

Preliminary experience with the Internet release of AIDA—an interactive educational diabetes simulator

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Abstract

This paper overviews the Internet release of AIDA, a freeware interactive educational diabetes simulator. Since its release on the World Wide Web as a non-commercial contribution to continuing diabetes education over 14000 people have visited the AIDA Web site—<http://www.diabetic.org.uk/aida.htm>—and over 5000 copies of the program have been downloaded, without charge. User responses thus far have been very encouraging. Example feedback and clinical experience reported by two insulin-dependent (type 1) diabetic patients, a patient's carer, the father of a diabetic teenager, a diabetes doctor and nurse educator, an endocrinologist and a postgraduate educator are presented. While such anecdotal, qualitative assessments are worthwhile and form a necessary step in the overall evaluation process—they are clearly subjective in nature and fully recognised as such. Given this, definitive outcome measures are highlighted as being required for the next stage in the evaluation process, and various objective evaluation criteria are proposed. A general protocol for the evaluation of interactive educational simulation tools, like AIDA, with patients is described and the concept of applying this in multiple centres—as a way of increasing study sample sizes—is discussed. It is highlighted that such a protocol could also be used to objectively compare a number of different interactive educational diabetes simulators. Clinicians who are interested in collaborating by enrolling patients into such a study are invited to contact the author, by email, at aida@globalnet.co.uk © 1998 Elsevier Science Ireland Ltd. All rights reserved.

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1. Introduction

There is increasing interest in the application of information technology (IT) in diabetes care. The

hope is that software tools may offer a means of improving the therapy offered to patients with diabetes; the expectation being that such IT-based techniques may be able to permit more patients to

be managed more intensively, in line with the experience of the Diabetes Control and Complications Trial (DCCT) [1]. In addition to database and decision support systems, an area of diabetes care in which computers may have a great deal to offer is education.

As in all branches of diabetes-IT numerous prototypes have been developed for use by patients, students as well as health-carers. A recent systematic two-part review of this topic can be found elsewhere [2,3], and two extensive compilations of recent clinical experience with such software tools can also be found in another diabetes-computing Special Issue [4,5]. For all these systems, evaluation has been, and remains, a key issue. This is especially the case in education, where showing a benefit from an intervention can be even more difficult than with decision support systems. While various diabetes-IT prototypes have been developed, with a very few exceptions none of these have really seen widespread acceptance or usage. Consideration of the reason 'why' repeatedly reveals that most prototypes have stumbled at the evaluation stage.

Compartmental models offer a rapid means of simulating plasma insulin levels following insulin injections, and calculating a blood glucose (BG) profile on the basis of this, allowing for carbohydrate intake. While such models are not accurate enough for individual patient simulation and glycaemic prediction [6–8] their interactive nature does permit 'what-if' type analyses to be performed, and realistic simulations to be obtained of what may happen to patients (in general terms) following adjustments in insulin or diet.

However, despite the fact that a number of simulators have been developed by different groups, and that novel more comprehensive educational systems now start to incorporate such simulations [9], it has not been demonstrated in objective terms that such simulators do any particular good for patients, students or health care professionals.

One difficulty may be that to show a statistically significant benefit may require a larger number of patients/users than any one centre or research group may be able to recruit or have computer facilities to support. This raises the

issue of the need for multi-centre studies, or if not a coordinated multi-centre trial in its usual sense, at least a study with a freely available common basic protocol which can be adapted to local needs. For this a well-documented protocol with agreed outcome measures is required.

While it is obviously important to learn as much as possible from previous evaluation experience in this field, before embarking on new work, to date there appear to have been relatively few attempts to evaluate such interactive simulators for diabetes educational use. That work which has been reported, has recently been reviewed elsewhere [10].

One of the more encouraging evaluations of an educational program in diabetes care has involved *Packy & Marlon* (Raya Systems, CA), a role-playing Super Nintendo video game in which children manage the diet and insulin of two elephants who have diabetes [11]. To optimise the educational benefits of this game players can select insulin plans which match their own. The scenario is a diabetes summer camp which has been raided by rats. The two elephants, *Packy & Marlon*, need to defend themselves by blasting the attacking rodents with peanuts and water from their trunks. They also need to find food and supplies—remembering to eat healthily, regularly check their BG levels, and take their insulin [11].

Packy & Marlon was assessed in two centres in a 6-month randomised controlled trial, in a cohort of 59 type 1 diabetic children. Half the cohort received the diabetes game to use at home as much as they liked, while the other half (the control group) received a video game with no health-care content. While significant improvements in HbA_{1c} were not demonstrated the authors quite correctly highlighted that the patients were reasonably controlled at the start (mean baseline HbA_{1c}: 8.3–8.5%) and therefore, the study quite possibly ran into a 'ceiling effect' [12]. Clearly to overcome this problem further randomised-controlled trials with diabetic children with more usual (poorer) glycaemic control would be required. Notwithstanding this, benefits were reported in diabetes self-efficacy, communication with parents about diabetes and self-care behaviour in the children who received *Packy &*

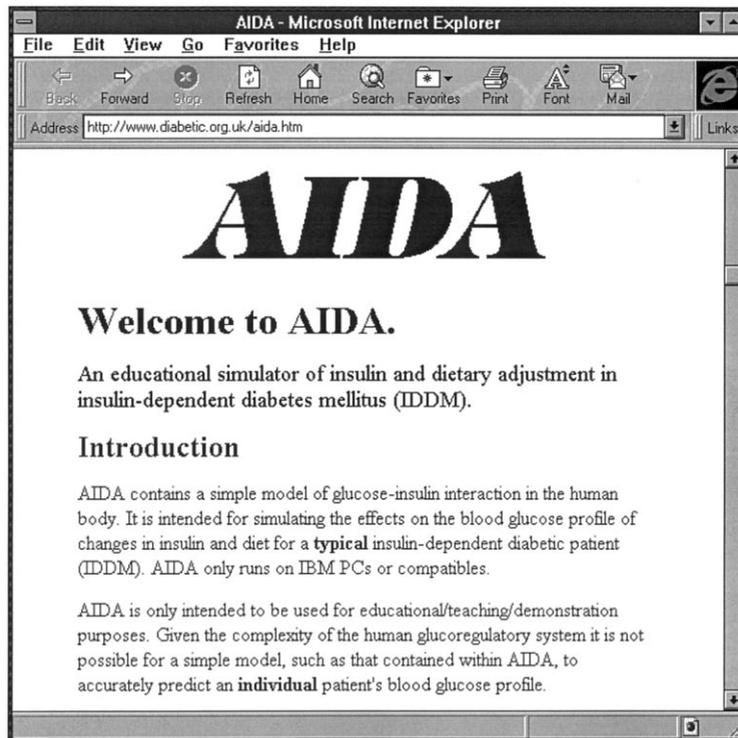


Fig. 1. Diabetes UK AIDA Web site, visited by over 14000 people since its launch. To date over 5000 copies of the AIDA freeware software have been downloaded from there, without charge.

Marlon. Also there was a decrease in unscheduled urgent doctor visits, a finding which if confirmed by larger studies would be most encouraging for children with diabetes. Furthermore the more a child played the diabetes game, the more friends they spoke with about diabetes [13]. Of particular note in this study—and of potential relevance to future work—the intervention lasted 6 months—and patients had unlimited access to the diabetes computer game at home.

Notwithstanding the *Packy & Marlon* evaluation—compared with the variety of educational tools which utilise simulators—there is a relative paucity of published evaluation data for the use of such software, certainly in diabetes care. Part of the reason for this undoubtedly is the work required to actually document a benefit from the use of such programs. However, another reason is likely to be the lack of standardised protocols for evaluating such simulation tools, as well as

uncertainty about the best actual method for the evaluation of such programs.

As will be demonstrated here, the Internet offers a possible means of disseminating software tools widely and rapidly for such an evaluation. The purpose of this paper is to present feedback experience obtained from the Internet release of one particular interactive educational diabetes simulator—called AIDA [14–16]—and outline in detail a protocol design which could be adopted, together with standard questionnaires [17–22], for the prospective and objective evaluation of such an educational tool.

2. AIDA background

AIDA can be downloaded without charge from the Diabetes UK Internet site on the World Wide Web (from: <http://www.diabetic.org.uk/aida.htm>) where it is being made freely available, as a

non-commercial contribution to continuing diabetes education (Fig. 1) [23,24].

The original AIDA system was developed in 1991–92 [25] and incorporated all the modelling, advisory and graphics functions of the current system. Unfortunately the software lacked any sort of dedicated data entry screen—therefore, interactive use required the editing of a text file which had to be saved before a new simulation could be run. This limitation severely impacted on the intuitive and interactive use of the program. With the help of an insulin-dependent (type 1) diabetic patient who had an interest in programming, AIDA was revisited in 1995 and a dedicated data entry screen added. In addition the whole system was streamlined and generally upgraded to make it more robust and suitable for more widespread distribution via the Internet.

In early 1996 a β -release version of AIDA was formally tested by approximately 60 patients and medical users (all with World Wide Web access). As a result of their feedback further refinements were made to the system—particularly related to technical issues to help ensure that the software would run on as wide a variety of PC hardware as possible. In June 1996, AIDA was formally launched on the Internet. Thus far, over 14000 people have visited the AIDA Web pages and over 5000 copies of the software have been downloaded from there. Other sites also store the AIDA software (e.g. the CompuServe Diabetes Forum, the CIX Balance (diabetes) archive, the Lehigh diabetes server, and the Diabetic DataCentre Web site)—however, downloads from these satellite sites are not all counted or recorded.

2.1. AIDA case study

The AIDA software comes with 40 educational case scenarios as standard, each of which represents a ‘snapshot’ of the metabolic status of a typical patient with respect to type 1 diabetes. It is easy for users to add or create further case scenarios, as required. Fig. 2a shows the AIDA data entry screen containing all the information used for the simulation of ‘Joy Wilson’, the first case scenario offered within the AIDA simulator. The only information that the user is provided about this

patient is that: ‘This woman is on three injections of short and/or intermediate acting insulin each day, with a split-evening dose. She wants to start a family, but consistently has had quite high blood glucose levels in the early afternoon, despite numerous attempts to normalise her control in anticipation of becoming pregnant. Clearly she could decrease the amount that she eats, but this would not be ideal during pregnancy. See if you can adjust her insulin doses to improve her glycaemic control’.

A baseline simulation for this case is shown in Fig. 2b. The upper graph shows the ‘observed’ blood glucose readings (\odot) recorded via the data entry screen, while the lower graph provides a composite display of information regarding insulin and carbohydrate intake. The distribution of the meals eaten can be seen in this panel along with the three times daily (split evening dose) regular (Humulin S) and intermediate-acting (Humulin I) insulin regimen that was being used. Superimposed on these graphs are predicted steady state BG and plasma insulin profiles as calculated by the AIDA model following parameter estimation [15]. A user definable normoglycaemic range (in this case set from 4–10 mmol/l) is also displayed, and the interactive clock function has been used to read values off the BG and plasma insulin curves.

From within AIDA one can also view the different glucose fluxes, to gain a deeper insight into the way in which glucose is handled in the human body. Fig. 2c demonstrates the different glucose fluxes for Joy Wilson’s baseline simulation (shown in Fig. 2b). The lowermost curve represents the excretion of glucose by the kidneys—which takes place when the BG level rises above the renal threshold of glucose (RTG). As the BG level increases during the afternoon (above the RTG which for this case is set at 9 mmol/l)—so an appreciable amount of glucose starts to be excreted into the urine. ‘UPTAKE’ represents the grouped peripheral, central nervous system and red blood cell utilisation of glucose; ‘NHGB’ is the net hepatic glucose balance (the production or utilisation of glucose by the liver); ‘GLUCOSE ABSORPTION’ is the systemic appearance of glucose from the gut; ‘RENAL EXCRETION’ being the loss of glucose via the kidneys into the urine. It has

Name **Joy Wilson** Weight **70.0** kg Case Number: **0001** AIDA v3.8
 Free Text This woman is on three injections of short and/or intermediate acting insulin each day, with a split-evening dose. She wants to start a family, but consistently has had quite high blood glucose levels in the early afternoon, despite numerous attempts to normalise her control in anticipation of becoming preg

MEALS:	Breakfast	Snack	Lunch	Snack	Supper	Snack
Time (hhmm):	0800	1000	1200	1550	1800	2230
Carbohydrate (g):	30	20	40	10	30	0

INSULIN INJECTIONS:	Number 1	Number 2	Number 3	Number 4
Preparations				
Time (hhmm):	0745	1730	2230	
Humulin S dose (U):	3	4	0	
Humulin I dose (U):	12	0	18	

GLUCOSTIX MEASUREMENTS:						
Time (hhmm):	0600	1130	1330	1700	2200	
Glucose (mmol/l):	4.1	8.0	9.9	10.3	10.8	

HYPOGLYCAEMIC EPISODES:	Number 1	Number 2	Number 3	Number 4
Time (hhmm):				

CLINICAL VARIABLES: RTG: **9.0** mmol/l CCR: **100** ml/min

INSULIN SENSITIVITIES: Hepatic (Sh): **0.4** Peripheral (Sp): **0.6**

(a) Esc=Simulator F1=Help F3=Quit F5=Info F6=Graphics F7=Options F10=Cases

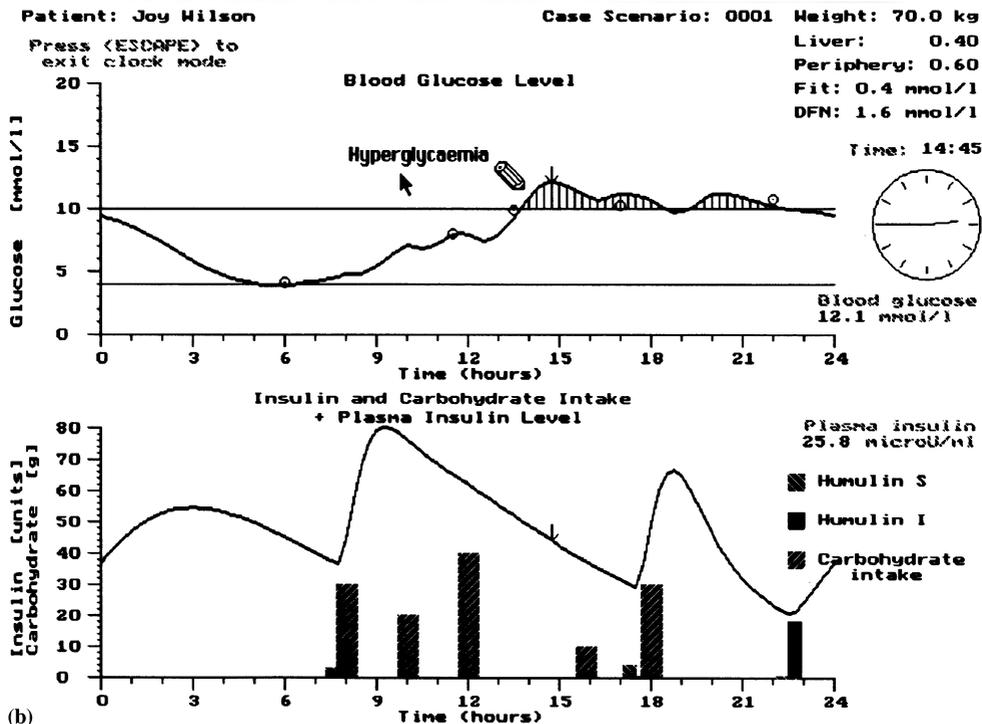


Fig. 2. (a) Data entry screen for AIDA v4.0 with clinical and nutritional data for case scenario number 0001 for 'Joy Wilson' who consistently has high blood glucose levels in the early afternoon. (b) Baseline simulation using the insulin, dietary and clinical data shown in Fig. 2a. The upper panel shows blood glucose information while the lower panel presents a composite display of information regarding insulin and carbohydrate intake. The distribution of meals eaten can be seen in this panel along with the three times daily (split evening dose) regular (Humulin S) and intermediate-acting (Humulin I) insulin regimen that was being used. A user definable normoglycaemic range (4–10 mmol/l) is shown superimposed, highlighting the hyperglycaemia which occurs in the afternoon. The interactive clock function allows values to be read off the blood glucose and plasma insulin curves (peak blood glucose = 12.1 mmol/l).

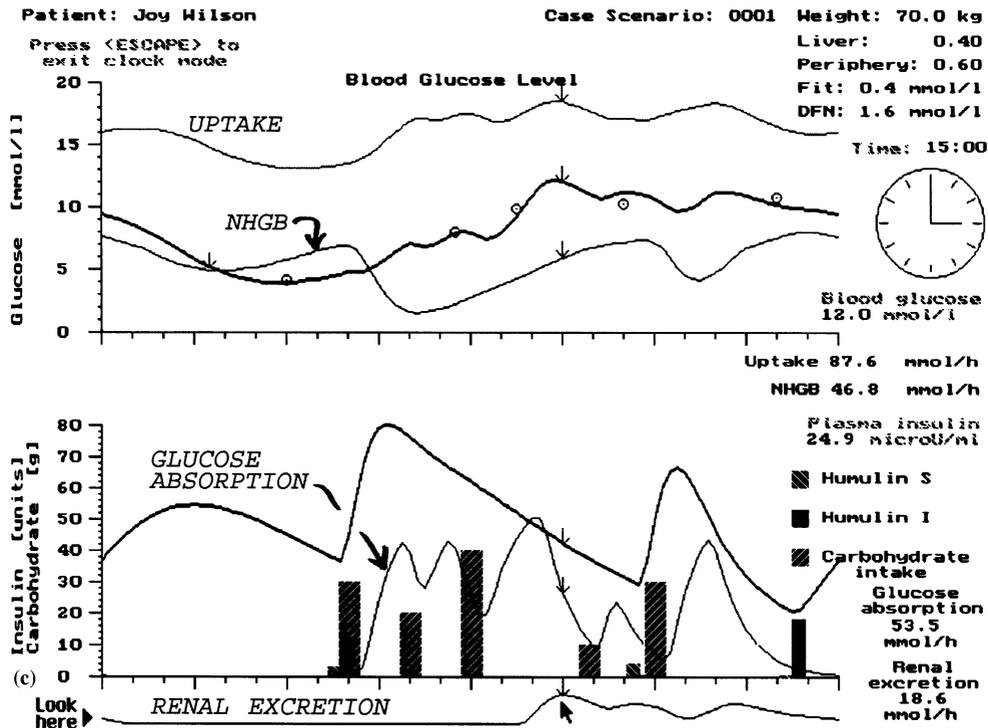


Fig. 2. (c) Demonstrates how the different glucose fluxes within AIDA can be displayed, for the simulation shown in Fig. 2b, possibly to help teach medical students about carbohydrate metabolism in type 1 diabetes mellitus.

been suggested that a display such as this, highlighting the different glucose fluxes within the system, may be particularly useful as a demonstration tool for teaching medical students about carbohydrate metabolism in type 1 diabetes mellitus [10].

Having performed baseline simulations like these users can change any of the input variables shown on the AIDA data entry screen to simulate the glycaemic effect of such changes. For example a user could simulate what would happen to a hypothetical patient's BG profile if the carbohydrate content of breakfast was increased by 10 g or if the supper time Humulin S dose was decreased by 4 units, or the injection time moved earlier or the meal time shifted later. A user could replace a split-evening dose insulin regimen with two combined injections per day or transfer a patient to Humulin M3 or Mixtard 30/70 in place of the previous short- and intermediate-acting preparations, or perhaps try the case scenario with a 'pen regimen' taking Ultratard nocte and Actrapid

three times daily before each main meal. The list of possibilities is endless—an infinite number of simulations can be performed with AIDA.

Fig. 3a shows what Joy's insulin regimen and simulated BG curve would look like if she forgot to take her morning insulin injection. As can be seen, omitting her morning insulin would send Joy markedly hyperglycaemic in the afternoon and leave her at significant risk of developing diabetic ketoacidosis.

AIDA can also be used to simulate the opposite situation where Joy takes her insulin, but rushes off to work without having breakfast (Fig. 3b). As can be seen, in such a situation Joy would be running a significant risk of hypoglycaemia in the mid-morning. While AIDA at present does not include functions for stress or exercise, the exertion of rushing off to work would increase peripheral glucose uptake compounding the low BG predicted to occur during the middle of the morning. Supposing a user wanted to see what the effect might be on Joy's BG profile of halving the

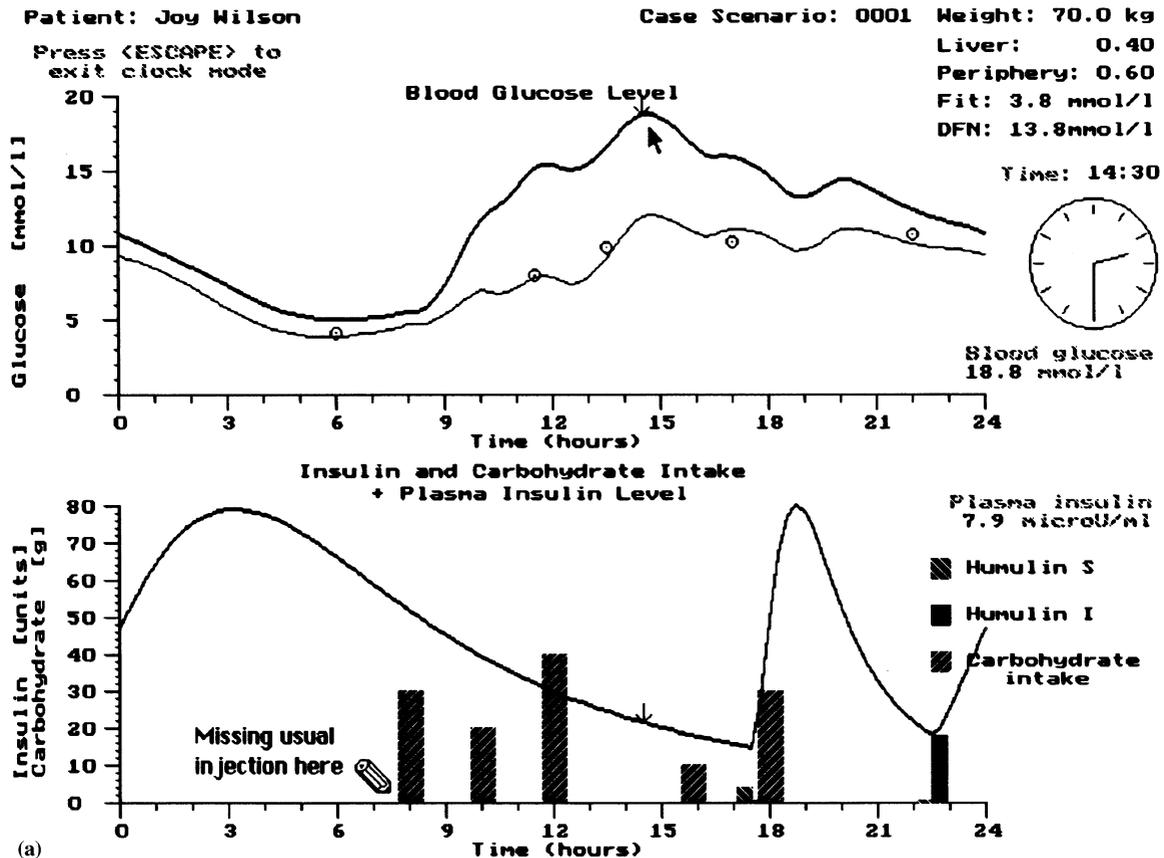


Fig. 3. (a) Demonstrates the effect on Joy's plasma insulin and blood glucose profile of missing her usual insulin injection before breakfast—the markedly increased blood glucose level in the afternoon (peak glucose = 18.8 mmol/l) being clear to see. (b) Demonstrates the effect on Joy's blood glucose profile of missing breakfast. The low blood glucose level which results leaves Joy at substantial risk of having a hypoglycaemic episode. (c) Demonstrates how by eating less carbohydrate for lunch (20 g as opposed to 40 g) Joy can reduce her blood glucose level in the afternoon when she previously was hyperglycaemic. (d) Problems identified in Joy's blood glucose profile and possible solutions (adjustments) suggested by the KBS (for data from Fig. 2a) are shown. Suggestions number 1 and 2 have been selected interactively by the user to increase the dose of the morning Humulin I and Humulin S injections.

carbohydrate content of lunch, this can also be simulated using AIDA. In this case reducing the size of lunch would significantly improve Joy's BG profile later in the day (Fig. 3c).

As intimated previously, there are an infinite number of insulin dosage and dietary adjustments which can be simulated using AIDA. Supposing, however, that a user is not quite sure what to try simulating next—a knowledge based system (KBS) built into AIDA can also be used to identify potential problems in the case scenario's 'observed' BG profile, and suggest various solutions

which might be worth simulating [15,26]. Such an option might be useful in an educational setting for medical or nursing students as a way of stimulating discussion about the different problems that individual patients might have in maintaining glycaemic control.

Fig. 3d shows the KBS' suggestions for Joy Wilson's original baseline case scenario data (given in Fig. 2a). In this particular instance the user has interactively elected on the right side of the screen to simulate the glycaemic effect of the first two suggestions, to increase the doses of the

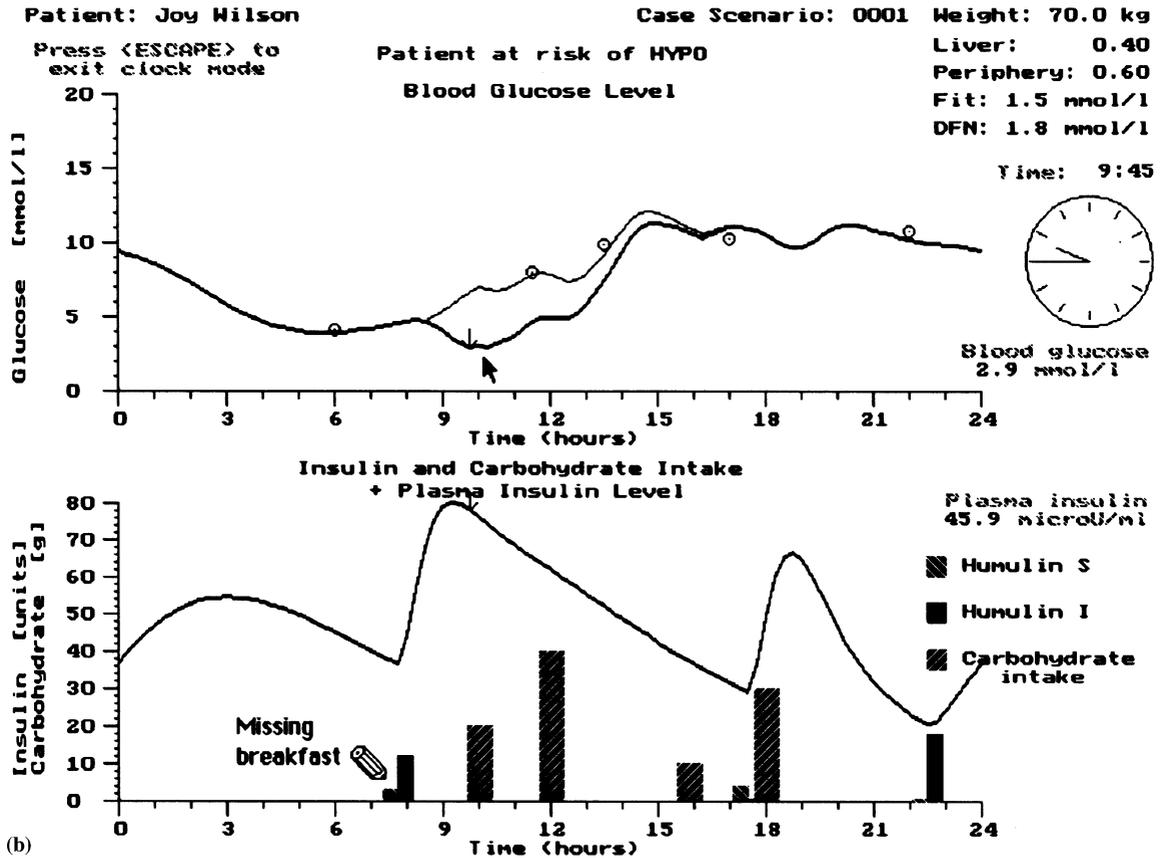


Fig. 3. (Continued)

morning Humulin S and Humulin I injections. A 20% dosage adjustment is automatically made to these injections and Fig. 4a shows the effect this would have on Joy Wilson's original baseline regimen. The old insulin regimen is shown for comparison on the left with the new regimen on the right. Fig. 4b shows the effects of these changes being simulated. As can be seen, increasing the dose of the short- and intermediate-acting insulin injected before breakfast significantly improves Joy's BG profile later in the day.

An extended version of this case study can be viewed on the Internet [24] via the 'View AIDA Demo' option. Should medical student users wish to investigate the model further, to obtain a deeper understanding of how the simulations are generated, this facility is also offered via on-line access to graphical representations of the model

(Fig. 5a) as well as its individual functions (Fig. 5b).

Thus far user feedback response about AIDA has been very positive. Various independent comments from type 1 diabetic patients, a patient's carer, the father of a diabetic teenager, a diabetes doctor and nurse educator, an endocrinologist and a postgraduate educator are documented below.

3. User reviews of AIDA v4.0

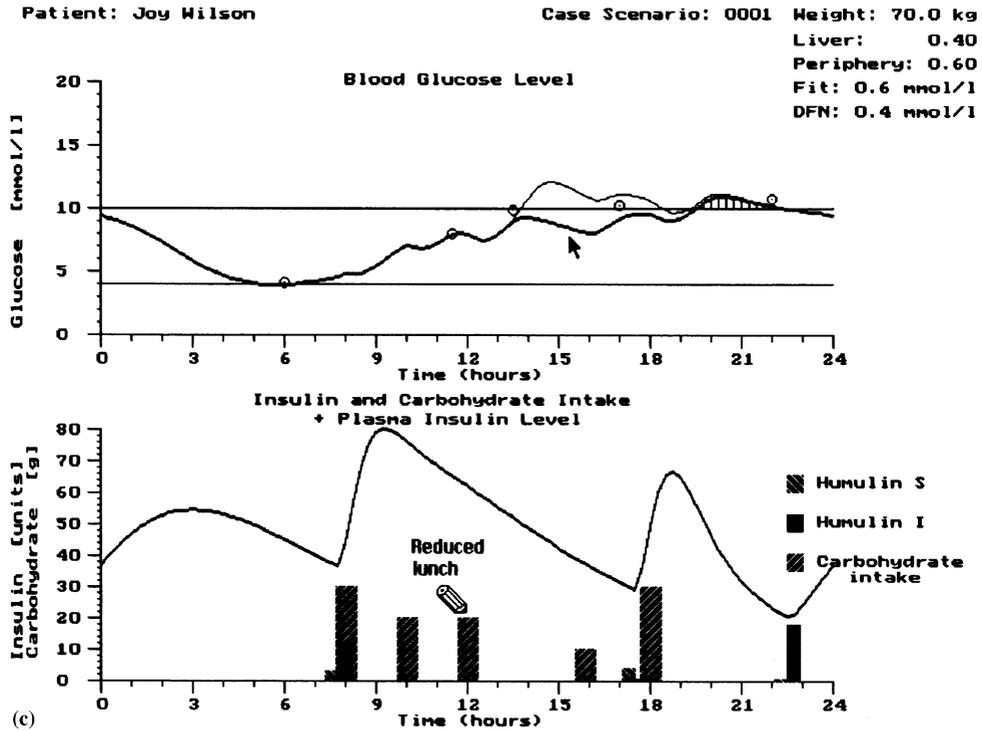
3.1. Patient feedback

3.1.1. What it does

AIDA is a modelling program which inputs the variables for the management of insulin-dependen-

dent diabetes (body weight, insulin, insulin sensitivity, and food as measured in grams of carbohydrate), then graphs the results to show the level of

blood glucose control throughout a 24-h period. Each variable can be altered and then graphed to display the differences in control from



(c)

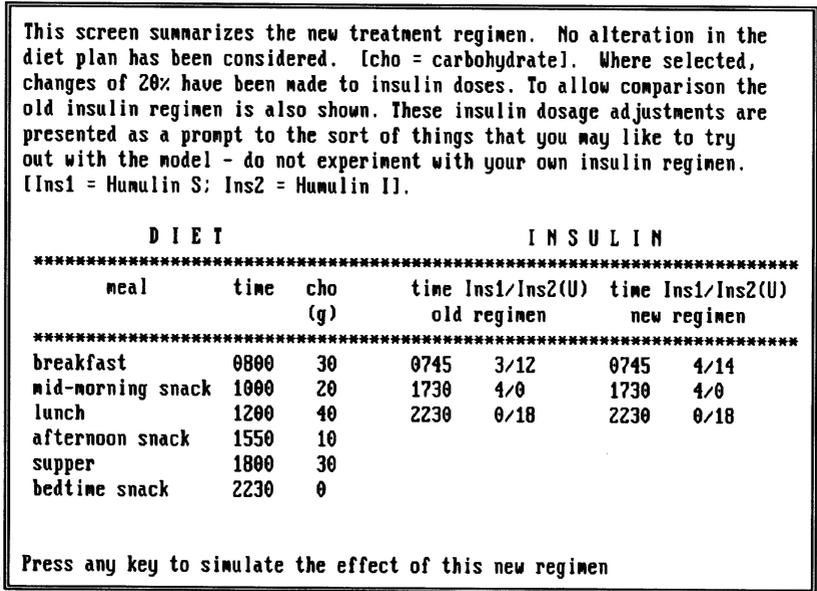
Possible problems in the "observed" blood glucose data from the current scenario are shown along with insulin-dosage adjustments which may help improve glycaemic control. You may like to try simulating the effects of some of these to see what happens to AIDA's blood glucose profile. To select a piece of advice press the 'Y' key. (Default = No)

NO.	ADJUSTMENT	PROBLEM TO BE SOLVED - blood glucose -	Y/N
1	increase dose of morning Humulin S	high before lunch	Y
2	increase dose of morning Humulin I	high before lunch high after lunch	Y
3	increase dose of evening Humulin S	very high at bedtime	N
4	decrease dose of bedtime Humulin I	low at dawn	N

Press any key to continue

(d)

Fig. 3. (Continued)



(a)

Patient: Joy Wilson

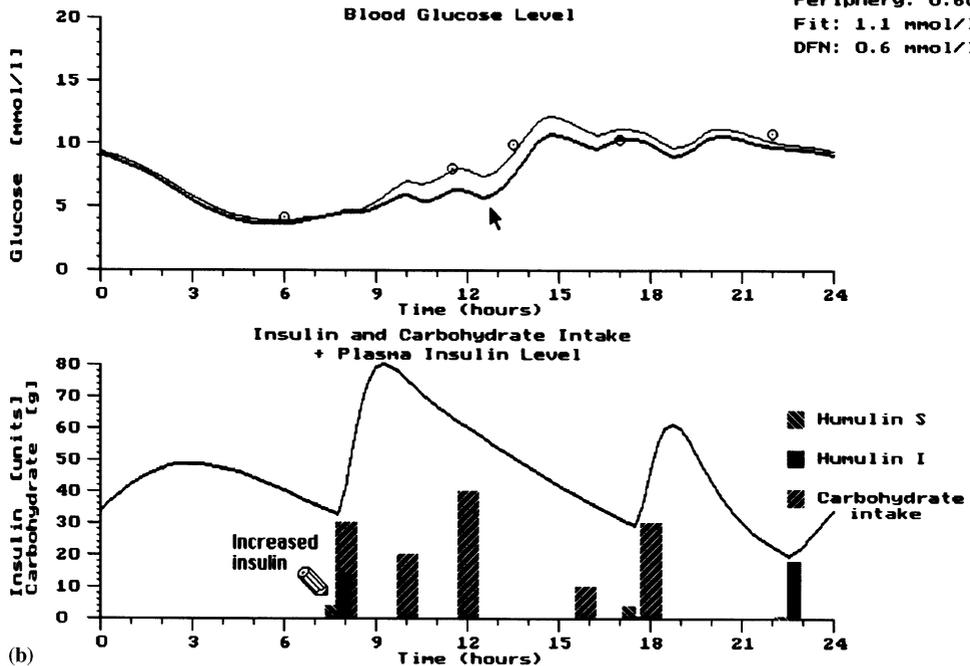
Case Scenario: 0001 Weight: 70.0 kg

Liver: 0.40

Periphery: 0.60

Fit: 1.1 nmol/l

DFN: 0.6 nmol/l



(b)

Fig. 4. (a) Summary of old and new therapeutic regimens following implementation of the suggestions shown in Fig. 3d. (b) Simulates the glycaemic effect of both of the adjustments selected interactively by the user in Fig. 4a, increasing the 07:45 Humulin S dose from 3 to 4 units and the 07:45 Humulin I dose from 12 to 14 units.

The AIDA model assumes a patient completely lacking endogenous insulin secretion (i.e. an insulin-dependent diabetic patient). It contains a single extracellular glucose compartment into which glucose enters via both intestinal absorption and hepatic glucose production. Glucose enters the portal circulation via first-order absorption from the gut, the rate of gastric emptying which provides the glucose flux into the small intestine being controlled by a complex process maintaining a relatively constant glucose supply to the gut during carbohydrate absorption. Glucose is removed from the extracellular space by insulin-independent glucose utilisation in the central nervous system (CNS) and red blood cells (RBC) as well as by insulin-dependent glucose utilisation in the liver and periphery. Hepatic and peripheral handling of glucose in the model are dealt with separately; the net hepatic glucose balance (NHGB) being computed as the sum of gluconeogenesis, glycogen breakdown and glycogen synthesis data derived for different blood glucose and insulin levels from nomograms in the medical literature. Glucose excretion from the extracellular space takes place above the renal threshold of glucose (RTG) as a function of the creatinine clearance rate (CCR). The only insulin input into the model comes from the absorption site following subcutaneous injection; the pharmacokinetics of insulin absorption being derived from descriptions of that process in the literature. The model contains separate compartments for plasma and 'active' insulin, the latter being responsible for glycaemic control while insulin is removed from the former by hepatic degradation. Insulin affects the NHGB characterised by a liver sensitivity parameter, S_h , as well as enhancing peripheral glucose utilisation described by a peripheral sensitivity parameter, S_p .

1 Insulin
2 Kidney
3 Liver
4 Brain
5 Gut
6 Muscle
7 Advisor
8 Parameters

(a) Press Esc to return to AIDA Press number to view function

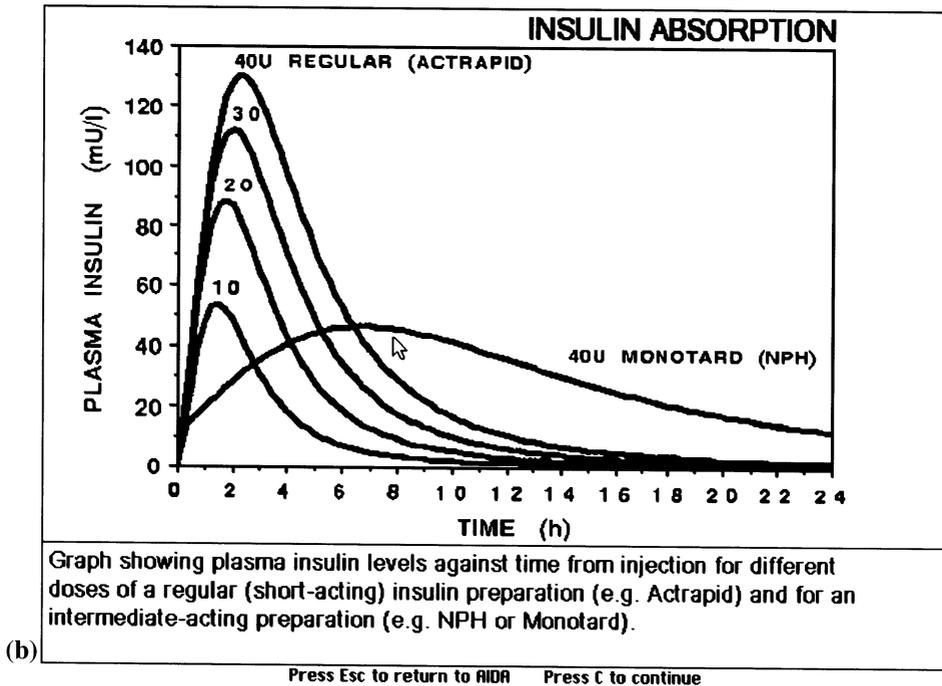


Fig. 5. (a) Interactive model representation accessible from the AIDA data entry screen. From Lehmann et al. [28]. Published by the British Diabetic Association, London, UK. Selecting '1 = Insulin' on this display yields Fig. 5b. (b) Graphical representation of plasma insulin level against time from injection for different doses of a regular (short-acting) insulin preparation (e.g. Humulin S) and an intermediate-acting preparation (e.g. Humulin I). From Lehmann et al. [28]. Published by the British Diabetic Association, London, UK.

the previous simulation. The program's database includes 40 case studies, each with a different set of variables and each representing a different set of control problems. The user can experiment with each case, adjusting one or all of the variables to see their effect(s) on blood glucose control. The user can even start with a 'clean slate', entering his or her own types of insulin, dosages, times of injection, carbohydrate consumption, meal times, insulin sensitivity, etc. The results can then be saved to the database and re-altered and re-graphed as desired.

3.1.2. *Review*

The authors of AIDA describe it as an 'educational' tool for assessing the variables of type 1 diabetes self-management, with the goal of achieving good control of blood glucose levels at all times of the day and night. In this they have succeeded to a remarkable degree. AIDA is not just another program to record and graph the user's personal self-management data; rather it is a serious attempt to help insulin-dependent diabetic patients consider the entire range of factors affecting their blood glucose control.

However, the authors caution—repeatedly and in no uncertain terms—that users should not treat the program as a therapy tool. In other words, they should not assume that changing an insulin type or dosage will have the same salubrious (or adverse) effects in the real world as may appear to be the case on the AIDA blood glucose control graphs. Some users may view this as a major flaw. They would, however, be missing the point. The real world knows no 'typical' or 'model' diabetic patients, only specific ones. Hence, AIDA's authors have not tried to substitute themselves for patients' own doctors. The program is a teaching tool—nothing more, nothing less.

By contemporary standards, AIDA is neither flashy nor colourful. Nor is the program simple to learn and use. It requires patience. The user manual should be read before proceeding. Screens are dense with text and input boxes, which are accessed serially with the tab (or shift-tab) key (the program is not 'mouse-able'). Therefore, it is unlikely that many users will be 'up and running' with AIDA 'right out of the box'.

However, despite these minor inconveniences (and despite an inability at present to program the effects of strenuous physical exercise—except by 'cheating' by cutting the amount of carbohydrates consumed), AIDA's rewards are considerable for insulin-dependent diabetic patients with a little patience and who seek to broaden their knowledge of the aspects of blood glucose control. (David Cohler, South Pasadena, CA, USA.)

This program simulates the glycemic effects of carbohydrates and insulin. It is intended to be a training tool, both for the individual diabetic and for the student of diabetes. The student is given cases where the patient is out of control, and asked to prescribe a new regimen to achieve euglycaemia. Answers are provided.

The individual diabetic can enter carbohydrates ingested and insulin taken, and compare this with actual blood sugar readings to understand, in general, what is happening. The program warns that its recommendations should not be used by the individual for modifying their regime; the only function of the recommendations is for the training described above.

The program is a DOS program with a user interface that is not altogether adherent to modern interface design principles; however, the program is a useful tool for the student and/or diabetic.

I highly recommend it for medical students, interns, and residents. For diabetic educators who want to use it in their training, it may well be a useful adjunct. Some diabetics may also want to experiment with the program for a better understanding of their disease, again, with the caveat that its recommendations are not intended to be used in lieu of a diabetologist. (Michael Wolfe, Reproduced from [27] with kind permission.)

3.2. *Patient carer feedback*

I am a friend of an insulin-dependent (type 1) diabetic patient. So that I could better understand how the human body reacts to glucose, insulin distribution, exercise, sleep, and carbohydrate absorption in patients with diabetes mellitus I decided to search the Internet for information. I was pleased to find the glycaemic control modelling

software (AIDA) available for download at no charge.

Of all the information I have found concerning this very complex disease, the AIDA software is for me the most educational I have seen to date. AIDA offers a hands on approach to understanding some of the variables involved in maintaining tight blood glucose control in the type 1 diabetic patient. For me learning by application is much easier than trying to absorb mounds of abstract information. From reading, conversation, and observation I had what I thought to be a good understanding of diabetes mellitus; however, using the AIDA software has given me a quantitative approach to the disease. Using the 40 supplied case scenarios, and having the ability to create my own example cases has taught me a great deal. For example, I enjoy cooking. By using the AIDA software I have learned how small changes in the dietary habits of patients with diabetes, relative to their insulin regimen, can profoundly effect their blood glucose level.

As a lay person I have found AIDA most useful and I hope that the software will find wide acceptance and use as an educational tool, for health-care professionals, diabetic patients and their carers. As a carer it is my observation that in particular many health care professionals could actually benefit from this type of educational modelling approach. Although AIDA may be considered complex, and despite the fact that it takes a little while to become familiar with all the program's functions, this should not deter prospective users from experimenting with the software. After all, the diabetes condition is also complex, and it takes even longer to 'get to grips' with its day-to-day management. (Bob Tregilus, Reno, NV, USA.)

3.3. Father of a diabetic teenager feedback

My daughter is 16 years old and has had diabetes for 3 years now. When she was first diagnosed, we were immersed in a great deal of information about what insulin is, and what is important for managing blood glucose levels. It was a challenge to understand all of this, and we did not appreciate the reality that management of

diabetes is a dynamic process. Each time a new blood glucose value is taken, one needs to consider what the next course of insulin therapy should be. Unlike some who want to take charge of their disease, my daughter wants to be left alone. And so I embarked on a journey to understand in a practical way what it means to manage diabetes. Early on in this journey I obtained a copy of AIDA for free and began to learn interactively from the different case studies provided.

I now have an understanding of what the activity profile of NPH insulin looks like over time, and experience with modifying the trial cases. Much of this knowledge is useful for the collaboration I have with my daughter, as we manage her disease together. My daughter has little interest in AIDA, but AIDA has been valuable for me to understand the possibilities for modification of her therapy. Most of the time we check this out with our case worker, but we are becoming more confident of our own decisions within certain limits. We still have much to learn, but diabetes, like other aspects of life, is a continuous learning process.

AIDA provides an important source of information, and offers a valuable demonstration of what can be accomplished through commitment and understanding. (Dr Glenn Vonk, PhD, Raleigh, NC, USA.)

3.4. Diabetes educator and nurse feedback

AIDA, an educational simulator for insulin dosage and dietary adjustment in diabetes, was recently reviewed by several of the nurse educators and medical staff of the Newcastle Diabetes Education Centre regarding its potential use in diabetes education.

Our initial impression of the program was that it is quite complex; it takes some time to thoroughly review the excellent written manual provided before you can begin using it effectively. In its present form it is not possible to have a quick 'play' with the software unless you are well versed in the mechanics of the program.

Several features of the program were thought to be worthwhile in diabetes education. Once the new user overcomes the problem of grasping the

basic concepts of the program it is interesting to alter the inputs for insulin dose and carbohydrate intake and see an immediate change in the blood glucose level as a result of these changes. With practice users tend to become immersed in the program, testing out their ideas. Being able to modify or add case scenarios allows patients to make the program relevant to their particular educational needs.

The software will be useful to many of the adolescents and younger patients that we see at the diabetes centre, but a reasonable level of computer literacy will be necessary for people to get the most out of the program. Many of those in the older age groups might have a problem using the program as they would first have to overcome their aversion to using computers; this problem might be eased a little by developing a Windows-type graphical user interface for the software.

Nevertheless, interpretation of the screen output is not difficult once the basic operational concepts are grasped by the user; overall, the software design is quite sophisticated, and with increasing operator experience the application becomes a pleasure to use. The approach used offers realistic data output following changes in input variables and the often subtle changes that are elicited by the operator make this one of the highlights of the program. Further development of this feature to expand analysis of the effects of exercise and stress on changes in blood glucose levels should be both interesting and useful. We suggest breaking the program up into easy, moderately difficult and difficult levels of interaction. This may prevent the user losing interest in the program before being introduced to its many benefits.

If used in the Newcastle Diabetes Centre as an adjunct to diabetes education it would be essential to have someone conversant with the program give hands-on instructions to the first time user. If the person being shown the program is reasonably computer literate this should not be too difficult. However, poor computer literacy could make this an ineffective process. Once the basic concepts of the program are grasped, it is easy to become absorbed in the program and be keen to explore all options available.

Feedback from staff members using the program was positive—they liked the program. They felt that the overall concept was good and the software had some excellent features that were useful for teaching purposes. The software was recently trialled under nurse educator supervision by four adolescents attending our Young People's Diabetes Clinic. Again, overall reaction was favourable, with three of the four expressing an interest to enter their own data and to monitor progress themselves. (Dr Kerry Bowen, MB BS PhD FRACP and Jane Scorer, BA RN, Director and Research Nurse, Newcastle Diabetes Education Centre, New South Wales, Australia.)

3.5. Endocrinologist feedback

The DCCT has demonstrated the benefits of good blood glucose control, however, achieving these results in the wider type 1 diabetic patient population is a challenge. One definite message is that diabetes education of both patients and health-care workers needs to go beyond broad guidelines and that a sound understanding of insulin and carbohydrate interaction is fundamental.

AIDA is based on a physiological model and as such provides a realistic simulation of glucose values and can demonstrate the effects of changing carbohydrate or insulin amounts (or timing). When discussing methods of improving blood glucose levels most clinicians concentrate on adjusting the insulin dose. Using AIDA with the different case scenarios provided, it becomes evident that dose adjustment is not always the answer and that changes to type or timing of insulin administration or to the distribution of carbohydrate intake may offer a better solution.

AIDA can be used as an educational tool either individually or in groups. When used as a demonstration/teaching tool it has provided a starting point for discussion on other topics such as the pros and cons of tight blood glucose control, advantages and disadvantages of various insulin regimens, age-related limits, methods of testing and the treatment of hypoglycaemia. As well as having a favourable response when showing patients, AIDA has also been useful for teaching medical students on their diabetes attachments.

Hypoglycaemia is the downside of maintaining tight blood glucose control and with the advisory function in AIDA, resolution of the hypoglycaemia takes priority over all other treatment options, as it does clinically. However, not all hypoglycaemic episodes are recognised clinically and by looking at the simulated glucose curve generated by AIDA potentially vulnerable periods during the day, for a given scenario, can be identified.

No computer program can hope to mimic the full range of factors which influence glucose homeostasis *in vivo*, and while certain variables like alcohol or exercise have not been included, the effects of these are easier to contemplate once a good grasp of the basics has been obtained.

AIDA provides a risk-free opportunity to experiment with different aspects of blood glucose control. While trial and error are a significant part of any learning curve, the principles acquired from using AIDA are invaluable. I have no hesitation in recommending the program as an educational tool to patients and students, as well as endocrinologists and other healthcare workers. (Dr Kathleen Hopkins, MD FRACP, formerly from Division of Endocrinology, Middlesex Hospital, London, UK.)

3.6. Postgraduate educator feedback

Thank you for your fine AIDA. The program has been used for teaching audiences of would-be physicians, general practitioners, as well as technicians. The program's simulations provide a very convenient 'back to real life' sense for technical lectures.

The non-endocrinologists especially found the demonstration of the need for gradual adjustment of calorie intake, timing and combination of fast- and slow-acting insulins, very instructive. They made use of the adjustable normoglycaemic ranges in a 'competition' between two or three people at a time, switching from low-insulin sensitivity patients to high-insulin sensitivity patients. The nurses here, not accustomed to the need for very regular blood glucose determination, are also going to have a demonstration of the software.

In my experience the program is sufficiently sophisticated to convey the effects of regular insulin-dosage adjustments—yet it is simple enough to be used by non-experts. Furthermore, most people will be able to use AIDA on their own. However, my experience is that especially in an audience, say of 6–10 people, this program is ideal because discussions about what to simulate next develop very rapidly.

I recognise the need for the warnings at the start of AIDA, but I believe that a program like this could enhance the knowledge of interested diabetic patients early on in their disease. However, I have no personal experience in this matter, having only used AIDA for postgraduate teaching. I agree that patients should not by any means see this as a direct way to adjust their own insulin-doses. Rather allowing patients and health-carers to learn basic rules—as AIDA does—seems a very smart and logical addition to other existing teaching methods. (Dr Björn Söberg, MD, Kommunehospitalet, University Hospitals of Copenhagen, Copenhagen, Denmark.)

While these users clearly derived benefits from AIDA, and while intuitively the benefits of such a program may seem apparent, formal evaluation is required as for any other medical intervention.

4. British Diabetic Association (BDA) assessment

In March 1996—during the β -testing phase of the AIDA project—the British Diabetic Association (BDA) was approached and offered the AIDA software, without charge, by the author as a non-commercial contribution to continuing diabetes education. The BDA undertook their own independent assessment of the program which involved distributing AIDA to a panel of potential end-users (health-care professionals and patients). Comments were solicited regarding the utility, clarity and safety of the software from approximately 15 users outside the BDA, as well as from various internal evaluators. Table 1 illustrates some of the questions asked of evaluators. As a result of the feedback received a decision was taken to offer AIDA to health-care professionals [28] through the BDA's health-care professional brochure [29].

While such independent assessments are very welcome, and a necessary step in the overall evaluation process [30], they are by their very nature subjective and fully recognised as such. Therefore there is a very real need to establish objective criteria which can be used to further evaluate such simulators. Also a clinical protocol is required and consultation needs to take place to establish the optimum means of undertaking evaluations of such interactive educational simulators.

5. Possible clinical applications of interactive educational diabetes simulators

There appear to be two main ways in which an interactive educational diabetes simulator, like AIDA, could be applied clinically.

(i) Demonstration use—by diabetes educators. In this situation the educators become proficient with the software and then use the program to illustrate various points to patients—during otherwise standard education sessions.

(ii) Direct use—by patients. In this situation patients would need to be guided through the learning curve of discovering how to use the software. However, thereafter motivated patients would be able to continue using the program—ideally more frequently than they would otherwise be seen in the clinic. This is the situation which many patients are effectively adopting with AIDA on the Internet.

In addition, in both the above cases health-care professionals in-training might also benefit from either demonstrated use, option (i)—sessions with a diabetes educator using the software, or option (ii)—direct use of the program themselves.

5.1. Possible methods of evaluating interactive educational diabetes simulators

Similar to options (i) and (ii) above—there are also two clear ways in which the potential benefits of an interactive educational diabetes simulator, such as AIDA, might be evaluated.

(i) Demonstration use. One might hypothesise that a diabetes educator using an interactive edu-

cational graphical simulator, like AIDA, might be able to communicate with a patient better than simply using a pen and paper/blackboard. This is effectively how the Garvan simulator [31,32] was assessed by Baldwin et al. [33,34].

However, of relevance to evaluation studies of interactive graphical simulators, it should be highlighted that the Garvan simulator was text based—recreating a log-book appearance—which might be construed as not very exciting and certainly could be less intuitive than a graphical representation of BG profiles (as provided for example by AIDA). Furthermore, the two studies undertaken to assess the Garvan simulator were only carried out for a relatively short period of time (1 month) in quite heterogenous and small groups of both type 1 and non-insulin dependent (type 2) diabetic patients of quite widely varying ages [33,34]. These factors may have impacted on obtaining a positive outcome in these studies.

One might also consider that a synergistic effect of diabetes educator plus simulator might take place—the two together achieving more than either on their own. While such a concept may theoretically be appealing, it is not immediately apparent that such an evaluation should be undertaken as a first study because diabetes educators are very professional, and highly skilled enough that they do an excellent job when they see a patient, and a computer may contribute relatively little to their ability to teach. By contrast whether or not the patient is motivated to learn may have a much greater impact on the outcome of teaching sessions.

The practical issue appears to be 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 [35,36]. For example, in the DCCT patients in the intervention group were seen fortnightly and often contacted by telephone every week [1].

The key issue for the application of computers in diabetes care therefore is whether IT tools might be able to assist in filling some of this gap between what is available routinely and what was available in the DCCT. For instance, does allowing a patient unlimited access to an interactive educational program in between formal visits to a diabetes educator improve knowledge, confidence,

self-management skills, glycaemic control, etc. This was how the *Packy & Marlon* video game was assessed [11]—with some interesting and encouraging results. Therefore a second way of evaluating an interactive educational diabetes simulator, like AIDA, would encourage direct use.

(ii) Direct use. This would allow patients frequent access to the program, for example every 2 weeks, and compare their outcomes with a matched control group who did not have access to the program, and who received routine standard educational input.

A purist might argue that the intervention group are thinking more about their diabetes than the control group. This would be exactly correct. However, if experimenting with a computer simulator for a couple of hours every fortnight can make patients think more about their diabetes—and as a result care is improved—so be it. That is an excellent result, because with the wide—and ever growing—availability of computers, patients would be able to have relatively unlimited access to such programs at home or at work. Intuitively it would seem much more cost effective long term to provide some software to patients for home use—than to attempt to arrange much more frequent hospital clinic visits. For example in the DCCT the annual clinical cost of intensive therapy was US\$4000 per year for multiple daily injections and \$5800 per year for continuous subcutaneous insulin infusions—approximately three times the cost of conventional therapy (\$1700 per year); these figures exclude research costs. A large portion of this cost difference was reported to be related to the greater frequency of out-patient visits and the greater resources used in self-care [37].

Clearly if a preliminary study such as that outlined here was successful—a follow-up study might be indicated in which the control group read a book on diabetes for 2 h every fortnight. However, for an initial assessment it would seem prudent to keep things as simple as possible. This is especially the case as a comparison with existing (standard) care is a well accepted clinical approach. Therefore, initially at least,

the control group should represent—as far as possible—what is normal education provision at present in the centre(s) participating in the study. Furthermore, it will be self-evident that no attempt is being made here to evaluate individual components of the system (e.g. the model or KBS)—rather it is the overall package which is to be assessed.

5.2. Outcome measures

Outcome measures should be assessed at the beginning of the study (baseline) and upon its completion (at 3 months). The outcomes proposed to be measured at these time points are summarised in Table 2. The frequency of use of the simulator and the number of simulations performed are automatically recorded by AIDA at the end of each session. Therefore, if a patient just read a magazine for 2 h during their simulation session this would show up as low usage—whereas if the patient actively tried out different options this would be apparent as high usage. Such data would also help to establish if any potential improvements in outcome measures correlated with usage of the simulator.

Various standard questionnaires are available for assessing diabetes knowledge, behaviour, and self-care [17–22]. In addition to these a series of specific scenarios testing the sort of concepts that users would be expected to learn from the simulator under review would also need to be included (e.g. about insulin dosage and dietary adjustment in the case of AIDA). These could be similar to some of the cases currently included on-line within AIDA, illustrating particular points (Figs. 2–4). For users who are children or adolescents, further evaluation-related questions could be asked of one of the parents, maybe even simply by telephone.

5.3. Evaluation protocol

A detailed protocol which could be used for the evaluation of an interactive educational simulator, like AIDA, is presented in Appendix A and summarised in Fig. 6.

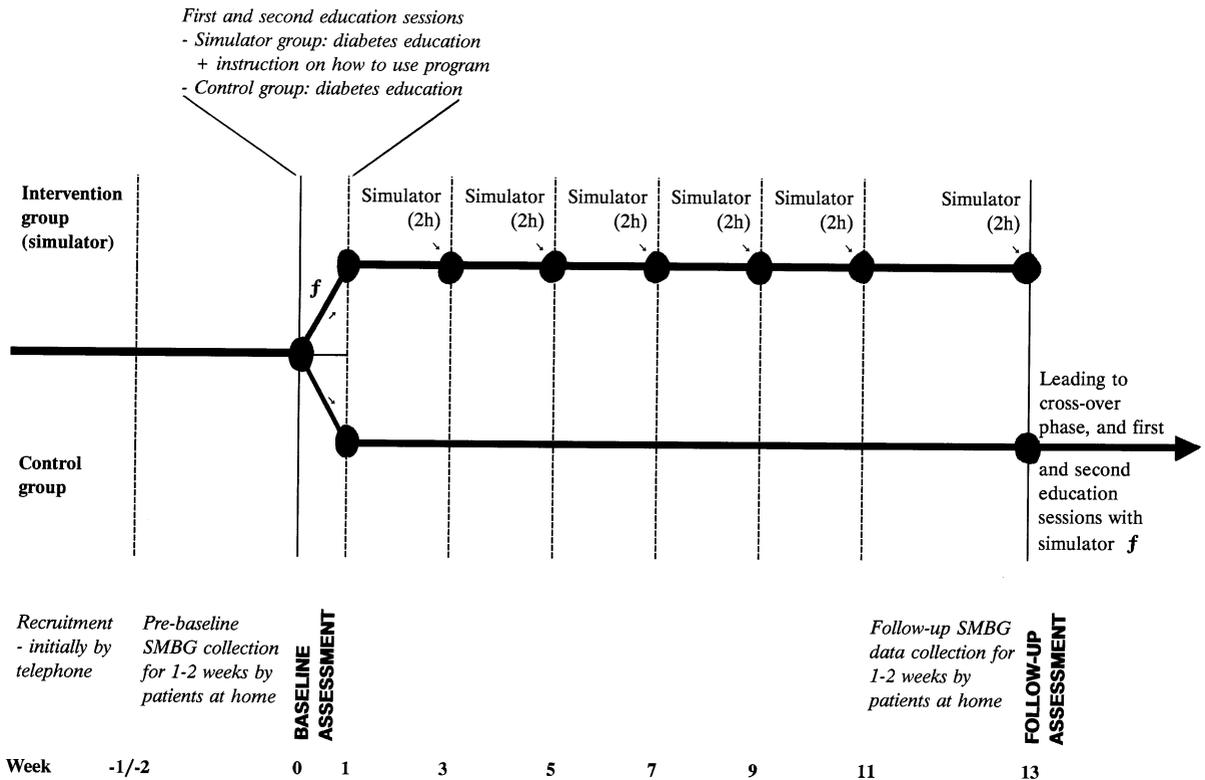


Fig. 6. Schematic summarising the evaluation protocol outlined in the Appendix A. Outcome measures are listed in Table 2. Assessments involve photocopying patient blood glucose logbook, measuring patient glycosylated haemoglobin (HbA_{1c}), and patient completing Diabetes Knowledge Assessment questionnaire. Baseline assessment is followed at the same visit by randomisation and the first 1 h education session. Follow-up assessment for the simulator group follows the sixth (final) session using the computer program.

6. Discussion

The widespread use of the AIDA simulator and the feedback received from Internet users around the world suggests that such programs can be of considerable use, both to health-care professionals and patients. The independent experience of the BDA in this respect also supports the application of such software tools—certainly by health-care professionals. However, establishing an objective (measurable) benefit from the use of such educational programs remains a challenge.

Other researchers in the field of diabetes education have reported improvements in patient understanding and retention when computers were used to assist instruction [38]. If interactive simulators were incorporated into such computer as-

sisted instruction programs, it is the author's belief that understanding of diabetes, and insulin and dietary adjustment could only be improved further. This is because simulators can now provide patients with an opportunity to put into practice their newly acquired knowledge in a realistic way. The positive reinforcement of success is an important component in successful education [39].

While this author is not alone in supporting the use of interactive diabetes simulators for educational use, in this era of evidence based medicine, the adoption of new technology and tools into clinical practice needs to be based on more than just 'belief' or conviction on the part of system developers. Objective evaluation studies are required.

Table 1

Questions posed of (a) health-care professionals, and (b) patients in the British Diabetic Association's assessment of AIDA

(a) Health-care professional questions:

1. Do you consider there is a demand for this type of product?
2. Is the product medically accurate?
3. In your opinion, does the product have educational (or other) value?
4. Is the product suitable for unsupervised use by people with diabetes?
5. Is the product useful in a clinical education situation?
6. Is the product useful for training of health care professionals?
7. What is your opinion of the content and design?
8. How, if at all, in your opinion, could the product be improved?
9. How computer literate do people need to be in order to make full use of the product?

(b) Patient questions:

1. Do you consider there is a demand for this type of product?
 2. Did you find the package easy to use?
 3. What is your opinion of the content and the design?
 4. How, if at all, in your opinion, could the product be improved?
 5. How computer literate do people need to be in order to make full use of the product?
 6. What value does the product have from the point of view of someone with diabetes?
 7. How much do you need to know about diabetes in order to benefit from the package?
 8. How, if at all, did your knowledge of blood glucose control increase after using the product?
-

As Donaldson has emphasised 'Various methods are available to evaluate information technology but they are not widely used. As a result, subjective methods (attitudes and opinions of users and systems designers) tend to subordinate established objective methods on the apparent premise that "the system is worthwhile, it's just difficult to show that this is so"' [40]. This is the very predicament in which many computer-aided learning (CAL) software developers find themselves. It is vital not to fall into this rut with CAL tools in diabetes. The quantitative nature of glucose homeostasis and

Table 2

Outcome measures for evaluation at baseline and 3 months follow-up

By questionnaire:

1. Knowledge
 - a. General knowledge (via standard DKN questionnaire)
 - b. Specific knowledge of insulin-dosage and dietary adjustment in diabetes (via example scenarios/cases)
2. Confidence
3. Self-efficacy
4. Frequency of self-monitoring of blood glucose
5. Frequency of self-adjustment of insulin doses
6. Frequency of doctor visits in past 3 months
7. Frequency of casualty visits in past 3 months

From patient logbook:

8. Previous 1–2 weeks of self-monitoring blood glucose measurements

By measurement:

9. Glycosylated haemoglobin (HbA_{1c})

By inspection:

10. How many times simulator was run
 11. How many simulations were performed with the program
-

DKN, Diabetes Knowledge Assessment.

diabetes care with absolute BG and HbA_{1c} levels which can be measured means that definite surrogate clinical endpoints are available to test out educational software. In this respect more interventional trials, including the documentation of hard clinical endpoints, are clearly required [10].

The purpose of interactive educational diabetes simulators is to create a learning environment for communicating and training intuitive thinking when dealing with insulin dosage and lifestyle adjustments. As Hedbrant et al. [41] have highlighted 'In some occupations, the training of process operators in handling a dynamical process is of extreme importance. Aircraft pilots and personnel in nuclear plants can represent two such professions, since both... systems... characteristics are hard to describe verbally or logically. The education is, therefore, based strongly on simulator training,

which has proved to be the most successful way—next to experiments with the real systems—of getting experience in the process’.

The perceived advantages of such a simulator-based training process therefore include the fact that:

(i) it creates a learning situation with efficient feedback which enables users to gain experience from the system. Users are guided by their own curiosity and begin to simulate and analyse situations of importance to themselves, which increases motivation and creates the basis for further experiments.

(ii) it forces users to handle and explain discrepancies between the behaviour of the simulator and the behaviour of the real system—in the case of patients—their own BG levels. Working in this way, users have to evaluate and reconsider their knowledge and experience critically over and over again, making their mental image of diabetes interactions more robust.

(iii) a simulator can help two users communicate by providing a medium for demonstrations and illustrations.

(iv) users end up as their own experts on the system. They are trained to identify problems and formulate strategies to solve them and they are also trained to recognise problems and choose a solution from an earlier formulated set of strategies [41].

Hedbrant et al. [41] concluded that such simulators can best be ‘used in a dialogue between the patient and a diabetes nurse or doctor... The doctor or nurses can guide the patient and keep track of his reasoning, like a driving school instructor with car and driving pupil’.

Furthermore, as Biermann and Mehnert [42] have previously highlighted in this journal, when assessing their DIABLOG simulation program, ‘The increasing number of young persons with computer experience suggests an increasing acceptance of computer simulation and learning programs’. Perhaps, therefore, it is no surprise that educational tools, like DIABLOG or AIDA, have been considered as potentially being of most use in establishing a thorough basic understanding of insulin-dosage adjustment in younger diabetic patients [10]. Given this, evaluation studies will need

to be tailored to address this particular sub-group of users.

The purpose of the clinical protocol outlined in Appendix A is to describe an approach which could be used to objectively assess the benefits of such interactive educational tools. There are several reasons for documenting such a protocol: (i) protocols used in the past have not always been well designed or rigorous, suffering at times from small sample sizes and heterogenous or too well controlled patient groups; (ii) many educational prototypes are never evaluated because of the lack of agreed protocols/outcome measures; (iii) those prototypes which are evaluated invariably are assessed using different protocols and outcome measures making objective comparisons between studies problematical; (iv) documenting such a protocol is the best way to achieve discussion and consensus about the optimum form for such an evaluation study. Furthermore, a widely publicised, freely available protocol could help to encourage the evaluation of such software tools in multiple centres, so increasing the overall sample size and generalisability of the results.

It should be self-evident that the protocol described is not proposed as, and does not represent, a ‘gold standard’ evaluation protocol—but rather a realistic first evaluation approach. If encouraging results were obtained with this—further more rigorous, better randomised studies (with stratification) could be considered. Detailed questionnaires have also not been included because numerous such questionnaires can already be found in the diabetes education literature [17–22]. Furthermore, the exact questions asked of users may subtly vary depending on the exact scope of the software program being evaluated. Also different questions will need to be posed for an evaluation study to be undertaken with patients as opposed to students or health-care professionals.

In connection with this, such a protocol might also be used for posting on the World Wide Web. Together with a suitable questionnaire, patients with Internet access would be able to assess their knowledge of how to adjust insulin and diet in diabetes prior to downloading a copy of the simulation program, or before using an interactive

on-line version of the simulator on the Web. Internet tracking software could then permit these patients to be identified and followed-up a period of time (e.g. 3 months) after the first knowledge assessment. This would allow a repeat assessment to be undertaken—which in turn would permit the educational utility of the software to be ascertained in a wide variety of patients; the major unresolved issues in such a study being complete reliance on patient self-reported data, and the potential for loss of patients to follow-up. By contrast large numbers of patients could probably be recruited, thereby substantially increasing the statistical power of the study.

Despite the encouraging reviews and feedback obtained with AIDA, a cautionary note should be sounded to put this work into perspective. Computer-based simulators, on their own, are not going to provide the whole answer to patient education. However this author is of the opinion that they can offer one potentially important component and may possibly enliven existing educational programmes. It should also be self-evident that on its own education will not provide the whole answer to improving glycaemic control either, and that diabetes education will best succeed as part of a concerted intensive diabetes management programme.

6.1. Conclusions

To date most system developers have been content with subjective, anecdotal reports of benefits of use for educational simulation tools. The few isolated examples of formalised evaluation studies being undertaken have recently been reviewed elsewhere [10]. However if this field is to move forward—and if wider use is to be made of such software tools—more rigorous evaluation studies are required, with a wider range of representative end users. A protocol for such a study is described in Appendix A and summarised in Fig. 6. It is hoped that recruitment of patients in widely varying centres, and possibly via the Internet, using this common protocol may enable the educational utility of the AIDA interactive simulator to be established in a large enough sample of patients to demonstrate statistically significant results.

7. System availability

A copy of the latest Internet release of AIDA (v4.0) overviewed here and a user guide are available without charge by writing to Dr E.D. Lehmann by email at: aida@globalnet.co.uk or at the Department of Imaging, National Heart and Lung Institute, Royal Brompton Hospital, Sydney Street, London SW3 6NP, UK. The AIDA software is also available free-of-charge from the Diabetes UK Internet site on the World Wide Web (from: <http://www.diabetic.org.uk/aida.htm>). AIDA runs on IBM PC or compatible 80386/486/Pentium based machines and requires approximately 2 Mb of hard disk storage space. Dr Lehmann would be particularly interested in hearing from fellow health-care professionals who might be interested in contributing patients to a multi-centre evaluation of the software for educational use.

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Appendix A. Evaluation protocol

Outlined below is a protocol for the evaluation of interactive educational diabetes simulators, like AIDA, in a cohort of patients with diabetes. This is summarised in Fig. 6. Outcome measures are listed in Table 2.

Sample size—To achieve reasonable numbers and appropriate statistical power it is estimated that at least 40 patients would need to be recruited for the intervention cohort, along with a similar number for the control cohort. It will be apparent that power calculations to determine the cohort size required to show a statistically signifi-

cant effect are difficult to undertake because it remains completely unclear what the size of the effect may be. Therefore, these estimates are based on previous work which has been unable to demonstrate statistically significant effects with smaller sample sizes (see ref [10] for an overview).

Recruitment—could probably be undertaken by telephone. Exclusion criteria in the first instance would be insulin-treated type 2 diabetic patients (i.e. patients with endogenous insulin secretion, a process not well catered for in most currently available interactive simulators) and type 1 diabetic patients who are well controlled. The latter is proposed as an exclusion criterion because clinical interest is particularly focused on patients with poorer glycaemic control. Therefore to avoid the study running into a ‘ceiling effect’ a criterion for inclusion, of glycosylated haemoglobin (HbA_{1c}) values $> 9\%$, might be appropriate, depending on the local assay normal range.

Randomisation—would be required either formally, using random numbers, or alternatively patients recruited into the study could be entered alternately into either the intervention (simulator) or the control group. Stratification of patients and controls by certain demographic criteria and baseline glycaemic control would only be appropriate with larger sample sizes.

Baseline data collection—upon recruitment into the study patients would be asked, by telephone, to collect self-monitoring BG (SMBG) data for 1–2 weeks and thereafter attend the diabetes clinic/education centre. At this time some simple demographic details about each patient would be recorded once, e.g. age, duration of diabetes, height, weight, gender, insulin regimen, etc.

Baseline visit—a photocopy would be made of the patient’s logbook (SMBG data) and arrangements made for blood collection for measurement of HbA_{1c} . The patient would be given a diabetes knowledge assessment questionnaire [17–22] to fill in, and after this had been done, the patient would receive the first education session.

First education session—both patients in the intervention group and control group would have an identical period of time with a diabetes educator, e.g. 1 h.

Controls—this time with a diabetes educator would take the form of a usual patient education session.

Intervention group (simulator)—this would take the form of a teaching session from a diabetes educator, showing the patient how to use the interactive simulator, as well as showing some of the ways in which the program could be used to view the effects of changes in insulin therapy and diet, i.e. the educator would be free to impart not only program related instructions but also diabetes related information. If appropriate each patient in the intervention group could be provided with their own copy of the simulator program and manual for home or work use.

Preliminary experience with AIDA suggests that patients will need more than one session to become conversant with the software. Therefore it is proposed that a second education session should be organised for 1 week after the first. This should be identical in form to the first session.

Controls—would receive further diabetes education during this second 1-h session.

Intervention group (simulator)—would receive further instruction on how to use the program, as well as diabetes education during this second 1-h session.

Follow-up visits: Intervention group (simulator)—this group would be given appointments to attend the diabetes centre and use the interactive educational simulator for 2 h at least every fortnight. A copy of the manual for the software should be available at each computer which patients are to use. However, in addition to this, if patients have any computing-related queries, there should be someone for them to ask. Instruction at this stage should be limited solely to which keys to press, and not impart any diabetes-specific information. Alternatively, if patients have access to a suitable computer at home or work they could undertake their follow-up simulator sessions away from the diabetes centre.

For patients using the software in the education centre (the vast majority)—after each session a diabetes educator should record how many times the program was run and how many simulations were performed.

After patients have had their fifth (penultimate) session with the computer, they would be asked to collect SMBG data for 1–2 further weeks, and return again in a fortnight.

After patients have had their sixth (final) session with the computer, the concluding questionnaire would be completed and arrangements made for a repeat measurement of HbA_{1c}. The patient's logbook of recent (past 1–2 weeks) SMBG data would also be photocopied.

Control group—after the initial two visits the control group should not be seen again by a diabetes educator for a further 3 months. One/two weeks before the end of this period the patient should be telephoned and asked to record SMBG data for 1–2 weeks. Upon attendance at the centre after 3 months—as for the intervention group—the concluding diabetes knowledge assessment questionnaire should be completed and arrangements made for a repeat measurement of HbA_{1c}. The patient's logbook of recent (past 1–2 weeks) SMBG data also should be photocopied.

Cross-over phase—as an 'inducement' for the control patients, and a way of increasing the statistical power of the trial, a partial cross-over design is proposed. Therefore, at the end of the main study (3 months), control patients could be offered to use the interactive simulator and entered into a second run of the intervention arm of the study. This would not require any simultaneous control group as each patient would have been their own control during the first 3 months of the study.

Given the current availability of computer facilities this arrangement would expose the maximum possible number of patients to the interactive educational simulator—without compromising the validity of the study. Theoretically, if these control patients all wished to use the simulator this could boost the study numbers considerably—but perhaps whether to proceed with such a cross-over phase could be decided following interim analysis of the data from the initial 3 month phase of the study.

It will be self-evident that a protocol such as this could also be applied to objectively compare two or more interactive educational diabetes simulators. If such a study was undertaken, close

attention would need to be paid to randomisation and stratification to ensure that patient baseline characteristics were similar in each study group.

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