

Diabetes Information Technology & WebWatch

Using the AIDA—www.2aida.org—Diabetes Simulator. Part 2: Recommended Training Requirements for Health-Carers Planning to Teach with the Software

ELDON D. LEHMANN, M.B. B.S., B.Sc.^{1,2} and PATRIZIO TATTI, M.D.³

ABSTRACT

The purpose of this article is to document some recommended training requirements for health-carers planning to teach using the AIDA interactive educational diabetes simulator. AIDA is a diabetes computer program that permits the interactive simulation of plasma insulin and blood glucose profiles for teaching, demonstration, and self-learning purposes. It has been made freely available, without charge, on the Internet as a noncommercial contribution to continuing diabetes education. Since its launch in 1996 over 200,000 visits have been logged at the AIDA Website—www.2aida.org—and over 40,000 copies of the AIDA program have been downloaded free-of-charge. This report describes various training requirements that are recommended for health-care professionals who are interested in teaching with the software. Intended goals of this article are to answer possible questions from teachers using the program, highlight some minimum recommended training requirements for the software, suggest some “hints and tips” for teaching ideas, explain the importance of performing more studies/trials with the program, overview randomised controlled trial usage of the software, and highlight the importance of obtaining feedback from lesson participants. The recommendations seem to be straightforward and should help in formalising training with the program, as well as in the development of a network of teachers “accredited” to give lessons using the software. This report, together with the previous article (Part 1, *Diabetes Technol Ther* 2002;4:401–414), highlights the utility of providing guidelines and suggesting recommended training requirements for health-carers planning to make use of educational medical/diabetes software.

¹Academic Department of Radiology, Barts and The London NHS Trust, St. Bartholomew’s Hospital, and Department of Imaging (MRU), NHLI (Imperial College of Science, Technology and Medicine), Royal Brompton Hospital, London, United Kingdom.

²Dr. Lehmann is a co-developer of the AIDA diabetes simulator.

³Endocrine and Diabetes Unit, Ospedale di Marino, Marino, Rome, Italy.

AIDA is an independent noncommercial development which is being made available free-of-charge via the Internet—at a dot org (.org) not-for-profit Website—as a noncommercial contribution to continuing diabetes education.

INTRODUCTION

DIABETES MELLITUS is a major chronic disease in industrialised countries. Previous data suggested that the disorder affected 3% of the population of Europe and approximately 100 million people worldwide; however, more recent surveys suggest that there is a growing epidemic of diabetes worldwide, with the incidence of the disease markedly on the increase.¹ As demonstrated by the Diabetes Control and Complications Trial (DCCT),² the incidence and severity of the later life complications that accompany diabetes can be considerably reduced if diabetic patients receive effective treatment leading to good glycaemic control. In general such treatment attempts to achieve normoglycaemia by maintaining a careful balance between diet, physical activity, and insulin therapy. However, education of diabetic patients to achieve this balance requires a level of clinical expertise that, although present in specialised diabetes units and some general (primary care) practices with an interest in diabetes, is not always to be found in other sectors of the health service.

The hypothesis underlying this work is that one way of making the required clinical expertise more widely available might be to use information technology (IT).^{3,4} The rationale underlying this interest in the use of IT is the hope that computers may offer a way of improving the therapy offered to patients with diabetes—permitting more patients to be managed more intensively—in line with the experience of the DCCT.²

One area of clinical diabetes care in which computers may particularly have a great deal to offer is education.^{5,6} There are many different aspects to diabetes education; however, learning facts is only one of these.⁷ It is well recognised that the ability to gain *experience* is also of great importance. In this respect it is not ideal for patients to learn about diabetes control solely from real life experiences because of the long time frames involved, aside from the possible very real dangers of hypo- or hyperglycaemia.⁸ For this reason, it has been suggested that an interactive simulation of a diabetic patient might offer one solution.⁹ In the same way that aircraft pilots and air traffic con-

trollers are trained on airplane and air traffic simulators, it should be possible for diabetic patients and health-care students to be trained to make appropriate responses to everyday situations using a diabetes simulator.^{8,10}

However, it should be stressed that the aim of such diabetes simulation software is to support, not compete with, existing diabetes education sessions.¹¹ Therefore the intention is that interactive simulators may in time become useful adjuncts to more well-established diabetes teaching tools. In this respect, at present there are simply not enough diabetes educators, or financial resources available, to provide the same standard of care to all patients with diabetes as was offered in the DCCT.² Therefore the concept behind our interest in interactive educational diabetes software is not to replace clinicians or educators, but rather to supplement their input. The hypothesis being that such IT tools might be able to help close the gap in care between what is currently available, on a routine basis, and what was made available in the DCCT.²

AIDA BACKGROUND

AIDA is a freeware computer program that permits the interactive simulation of plasma insulin and blood glucose profiles for demonstration, teaching, and self-learning purposes. It has been made freely available, without charge, via the Internet as a noncommercial contribution to continuing diabetes education. In the 6+ years since its original World Wide Web launch over 200,000 people have visited the AIDA Web pages at www.2aida.org and over 40,000 copies of the program have been downloaded, *gratis*. Further copies have been made available, in the past, on diskette by the system developers and from the British Diabetic Association (now called "Diabetes UK"), London, U.K.¹²

The AIDA software has been previously described in detail elsewhere in this journal.⁷ Briefly, it incorporates a compartmental model that describes glucose–insulin interaction in patients completely lacking endogenous insulin secretion. It contains a single extracellular glucose compartment into which glucose

enters via both intestinal absorption and hepatic glucose production. The AIDA model also contains separate compartments for plasma and "active" insulin,^{13,14} with the latter being responsible for glycaemic control while insulin is removed from the former by hepatic degradation. The actual mathematics underlying the model have been fully documented elsewhere.¹³ Details of the AIDA model are also accessible from within the AIDA software package, and can be viewed and printed separately via the Internet (from www.2aida.org/technical). Sample case studies using AIDA have been described previously in this journal.^{7,15-17} Further examples of the sort of simulations that AIDA can offer can also be found elsewhere in other journals^{6,18} and at www.2aida.org/demo on the Internet.

In Part 1¹⁷ of this two-part article we documented various recommended guidelines for health-carers planning to teach with AIDA and covered, amongst other things, possible questions from patients and potential difficulties that may be encountered by participants of diabetes simulation lessons using the software.

POSSIBLE QUESTIONS FROM TEACHERS

It is possible, if trying to train some additional teachers to use AIDA, that they may have some questions of their own. Answers to some of these can be found in the "Frequently Asked Questions" (FAQ) section of the AIDA Website, which can be accessed directly at www.2aida.org/faq on the Internet. These include:

Question: "How can one change the blood glucose units from mmol/L to mg/dL?" *Response:* In the downloadable, PC-based version of AIDA—from the data entry screen—press the <F7> function key for "Options" and then press the letter key—a—to toggle (switch) the blood glucose units from mmol/L to mg/dL (or back again). In AIDA online—scroll down the opening page at www.2aida.org/online to the heading that says "Options." Here under the first entry it will be possible to select the preferred blood glucose units (mmol/L or mg/dL).

Question: "When will exercise become avail-

able for simulation in AIDA?" *Response:* It is difficult to give a definite prediction for this—but an updated version of AIDA incorporating exercise will become available for downloading for free from the AIDA Website in due course. If you would like to be automatically informed by electronic mail when this enhanced version of the program is released, you can join the low-volume AIDA registration/announcement list by sending a blank e-mail note to subscribe@2aida.org This AIDA list—which currently has over 2,200 subscribers—is open to anyone who wishes to join, but is closed in the sense that only AIDA's developers can actually post messages to the list. As a result traffic on the list is very infrequent/virtually nonexistent. However, this is the most efficient way of keeping a large, and growing, audience informed about new developments with the software.

Question: "What does AIDA stand for?" *Response:* The AIDA name is a historical name that has been kept because it is quite fun and different. A long time ago some of the original AIDA developers were tasked with trying to construct a prototype computer program that might be able to offer some advice on insulin dosage adjustment. This program incorporated a simulation engine, and a knowledge-based system, and was called an Automated Insulin Dosage Advisor (or "AIDA" for short).^{19,20}

However, it soon became apparent that the simulation engine was not sufficiently accurate for individual patient blood glucose prediction or therapy planning.²¹ Notwithstanding these limitations, it was also apparent that the simulation approach—while not being useful for therapy^{22,23}—potentially had a lot to offer for education.²⁴ Given this, a decision was taken to restructure the program for teaching/self-learning use. However, the AIDA name stuck, and the educational program that has been refined and developed since, over time, is also now still called "AIDA."

Question: "Does AIDA advise my patients what insulin dose to inject?" *Response:* No. Definitely not. AIDA is purely an educational tool, intended solely for self-learning, teaching, and/or demonstration purposes. It is not meant for individual patient blood glucose prediction or therapy planning. Basically, for

someone with diabetes, the simulator is not sufficiently accurate to predict his or her own personal blood glucose profile. This is because everyone is different, and therefore each person's diabetes is different. As often stated on the Web, "diabetics do not all wear the same sized shoes"—implying that just as each person with diabetes is an individual, and different, so his or her metabolism and glycaemic control will vary. AIDA can only offer an approximation as to what an *example* patient's blood glucose profile might look like. Given this, while your patients might be able to use this program to learn, the program is not accurate enough for therapy planning.

Question: "If my patients cannot match their own personal regimen/therapy plan using AIDA, then is it of any use to them?" *Response:* Yes. We occasionally come across the *misconception* that one needs to be able to recreate one's exact regimen to be able to use AIDA for a particular individual. This is incorrect. AIDA will rarely be able to accurately reproduce an individual's blood glucose profile. And even if it works for one person, it will not necessarily work for another. No noninvasively calibrated model will be able to recreate all individuals' blood glucose profiles accurately.^{21,23} Given this, we are not so much aiming for accuracy with AIDA, as for realism.

In this respect, once we have achieved an element of realism the idea is to educate. People can learn not just by reproducing what they are doing at the moment, but also by exploring alternative options and getting a clearer idea as to what might be possible to improve glycaemic control.

Using a flight simulator analogy, if one always flies the London to San Francisco route—a flight simulator that allows one to practice landings in London and San Francisco may be of interest—but ultimately will not necessarily be as accurate or realistic as the real thing. In addition the true strength of the simulator will come from being able to simulate alternative flight paths and landings in other less familiar airports, for instance, in an emergency situation. In the flight simulator analogy this might be an emergency landing en route in Baltimore or Greenland.

Therefore we see one of the key roles of an

educational simulation program such as AIDA as being to broaden people's perspectives and horizons—and help them gain experience in a wide range of different situations by adjusting the computer's (AIDA's) insulin and diet regimen—safe from the risks of hypo- or hyperglycaemia.

Question: "My patients use insulin type ABCDE. As AIDA does not include insulin type ABCDE, is it of any use to them?" *Response:* Yes. It is a sometimes expressed view that if AIDA cannot simulate an exact diabetes regimen for a particular individual, then it is not possible to be used by that person. Similarly it is sometimes stated that without a particular feature (e.g., Humalog/lispro, exercise, certain pump regimens, etc.) the program cannot be used by that individual. This actually rather misses the point of the program. The aim of AIDA is not to exactly reproduce an individual's own regimen and therefore provide individual blood glucose predictions and simulations. Rather the idea is for a user to be able to gain wider experience of changes in insulin and diet in diabetes, as a way of learning about the processes involved. In this respect we are not just aiming to simulate an individual's own regimen. If AIDA can match an individual's blood glucose profile, that is obviously great. However, we actually also wish to be able to provide wider experience of other regimens via use of the program.

Question: "How can I simulate pump regimens using AIDA?" *Response:* AIDA does not at present cater for dedicated pump regimens. However, we have come across some insulin pump users who have been making use of AIDA.²⁵ Basically they are using two entries for long-acting insulin (e.g., ultratard) to provide a "basal"-like background level of insulin, and then supplement this with some short-acting (regular) insulin to provide boluses. In this way some people seem to be finding the simulator of use, even for pump education.

We do not have too much experience with this, but a trial Insulin Pump Web page has been set up at www.2aida.org/pump that provides more information. Clearly this can only address the more basic of pump regimens. Nevertheless, as people have been making use of this approach themselves it seemed that it

might be worthwhile to make this known to a wider audience via the Internet. In this respect, if this can help some people learn a bit, or broaden their experience, then we think this will have been worthwhile. As often stated on the Web, "people's mileage may vary." So what works for one person clearly may not be so useful for someone else, and vice versa. Connected with this, it is important to note that a lot of people—particularly outside the United States—may not necessarily have the latest, most sophisticated programmable pumps, so some basic regimens for them may actually be very appropriate.

MINIMUM RECOMMENDED TRAINING REQUIREMENTS

One issue worthy of special consideration here is how much training is enough before starting to teach using AIDA? This is not an easy question to answer as the experience needed has to be defined on the basis of time spent with the program. However, teacher experience and teacher learning—like any participant learning—generally has a strongly individual component. Nevertheless, as a minimum we think that a sound knowledge of the program requires not less than 16 h to be spent using the software on a number of separate occasions. Furthermore, at least 100 diabetes simulations should be run. In addition the length of time between deciding to start teaching with AIDA and actually running the first lesson(s) is recommended to be at least 2 months—to give time to gain proper experience with the

software and obtain a hard copy AIDA manual by post from the AIDA developers. This should also allow sufficient time to read the supporting AIDA documentation/manual and articles, and have any questions about the software answered by the program's authors via e-mail.

Incidentally it should be made clear that the numbers suggested above are purely empirical since this topic has not been systematically studied. However, these suggestions apply equally both to a teacher and to a computer operator¹⁷ (if different). In learning to use the program, it may also help for aspiring AIDA teachers to keep some sort of log book of their usage of the software. Such a log book could record the sort of information shown in Table 1.

Much of this information is automatically recorded by the AIDA software. For instance, from the PC AIDA v4.3a software graphical display pressing the I key for Info (Information), followed by the <Escape> key, twice, will display some AIDA usage statistics, as shown in Figure 1. This records when the current version of the software was first set up on the machine, how many times the program has been run, and how many simulations have been performed during the current session—as well as in total since AIDA was installed. Review of this screen at the end of each self-learning session with the program will provide useful objective data about how much the program has actually been used. Similarly, in a study/trial situation this screen can provide useful information at the end of each class regarding the actual number of simulations run per lesson.

The AIDA software comes with 40 case sce-

TABLE 1. DATA ITEMS RECOMMENDED FOR RECORDING ON AN ON-GOING BASIS IN AN AIDA TEACHER'S LOGBOOK

1. On how many separate occasions were AIDA and/or AIDA online used (with dates and approximate start times for each session)?
2. How many separate times was the program run?^a
3. How many simulations were run?^a
4. Over what period of time was AIDA used (time from installation to present in weeks/months)?^a
5. How many different case scenarios were experimented with/accessed?
6. How much time was spent actually using the program (estimate approximate finish time for each session)?
7. How many new cases were created?^b

^aInformation accessible by pressing the I key, for Info, while viewing the AIDA graphical (simulation) display. Then pressing the <Escape> key twice will show the AIDA "USAGE STATS" display (see Fig. 1).

^bNew case scenarios can be exported from the AIDA database (see Fig. 2) and e-mailed to the AIDA authors at www@2aida.org as a simple file attachment. In this way new cases can be incorporated into future free releases of an expanded AIDA case scenario database.

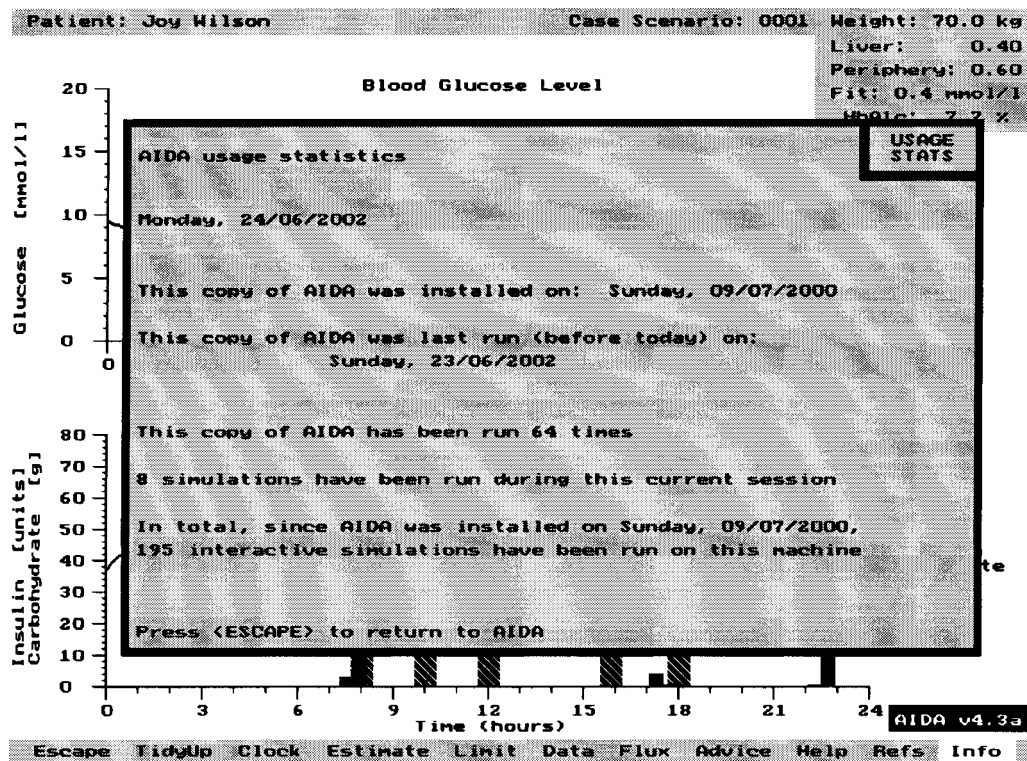


FIG. 1. Usage statistics section of PC AIDA software to access details of how many times program run, how many simulations run, as well as when software first installed and last run. This screen can be accessed from the AIDA graphical (simulation) display by pressing the *I* key (for Info), and then pressing the (Escape) key, twice.

narios that can be simulated as standard. Details of these have been summarised in Part 1 of this article.¹⁷ It is recommended that prospective AIDA teachers should spend some time experimenting with a range of these scenarios. However, in addition it would be sensible for future teachers to create three or four new case scenarios of their own for storing within their local AIDA database. If possible it would also help if teachers could export these and e-mail them to www@2aida.org for discussion and possible inclusion in the next (updated) main, central AIDA case scenario database. Figure 2 (a and b) shows the export function being accessed from the AIDA PC data entry screen—allowing the case scenario data to be saved as an ASCII (comma separated value) text file, which can be easily sent via e-mail as a file attachment.

Prospective AIDA teachers would also be advised if possible to attend a workshop about actually teaching with AIDA. If such a work-

shop is not available locally then it is recommended that aspiring teachers should spend some time reviewing the material freely available at the AIDA Website—www.2aida.org—and using AIDA online at www.2aida.org/online as well as making use of the Diabetes/Insulin Tutorial at www.2aida.org/tutorial on the Web. Furthermore, if a workshop is not available locally, future teachers are also very welcome to contact the AIDA authors directly at www@2aida.org to discuss use of the software more fully.

In addition, in due course a dedicated AIDA discussion forum is planned where AIDA users will be able to exchange hints and tips about the software directly with other AIDA users. Further information will be made available at www.2aida.org/forum on the Web.

Table 2 provides a summary checklist of items that AIDA teachers are recommended to have done before embarking on giving lessons to patients using the software.

a

Name Joy Wilson Weight 70.0 kg Case Number: 0001 AIDA v4.3a
 Free Text This woman is on three injections of short and/or intermediate acting
 in tart a family, but
 con arly afternoon, des
 pit on of becoming preg
 MEA Supper Snack
 Tim 1800 2230
 Car 30 0

*** I M P O R T / E X P O R T C A S E ***

This option allows you to export the current case scenario to a standard format text file stored in the AIDA installation / runtime directory, or import data from the text file into the current case scenario. This facility allows case scenarios to be swapped or transferred between computers, and users, e.g. via email / the Web.

Press <letter key> to select option

(a) Export current case to AIDATFR.CSV
 (b) Import data from AIDATFR.CSV to current case

Press <Esc> to return to the Options Menu

INS ber 3 Number 4
 Pre 30
 Hum 0
 Hum 18

GLU
 Tim
 Glu

HYP Number 4
 Tim

CLI l/min

INSULIN SENSITIVITIES: Hepatic (Sh): 0.4 Peripheral (Sp): 0.6
 Esc=Simulator F1=Help F3=Quit F5=Info F6=Graphics F7=Options F10=Cases

b

Name Joy Wilson Weight 70.0 kg Case Number: 0001 AIDA v4.3a
 Free Text This woman is on three injections of short and/or intermediate acting
 in tart a family, but
 con arly afternoon, des
 pit on of becoming preg
 MEA er Snack
 Tim 0 2230
 Car 0 0

*** DATA SUCCESSFULLY EXPORTED ***

The current case scenario has been successfully exported to AIDATFR.CSV

This file can be found in your AIDA installation directory. CSV stands for Comma Separated Values. This file format can be transferred between computers in ASCII (text) format - e.g. as a file attachment - and can be imported into spreadsheets such as MS Excel.

Please note: lengthy free text descriptions may have been truncated during the case export process.

Press <Esc> to return to the Options Menu

INS 3 Number 4
 Pre
 Hum
 Hum

GLU
 Tim
 Glu

HYP ber 4
 Tim

CLI n

INSULIN SENSITIVITIES: Hepatic (Sh): 0.4 Peripheral (Sp): 0.6
 Esc=Simulator F1=Help F3=Quit F5=Info F6=Graphics F7=Options F10=Cases

FIG. 2. a: Import/export function screenshot from AIDA v4.3a. This option allows users to export the current case scenario to a standard format text file, or import data from a previously stored text file. In this way case scenarios can be swapped or transferred between computers, and users, via e-mail/the Web/etc. This facility can be accessed from the AIDA data entry screen by pressing the <F7> function key for "Options" and then pressing the h key for "Case scenario import/export menu." b: Export function screenshot from AIDA v4.3a showing the display once a case scenario has been successfully exported by selecting option (a) in panel a. (The AIDATFR.CSV ASCII text file containing the exported case scenario data is stored on the user's hard disk in the AIDA installation directory.)

TABLE 2. CHECKLIST OF THINGS THAT AIDA TEACHERS ARE RECOMMENDED TO HAVE DONE BEFORE EMBARKING ON GIVING LESSONS TO PATIENTS WITH THE SOFTWARE

-
1. Have run >100 simulations: YES NO
 2. Time from deciding to start teaching with AIDA to actually running first lesson >2 months:
 YES NO
 3. Have spent >16 h using software: YES NO
 4. Have created >3 new AIDA case scenarios: YES NO
 5. Have read AIDA hard copy manual: YES NO
 6. Have checked are using latest release of the AIDA PC software at www.2aida.org/latest: YES NO
 7. Have attended a workshop about teaching with AIDA—or if this is not available locally—have used AIDA online at www.2aida.org/online and have worked through the Diabetes/Insulin Tutorial at www.2aida.org/tutorial: YES NO
 8. Have tried to create and run one or two workshops of own using the software locally for health-care students/junior doctors/nurses or other allied health-care professionals in own hospital/clinic—before embarking on giving lessons to patients: YES NO
- If contemplating running a trial/study using the software (recommended):
9. Have read the protocol paper,²⁶ study questionnaires,^{15,27} pilot study results,^{28,29} and the accompanying guidelines¹⁷: YES NO
 10. Have obtained local Ethical Committee written permission for the study: YES NO
 11. Have obtained written, signed informed consent from all study participants: YES NO
 12. If unable to attend a local Workshop using the software—have made contact via the AIDA Website at www.2aida.org/interest to obtain an AIDA hard copy manual, and the most up-to-date information about the program and study usage of the software: YES NO
-

TEACHING IDEAS

There will always be hints and tips as to how lessons with AIDA might be optimised or improved. A selection of these are documented below in case these might be of use to prospective AIDA teachers.

As a teaching tip it may be useful to test the immediate recall of the participants at various times during the lessons. This kind of testing can be used at the end of an explanation and can augment the educational value of the classes. In other words the teacher should ask the participants to repeat back his/her words, or summarise his/her explanation, interrupting it at an appropriate time, and leaving the subjects to complete the sentence. In this way the teacher can see if the participants have really understood the explanation.

In the future it might be useful to be able to tailor the exact content of the lessons to the particular needs of the participants. In this respect it may be helpful to prepare an introductory questionnaire with, say, 20 multiple choice questions aimed at identifying the main weaknesses in the knowledge of the participants. However, initially, until experience has been gained locally with the software, it may be easier to confine the lessons to preselected topics.

An important suggestion is to repeat the explanation of the lines and symbols on the AIDA graphs more than once, especially during early lessons. In this respect do not take anything for granted. Remembering that people do not necessarily like to admit that they do not understand something may actually improve the educational value of the lessons.

Similarly do not scold or rebuke anyone. This is not a school classroom. If anyone is in difficulty simply help him or her, or switch that person's role monitoring a particular parameter with that of another participant, without any comment. If possible find a different reason for doing that.

As intimated above, all aspiring AIDA teachers are strongly advised to obtain a copy of the hard copy AIDA manual.^{12,17} This is freely available by air mail from the AIDA authors and gives maximum details about how to use all parts of the program. Prospective AIDA teachers need to read this fully to completely understand all the functions of the program, prior to embarking on giving lessons with the software.

There are a number of other ways in which AIDA teachers might be able to enhance their usage of the program. Periodic local meetings with other diabetologists/endocrinologists/

diabetes educators/diabetes specialist nurses to discuss interesting case scenarios simulated using the program may help. Similarly videotaping selected lessons could also be used to refine the capabilities of the teaching and usage of the software. Periodic review of such videotapes—possibly with health-care colleagues—could also be useful. However, local legal/ethical issues of videotaping patients may need to be addressed; although it might be feasible to derive benefit from this approach by videotaping the teacher and the computer screen—without necessarily videotaping the faces of, and thereby identifying, any of the patients.

For teachers who are planning to give lessons with AIDA, a useful piece of advice may be to start with a workshop of their own using the software. The workshop could involve teaching medical students, junior doctors (interns), student nurses, qualified general nurses, diabetes specialist nurses/educators, pharmacists, or primary care physicians (general practitioners)—or a range of participants from these categories. In fact the exact makeup of the audience is less important than the fact that such a workshop can offer the teacher some good practice with teaching using the program, before embarking on a series of more formal lessons with patients.

This will be particularly important for randomised controlled trial (RCT) usage of the program (see below), where it will be important to avoid a learning curve for the teacher. Given this, the teacher should have taught beforehand with the program—which reinforces the idea about running (and teaching) some AIDA-related workshops for health-care students/colleagues prior to embarking on teaching a series of RCT lessons using the software with patients.

RATIONALE FOR STUDIES/TRIALS

We have intimated before³⁰ about the role of enthusiasts/believers as compared with non-believers/"cynics" when considering novel diabetes computer applications, such as AIDA. However, perhaps special mention should be made about this here.

We think it is fair to say that there are dia-

betes health-care professionals who are enthusiastic about the use of IT to assist in a wide range of different ways in the provision of clinical diabetes care. However, we also believe that to date the true role for computers has not been objectively nor rigorously demonstrated. For this reason—while there are enthusiastic "believers"—there remain many health-care professionals and health-care managers who may not be so enthusiastic and who may actually be quite sceptical as to the possible benefits of computer technology in routine clinical practice, today. We see one of the key roles of software developers and users as actually being to convince those who might be more sceptical as to the potential benefits of computerisation. By definition readers of this journal, and this "Diabetes Information Technology & Web-Watch" column, are likely to be quite amenable to considering some of these novel computer technologies in a favourable manner.

However, we all have to recognise that less enthusiastic colleagues who do not subscribe to a diabetes technology journal may be less easily convinced. We are of the opinion that persuading such less enthusiastic colleagues about the possible benefits of computer-based educational tools can only take place via rigorously conducted clinical RCTs that yield objective medical outcome data.^{26–29}

We accept that it could take quite some time to acquire such evidence from RCTs. However, in our opinion it is the lack of such credible evidence that has held back the more widespread application of such technologies to date in clinical diabetes care. Put simply, for most diabetes software, the program's developers may feel that a piece of software does some good, and a few enthusiastic colleagues may have given it a try, but there seem to have been few credible efforts to evaluate the software in other, independent settings—remote from where the program was developed. As a result few nonenthusiasts have become convinced of such programs' utility. We are keen, if possible, to avoid this situation arising with AIDA—and therefore have embarked on a range of studies to try and evaluate the software in different settings,^{15,16,29} with different end users.

We hope the current recommendations and accompanying guidelines¹⁷ may be of some use

for colleagues who are interested in teaching using AIDA. However, we also hope that such colleagues may collaborate in the evaluation of the software and enrol some of their patients in more formal RCTs using the program.

RCT USAGE

Novel technologies can be introduced into clinical practice sometimes with little by the way of validation or evaluation. As we have highlighted before in this journal,³⁰ it behoves system developers to test out their programs as rigorously as possible. Similarly rather than just embarking on teaching using the software—ideally it should be incumbent on people who wish to give lessons using the program to carry out some sort of evaluation of the software in an educational setting. Otherwise how is it possible to assess whether the teaching intervention actually does any good? Furthermore we feel it is important to document the results of such studies—otherwise the larger diabetes community will not get to hear about successes (and failures) with using the software to teach. Therefore we see the RCT evaluation of AIDA as simply being an extension of ordinary usage of the program, with the collection of some additional study data. However, before embarking on such a study the trial investigators/teachers will need to be fully familiar with the software and how best to teach using it.

A protocol for evaluating the educational use of the program has been described,²⁶ and questionnaires that could be used to assess the possible benefits of the software have been published.^{15,27} A preliminary, small, pilot study using this protocol has also been run,^{28,29} but further studies are still very much needed.

In addition to all the general recommendations for use of the program highlighted above, there are also some specifics that need to be considered for RCT usage of the software.

Participation in a trial requires robust data collection, with reliable recording of information about participants. There also needs to be a method for storing anonymised patient data, and questionnaire responses. Keeping a log-book of usage of the program to summarise the number of simulations run, length of lessons,

number of cases accessed, etc. (Table 1)—may even help in nonstudy situations—but will be of particular importance in a trial. Standardised haemoglobin (Hb) A₁ assessments of patient blood samples—both within a particular hospital/centre and between centres will be of importance. Furthermore, knowing the normal range for the HbA₁/HbA_{1c} assay used locally will also help in making comparisons between results from different study centres.

In the study situation it will be important to differentiate between patients who are lost to follow-up and those who have to be dropped because they become disruptive to the lessons, for whatever reason.

Despite the fact that teaching with AIDA is an innocuous intervention, in the trial setting written local Ethical Committee permission for the study should be sought, and received, prior to commencing lessons. Furthermore, written, signed, informed consent needs to be obtained from each participant. A generic consent form that can be used for this purpose, or modified as required to conform with local hospital/clinic arrangements, can be found in Appendix I or at www.2aida.org/consent on the Web.

Finally, in the study situation it will be important to have a control group who receive conventional/standard, non-computer-based educational sessions. Details of how such non-AIDA-based lessons might be arranged can be found elsewhere,^{26,27} with the control lessons consisting of whatever is standard existing diabetes education in the local hospital/clinic setting.

In order to encourage patients to participate in such a study—even though they may not be randomised initially to receive the novel (AIDA) intervention—we have found it helpful to operate a partial cross-over design for the RCT. The relative merits of this approach have been discussed elsewhere.³⁰ However, at least in this way participants initially randomised to the control group can be offered—after an appropriate “washout” period—the novel (AIDA) intervention, if they so wish.

FEEDBACK FROM THE LESSONS

Obtaining feedback from the participants is a critical aspect of teaching classes with the pro-

gram since only in this way can the lessons realistically be improved.

There are three types of feedback that we have been collecting regarding use of the program: (1) immediate feedback, at the end of each lesson; (2) "before and after" evaluations to assess changes over the course of the lessons; and (3) feedback about the software, at the end of the course.

For immediate feedback, at the end of each lesson, we have prepared a one-page general questionnaire²⁷ to collect some data from the participants and give them an opportunity to pass back any comments on the lesson.

For the "before and after" evaluations we have drawn up a more formal questionnaire,²⁷ which can be used at the beginning and end of a cycle of lessons to assess any increase in patient knowledge and expertise in a range of areas. The topics covered by this more detailed questionnaire include: (1) self-confidence, (2) quality of life and metabolic control, (3) social and emotional impact of diabetes on lifestyle, (4) attitudes towards self-monitoring of blood glucose, (5) prior knowledge about diabetes, and (6) "what-if" type questions, and some baseline (demographic) details.²⁷

For use at the end of the course, we have also generated a third questionnaire¹⁵ to obtain more general feedback about the software from participants exposed to the AIDA diabetes simulator. In any workshop/study setting it would be useful to obtain such feedback to learn more about what people think of the program.

A fourth, brief questionnaire could also be completed by relatives of patients, at least at the end of the cycle of lessons to assess whether, in their view, there has been any change (improvement) in the knowledge/expertise of their relative. While such feedback would clearly be particularly subjective, it would nevertheless still be of interest to establish if carers of patients had noticed any difference in their relative's diabetes control, confidence, etc. An example relative's/carers' questionnaire that can be used for this purpose can be found in Appendix II.

Detecting changes in the patients' HbA_{1c} levels is a further way of obtaining a type of feedback about the lessons that is not so subjective, nor dependent on participants' "impressions." The HbA_{1c} level reflects the mean blood glu-

cose level during approximately the last 3 months. Therefore we have recommended checking HbA_{1c} levels both before and 1 month after the end of a cycle of lessons in order to allow sufficient time for an impact of the new knowledge to manifest itself.²⁶ An additional method of monitoring whether the lessons with the simulator are doing any good is to get participants to record the number of symptomatic hypoglycaemic episodes that they experience before and after the course of lessons. Two representative weeks of data collection—one before the lessons start, and the other after the completion of the lessons—may be useful for this.²⁶

DISCUSSION

Despite its deceptively simple appearance, teaching using AIDA can be challenging. Certainly to obtain maximum benefit for lesson-participants can involve a learning curve for teachers. This learning curve typically requires some time to overcome, and depends on both the skills of the individual and the frequency with which the program is used. Optimal training with the program requires hands-on usage by an experienced individual who understands the pathophysiology of diabetes. Our hope is that thorough training with the software should help to establish higher-quality lessons—although it is recognised that evidence for this at present is limited.

We would urge health-care professionals who are considering running lessons using AIDA to formalise the process by obtaining feedback from the subjects about the lessons. Participating in a larger multicentre trial using the software and enrolling patients into such a study need not take much extra time (over and above just running the lessons), and clearly is the best way of more formally establishing the benefits and limitations of using the program for teaching.

Health-care professional colleagues who are considering using AIDA to teach during lessons might also find it helpful to consider the issues involved in running AIDA-based lessons and the steps they may need to take: (1) to prepare beforehand, (2) to enrol participants in a formal study, (3) to actually give the

lessons, and (4) to collect and analyse data from the classes. It might also be beneficial for prospective teachers to keep a logbook of their usage of the software (Table 1), prior to embarking on giving lessons with the program.

To summarise, the purpose of the logbook is threefold. Firstly, it provides a record of usage of the software, in the training/learning period, before giving lessons using the program. Secondly, the sort of data collection required for such a log book (Table 1) would also be of use in an RCT setting—for documenting the length of lessons, the number of simulations run, etc. Thirdly, a logbook (or notebook) offers a useful way for teachers to write down and collect together in one place ideas for simulations/lessons that can then be tried out using the software.

Furthermore it would be recommended that, on an on-going basis, ideally at least 100 simulations should be run each year to maintain familiarity with the program. This can be checked using the AIDA usage statistics facility (Fig. 1).

It should be emphasised that we do not wish to create unnecessary “hurdles” for those who wish to teach using the software. In particular we do not want to make this process too difficult or proscriptive. However, at the same time we would like to ensure appropriate standards are maintained. In this respect, the training requirements documented above are the *minimum* recommended. Individuals or individual centres may wish to do more with the program, before embarking on running classes using the software. Table 2 contains a checklist of things that teachers are recommended to have done before embarking on giving lessons with AIDA.

In general, longer-term, medical software developers may need to aim for an “accreditation” process for potential teachers to go through, possibly leading to “certification” to teach with a particular program, prior to embarking on giving lessons with the software. This may become of increasing importance if attempts are made to try and expand the approach and spread the concept of computer-assisted diabetes teaching/learning to other centres.

In this respect, although programs like AIDA must still be considered very much research

tools—prior to becoming more routinely used clinical tools, formal certification requirements, courses, and ongoing continuing medical education issues will need to be addressed. However, before this happens much more evidence is needed from RCTs to establish the medical effectiveness/efficacy of the whole diabetes simulation/education approach.

Connected with this, while we are obviously firm believers/enthusiasts and feel certain that a simulation program like AIDA can have something to offer diabetes education—in this era of evidence-based medicine we recognise that at present such simulation programs remain completely unproven interventions. Therefore we have embarked on trying to establish what the medical efficacy of the approach might be. Training up other health-care professionals to teach using the software will be an important part of this. Hopefully the recommended guidelines¹⁷ and suggested training requirements will help with this.

SYSTEM AVAILABILITY

The latest release of AIDA (v4.3a) can be downloaded, without charge, from 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 online, is also available for use free-of-charge at www.2aida.org/online on the Web. This allows AIDA’s diabetes simulations to be run from any computer, anywhere, provided it has an Internet connection and a graphical display.

An interactive educational Diabetes/Insulin Tutorial that has been integrated with AIDA online can also be accessed without charge at www.2aida.org/tutorial on the Web. This allows visitors to dynamically simulate some of what they have learnt in the tutorial about balancing insulin and diet in diabetes, using AIDA online.

People who wish to be automatically informed about future updates and enhance-

ments to the AIDA/AIDA online 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 teaching in their clinics using AIDA or by applying a standardised RCT protocol^{26,27} in an evaluation of AIDA in clinician-, specialist nurse-, or 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 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."

APPENDIX I: EVALUATION OF THE TEACHING UTILITY OF A COMPUTERIZED DIABETES SIMULATION CONSENT FORM PROGRAM

Background Information: Your doctor/diabetes clinic is interested in using a novel computer program for education about diabetes. This program can simulate many of the different types of diabetes problems that people with diabetes can encounter, and allows users to try and solve them in different ways. However, although many people have used this simulation program for diabetes teaching and self-learning, its actual role in supporting the education of people with diabetes mellitus remains to be formally confirmed.

The current study aims to address this issue by conducting a 'randomised controlled trial' using the simulation program in diabetes lessons. One half of a group of people with diabetes will be randomly assigned to receive

lessons with the diabetes simulator first, while the other half of the group will receive standard (or conventional) lessons about diabetes first. Those people that are randomly assigned to receive conventional lessons first, will subsequently be offered a set of lessons with the diabetes simulator, a month after the end of their conventional lessons. In this way, everyone who participates in this study should have a chance to receive lessons involving the novel diabetes simulator.

Understanding of Participant: I have been asked to take part in a study that evaluates the usefulness of a novel diabetes simulation program. To this end I will take part in a study consisting of six conventional lessons (with graphs, transparencies & oral presentations) and/or six lessons with a computerized diabetes simulator. I understand that the exact dates and times of the lessons will be arranged directly with my fellow participants & I, and that the sequence of my participation in the study (conventional/standard lessons first or simulation lessons first) will be randomly determined.

My involvement will be limited to:

- 1) I will complete a logbook with my home blood glucose values the week before the start of the lessons, and the week following the end of the lessons. I will also record any symptoms of hypoglycaemia ('hypos') and the blood glucose value at that time.
- 2) I will have my glycosylated haemoglobin (HbA_{1c}) level checked before the start of the lessons, and one month after the end of the lessons.
- 3) I will complete some questionnaires regarding my subjective feeling of well being, and the impact of the lessons on my perceived well being.
- 4) I will participate actively in the lessons.

I understand that there is no risk to my health from this study, and that no form of medical therapy will be introduced for study. *I note that the diabetes simulator cannot be used to tailor my individual therapy. I appreciate that the only aim of the simulation program is to help me*

understand the mechanisms that govern blood glucose control in the human body, so I may understand better the processes involved in balancing insulin and diet in diabetes therapy. However it is quite clear to me that any insulin dosage adjustments made during the course of the study will be absolutely independent of the diabetes simula-

tor, and will be discussed fully with my diabetologist/diabetes educator, as per normal.

I agree not to make use of the computerized diabetes simulation program myself during the period of the study to avoid unnecessarily influencing the results.

The study has been explained to me by _____ and I have had all my questions answered.

Participant's name: (please print) _____

Participant's signature: _____

Date: ____/____/20__

Principal Investigator: (Dr. _____) (* Please print name)

Principal Investigator's signature _____

Date: ____/____/20__

Witness: Diabetes Educator/Nurse (_____ *)

Diabetes Educator/Nurse's signature _____

Date: ____/____/20__

Centre Name: Department of Diabetes/Endocrinology** (** Please delete as applicable)

Hospital/Clinic: _____

Clinic Address: _____

Centre ID Number (if applicable): _____

Local Ethical Committee Reference Number (if applicable): _____

APPENDIX II: RELATIVE'S/CARER'S QUESTIONNAIRE

Questionnaire for the relative's/carer's of subjects with diabetes who attended a series of lessons with the AIDA diabetes simulator.

- i. What is your relation to the patient? (parent, sibling, husband/wife, friend, other) _____
 - ii. How old is your diabetic relative? _____ years
 - iii. What is your degree of involvement in diabetes therapy?
(Grade your answer on a scale from 0 to 6, with 0 = *no involvement*; and 6 = *complete involvement*)
- 0 1 2 3 4 5 6
- iv. How long have you been coping with supporting someone with diabetes?
_____ days _____ months _____ years (please state number)
 - v. Did you know that your relative recently underwent a simulator-based training course? Yes No
 - vi. Did you observe any difference in his/her behavior before *versus* after? Yes No
 - vii. Does he/she seem more or less confident since the classes? More Less
 - viii. Does he/she seem more or less relaxed since the classes? More Less
 - ix. Do you think his/her degree of blood sugar control is improved or worsened?
 Improved Worsened

- x. Does your relative seem to take his/her BG self-monitoring more or less seriously?
 More Less
- xi. Do you think the lessons helped him/her? Yes No
- xii. Did he/she report his/her impressions? Yes No
- xiii. If yes, what did he/she think about the lessons? _____

- xiv. Did your relative obtain his/her own copy of the diabetes simulation program?
 Yes No
- xv. Did your relative show you the diabetes simulation program? Yes No
- xvi. How do you rank the usefulness of this program on a scale? (0 = *not relevant*; 6 = *extremely relevant*)
0 1 2 3 4 5 6
- xvii. Based on your own experience, do you think this program can help a relative to support someone with diabetes? (0 = *not at all*; 6 = *very much so*)
0 1 2 3 4 5 6
- xviii. Based on your own experience, do you think this program can help overcome the usual lack of information and the 'loneliness' of a diabetic subject? (0 = *not at all*; 6 = *very much so*)
0 1 2 3 4 5 6
- xix. Based on your own experience, do you think this program can help overcome the sense of 'despair' for not being able to help that the relative of a diabetic subject may sometimes feel at the start of the disease? (0 = *not at all*; 6 = *very much so*)
0 1 2 3 4 5 6
- xx. Would you yourself like to have a series of diabetes simulator lessons? Yes No

REFERENCES

1. Zimmet P, Alberti KG, Shaw J: Global and societal implications of the diabetes epidemic. *Nature* 2001;414:782-787.
2. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993;329:977-986.
3. Home PD: Diabetes and the number revolution. *Diabet Med* 1991;8:400-401.
4. Lehmann ED, ed. Special Issues: Application of Information Technology in Clinical Diabetes Care. *Med Inform* 1996;21:255-378, 1997;22:1-120.
5. Lehmann ED, Deutsch T: Application of computers in diabetes care—a review. *Med Inform* 1995;20:281-302, 303-329.
6. Lehmann ED: Preliminary experience with the Internet release of AIDA—an interactive educational diabetes simulator. *Comput Methods Programs Biomed* 1998;56:109-132.
7. Lehmann ED: Experience with the Internet release of AIDA v4—an interactive educational diabetes simulator. *Diabetes Technol Ther* 1999;1:41-54.
8. Lehmann ED: Interactive educational diabetes simulators: future possibilities. *Diabetes Nutr Metab* 1999;12:380-387.
9. Lehmann ED: Interactive educational simulators in diabetes care. *Med Inform* 1997;22:47-76.
10. Lehmann ED: Application of computers in clinical diabetes care. *Diabetes Nutr Metab* 1997;10:45-59.
11. Lehmann ED: Spontaneous comments from users of the AIDA interactive educational diabetes simulator. *Diabetes Educ* 2000;26:633-643.
12. Lehmann ED, Deutsch T, Broad D: AIDA: An Educational Simulator for Insulin Dosage and Dietary Adjustment in Diabetes. London: British Diabetic Association, 1997.
13. Lehmann ED, Deutsch T: A physiological model of glucose-insulin interaction in type I diabetes mellitus. *J Biomed Eng* 1992;14:235-242.
14. Berger M, Rodbard D: Computer simulation of plasma insulin and glucose dynamics after subcutaneous insulin injection. *Diabetes Care* 1989;12:725-736.
15. Tatti P, Lehmann ED: Utility of the AIDA diabetes simulator as an interactive educational teaching tool for general practitioners (primary care physicians). *Diabetes Technol Ther* 2001;3:133-140.
16. Tatti P, Lehmann ED: Use of the AIDA diabetes simulation software—www.2aida.org—as an interactive educational tool for teaching student nurses. *Diabetes Technol Ther* 2001;3:655-664.
17. Tatti P, Lehmann ED: Using the AIDA—www.2aida.org—diabetes simulator. Part 1: Recommended guidelines for health-carers planning to teach with the software. *Diabetes Technol Ther* 2002;4:401-414.
18. Lehmann ED: The freeware AIDA interactive educational diabetes simulator—<http://www.2aida.org>—

- (1) A download survey for AIDA v4.0. *Med Sci Monit* 2001;7:504-515.
19. Lehmann ED, Deutsch T: AIDA: an automated insulin dosage advisor. In: Frisse ME, ed. SCAMC Proceedings, 16th Annual Symposium on Computer Applications in Medical Care. New York: IEEE Computer Society Press, 1992:818-819.
 20. Lehmann ED, Deutsch T: AIDA²: a Mk. II automated insulin dosage advisor. *J Biomed Eng* 1993;15:201-211.
 21. Lehmann ED, Hermanyi I, Deutsch T: Retrospective validation of a physiological model of glucose-insulin interaction in type 1 diabetes mellitus. *Med Eng Phys* 1994;16:193-202. [Published erratum appears in *Med Eng Phys* 1994;16:351-352.]
 22. Lehmann ED, Deutsch T: Computer assisted diabetes care: a 6 year retrospective. *Comput Methods Programs Biomed* 1996;50:209-230.
 23. Lehmann ED, Deutsch T: Compartmental models for glycaemic prediction and decision-support in clinical diabetes care: promise and reality. *Comput Methods Programs Biomed* 1998;56:193-204.
 24. Lehmann ED, Deutsch T. An interactive, educational model for insulin dosage and dietary adjustment in type I diabetes mellitus. In: Frisse ME, ed. SCAMC Proceedings, 16th Annual Symposium on Computer Applications in Medical Care. New York: IEEE Computer Society Press, 1992:205-209.
 25. Lehmann ED: Further user comments regarding usage of an interactive educational diabetes simulator (AIDA). *Diabetes Technol Ther* 2002;4:121-135.
 26. Tatti P, Lehmann ED: A randomised-controlled clinical trial methodology for evaluating the teaching utility of interactive educational diabetes simulators. *Diabetes Nutr Metab* 2001;14:1-17.
 27. Lehmann ED, Tatti P: Questionnaires for a randomized controlled trial methodology to evaluate the teaching utility of diabetes simulation programs. *Diabetes Technol Ther* 2001;3:293-305.
 28. Tatti P, Lehmann ED: Preliminary results from a randomised controlled clinical trial for evaluating the teaching utility of an interactive educational diabetes simulator (AIDA) [abstract]. *Diabetes* 2001;50(Suppl 2):A25.
 29. Tatti P, Lehmann ED: A prospective randomised-controlled pilot study for evaluating the teaching utility of interactive educational diabetes simulators. *Diabetes Nutr Metab* 2002;15:in press.
 30. Lehmann ED, Tatti P: Randomised controlled trial design for simulator use in diabetes education: some issues for consideration [letter]. *Diabetes Technol Ther* 2002;4:258-269.

Address reprint requests to:

*Dr. Eldon D. Lehmann
Academic Department of Radiology
St. Bartholomew's Hospital
London, EC1A 7BE, U.K.*

E-mail: info-www@2aida.org

Web: www.2aida.org/lehmann