do all my things because of my diabetes
- 0 1 2 3 4 5 6
-

- 9.o All things considered, I feel satisfied with my life 0 1 2 3 4 5 6
- 9.p I can do anything I set out to do 0 1 2 3 4 5 6
- 9.q I would like to change many things about myself 0 1 2 3 4 5 6

SECTION IV—Attitudes towards SMBG

Qu. 10. When you do not test your blood glucose, how often is it because:

(0 = *Never* 3 = *Sometimes* 6 = *Always*)

- 10.a You forgot 0 1 2 3 4 5 6
- 10.b You do not believe it is useful 0 1 2 3 4 5 6
- 10.c The time or place was not appropriate 0 1 2 3 4 5 6
- 10.d You do not like to do it 0 1 2 3 4 5 6
- 10.e You ran out of test materials 0 1 2 3 4 5 6

(0 = *Not relevant* 3 = *Sometimes is relevant* 6 = *Always relevant*)

- 10.f How important is it that you follow exactly your test schedule for measuring blood glucose 0 1 2 3 4 5 6
 - 10.g How much does blood glucose (BG) testing help you control your diabetes 0 1 2 3 4 5 6
- (0 = *Never* 3 = *Sometimes* 6 = *Always*)
- 10.h How often do you adjust your insulin dose on the basis of your BG test results? 0 1 2 3 4 5 6
 - 10.i How often do you adjust your diet on the basis of your BG test results? 0 1 2 3 4 5 6
 - 10.j How often do you adjust your physical activity on the basis of your BG test results? 0 1 2 3 4 5 6

SECTION V—Prior knowledge about diabetes

Qu. 11. Place an X to indicate whether each item below is associated with hyperglycemia or hypoglycemia as a *sign* or *symptom*.

- | | | |
|-------------------------|---|--|
| 11.a No glycosuria | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |
| 11.b Dry skin and mouth | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |
| 11.c Happens slowly | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |
| 11.d Increased thirst | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |

Qu. 12. Place an X to indicate whether each item below is associated with hyperglycemia or hypoglycemia as a *cause*.

- | | | |
|------------------------|---|--|
| 12.a Too much insulin | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |
| 12.b Too much exercise | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |
| 12.c Too much food | <input type="checkbox"/> <i>Hyperglycemia</i> | <input type="checkbox"/> <i>Hypoglycemia</i> |

Qu. 13. Insulin reactions (hypoglycemic episodes) are likely to occur:

- | | | |
|--|-------------------------------|--------------------------------|
| 13.a During vigorous exercise | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 13.b During the peak action of your insulin | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 13.c Just before meals | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 13.d During any of the times mentioned above | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |

Qu. 14. One mL of U-100 insulin contains:

- | | | |
|----------------|-------------------------------|--------------------------------|
| 14.a 1 Unit | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 14.b 40 Units | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 14.c 80 Units | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |
| 14.d 100 Units | <input type="checkbox"/> TRUE | <input type="checkbox"/> FALSE |

SECTION VI—"What-if" type questions

15.a **How many extra Humalog insulin units would you need to add if you increased your lunch by 20 more grams of sugar?** 1 2 3 4 5 *don't know*

15.b **Which of the following is a reasonable action if you double the carbohydrate content of your breakfast (from 20 grams to 40 grams)**

- (i) Increase your fast-acting insulin from 5 units to 6 units
- (ii) Increase your fast-acting insulin with 3 more units
- (iii) Decrease your fast-acting insulin by 1 unit
- (iv) Decrease your fast-acting insulin and add 4 units of Intermediate acting insulin

15.c **If I normally inject 6 units of Humalog before breakfast (30 grams of carbohydrate), and my fasting blood glucose this morning is 55 mg/dL (3.1 mmol/L) what should I do?**

- (i) Only inject 5 units of Humalog
- (ii) Inject 7 units of Humalog
- (iii) Add 10 grams of carbohydrate to breakfast, and make no change to my insulin regimen
- (iv) Add 10 grams of carbohydrate to breakfast and inject 5 units of Humalog
- (v) Add 10 grams of carbohydrate to breakfast and inject 7 units of Humalog
- (vi) (your option) _____

15.d **If I inject the usual dosage of short-acting insulin (Humulin R, Actrapid) at lunch, but I eat much less than usual, how many hours later is a hypoglycemic episode most likely?**

0 1 2 3 4 5 6 7 8

- 15.e **If I have my rapidly acting insulin (Humalog) injection at 8:00 a.m. and my breakfast at 08:20 a.m.**
- (i) How many hours after the injection do you think that the peak blood glucose is most likely to occur? 0 1 2 3 4 5 6 7 hours
- (ii) How many hours after the injection do you think that a hypoglycemic episode is most likely to occur? 0 1 2 3 4 5 6 7 hours
- 15.f **If I run for 20 minutes, 5 hours after a dose of rapidly acting (Humalog) insulin and my post-exercise blood glucose is 55 mg/dL (3.1 mmol/L), how many grams of carbohydrate should I eat to prevent a hypoglycemic episode?** 5 10 15 20 grams
- 15.g **If I feel an impending “hypo” 2.5 hours after a rapidly acting (Humalog) insulin injection and my blood glucose is 55 mg/dL (3.1 mmol/L),**
- (i) How many grams of carbohydrate should I eat? 5 10 15 20 grams
- (ii) Should I continue checking my blood glucose? YES NO
- 16.a **Joe has type 1 diabetes and uses a 4 dose regimen (3 rapidly acting [Humalog] injections and 1 intermediate-acting [NPH] injection at bedtime). His fasting blood glucose is usually in an acceptable range. Last night he increased his usual dose of intermediate-acting insulin with 2 more units, and yet this morning his blood glucose is >300 mg/dL (>16.7 mmol/L). What should he do?**
- (i) Increase his morning rapidly acting insulin
- (ii) Increase his morning rapidly acting insulin and his bedtime intermediate-acting insulin
- (iii) Increase his morning rapidly acting insulin to reduce his blood glucose and re-sample his blood glucose at 03:00 a.m. the following night
- (iv) Other (give your own answer) _____
- 16.b **Last night Joe did not have dinner and did not take his bedtime insulin injection. This morning he has a blood glucose level of 400 mg/dL (22.2 mmol/L) and ketone bodies in his urine.**
- (i) This is because he could not sleep during the night (insomnia and stress)
- (ii) Insulin has accumulated in his body
- (iii) There is another explanation apart from food
- (iv) Other (give your own answer) _____
- 16.c **Joe’s normal blood glucose is always 250 mg/dL (13.8 mmol/L) before breakfast and 120 mg/dL (6.7 mmol/L) 2 hours after dinner. What would you suggest to improve his blood glucose control?**
- (i) Reduce the rapidly-acting insulin before dinner
- (ii) Increase the bedtime intermediate-acting insulin dose
- (iii) Increase the rapidly-acting insulin before breakfast
- (iv) Other (give your own answer) _____

- 16.d **Bob ate twice his usual amount of carbohydrate at dinner. He had already injected his 10 units of rapidly acting (Humalog) insulin. What should he do?**
- (i) Try to vomit
 - (ii) Add one more rapidly-acting (Humalog) insulin injection (of 3 units more)
 - (iii) Increase his intermediate-acting (NPH) insulin dose at bedtime
 - (iv) Other (give your own answer) _____
- 16.e **My doctor asked me to check my blood glucose at 3:00 a.m. Why?**
- (i) He wants to know if I am a reliable person
 - (ii) He has no real purpose
 - (iii) Other (give your own answer) _____
- 16.f **I had my usual intermediate-acting (NPH) injection at 11:00 p.m. If my blood glucose at 03:00 a.m. is 120 mg/dL (6.7 mmol/L), what will happen next?**
- (i) A hypoglycemic episode at approximately 05:00 a.m.
 - (ii) Nothing will happen
 - (iii) Depends on the time course of my last insulin injection
 - (iv) Other (give your own answer) _____
- 16.g **This evening I will have my nephew's birthday and I will eat more than usual. What should I do?**
- (i) Increase my rapidly-acting insulin before dinner
 - (ii) Increase my intermediate-acting insulin at bedtime
 - (iii) Do both the above
 - (iv) Check my blood glucose at 03:00 a.m.
 - (v) Take 2 injections of rapidly acting insulin: the first at 10:00 p.m. and the second at 06:00 a.m.

**APPENDIX 2:
DIABETES EDUCATIONAL LESSONS—GENERAL QUESTIONNAIRE**

- L1. Today's date _____ / _____ / _____
- L2. Lesson number 1 2 3 4 5 6
- L3. Educational intervention Simulator (AIDA) / Conventional teaching
- L4. Phase of study 1 2
- L5. Teacher / Facilitator / "Wizard" Doctor / Nurse

L6. Do you feel more confident with the information you received today? (Rank on the scale)

(0 = not at all confident 6 = very confident)

0 1 2 3 4 5 6

L7. What area(s) do you feel have not been covered enough?

L8. How do you rank today's information?

(0 = not at all useful 6 = very useful)

0 1 2 3 4 5 6

SYSTEM AVAILABILITY

The AIDA diabetes simulation software continues to be developed and upgraded. The latest release of AIDA (v4.3) can be downloaded, without charge, from <http://www.2aida.org> on the Internet. The program runs on IBM PC or compatible 80386 / 80486 / Pentium based machines and requires approximately 3 Mb of hard disk storage space. The software can also be used on Apple Macintosh computers running PC emulators such as Virtual PC or SoftWindows. A fully Internet-based version of AIDA, called "AIDA on-line," is also available for use free-of-charge at <http://www.2aida.org/online> on the Web. People who wish to be automatically informed about future updates and enhancements to the AIDA/"AIDA on-line" diabetes software range can subscribe (for free) to the AIDA diabetes simulator announcement list by sending a blank email note to: subscribe@2aida.org

Any readers who might be interested in collaborating by applying the randomized controlled trial protocol overviewed above in an evaluation of AIDA in their own unit(s) for clinician/specialist nurse/educator-led patient teaching sessions are invited to contact one of the authors. Further information about the evaluation of AIDA for patient use can be found at <http://www.2aida.org/evaluate> on the Web.

FURTHER TOPICS

If you would like to suggest further topics or Websites for future "Diabetes Information Technology & WebWatch" columns, please email information—with a brief description of the site/suggestion—to Dr. E.D. Lehmann:

info-www@2aida.org (please write *Diabetes WebWatch* in the subject line). You can also fax information to: (503) 218-0828, quoting Diabetes Information Technology & WebWatch.

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