Computerised Decision-Support Tools in Diabetes Care: Hurdles to Implementation

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ABSTRACT

In this Diabetes Information Technology & WebWatch column hurdles to the use of computerised decision-support tools in clinical diabetes care will be considered. The clinical background with respect to insulin-dependent (type 1) diabetes mellitus and the Diabetes Control and Complications Trial is reviewed, and an overview is given of various computer applications. The use of decision-support tools is discussed, and the importance of identifying the proposed user, e.g., health-care professional, student, or patient, is highlighted. Validation/evaluation issues are considered as important topics that remain to be properly addressed for many decision-support prototypes. The column concludes by highlighting that in this era of evidence-based medicine well-conducted, rigorous evaluation and validation studies are required to inform decisions about whether or not to make use of current computerised decision-support prototypes.

CLINICAL BACKGROUND—THE DCCT

The Diabetes Control and Complications Trial (DCCT)\(^1\) has demonstrated conclusively that control matters in patients with insulin-dependent (type 1) diabetes mellitus (IDDM). The downside of intensive insulin therapy in the DCCT was a threefold increase in the frequency of severe hypoglycaemia (requiring another person to provide treatment to rectify the episode) and an average weight gain 5 years into the study of 4.6 kg, compared with the conventional therapy group. The trial also revealed that any reduction in blood glucose (BG) levels was accompanied by an increase in the risk of hypoglycaemia.

Despite the many advances that have been made in diabetes therapy in recent years, hypoglycaemia still remains an important limiting factor in the intensive management of patients with IDDM.\(^2\) Furthermore, for many patients with diabetes the risks of going “hypo” far outweigh many other considerations.

In this respect, it is well recognised that not all patients with diabetes will be suitable for (or will want) intensive insulin therapy, and that patient-specific BG targets need to be set based on an individual assessment of overall benefit.
and risk. This risk–benefit balance may be altered when complications are already advanced,\(^3\) in the young, potentially neurodevelopmentally at risk from hypoglycaemia,\(^2\) or in the elderly with additional pathologies.\(^4\)

However, diabetologists are now faced with a conundrum—intensive insulin therapy clearly reduces the risks of later life complications but increases patients' chances of going "hypo." Following publication of the main DCCT results,\(^1\) the American Diabetes Association (ADA) recommended that a primary treatment objective for patients with IDDM should be glycaemic control at least equal to that achieved in the intensively treated cohort of the DCCT.\(^5\) How can clinicians in routine practice be expected to accomplish this?

The resources needed to ensure really tight glycaemic control in the DCCT were enormous. Specialist staff were recruited to maintain contact with patients who were often seen fortnightly in hospital, and contacted even more frequently by telephone during the day as well as at night. Efforts were redoubled at times of minor illness or emotional upset. Team meetings took place weekly to maintain these standards.\(^6\)

While it may not normally be possible to see or contact patients this frequently, one way of ensuring better care for motivated patients with IDDM—and perhaps to achieve the goals demonstrated by the DCCT in routine clinical practice—may well be through the application of information technology (IT). In this Diabetes Information Technology & WebWatch column various issues related to the application of IT—and in particular decision-support tools—in clinical diabetes care will be discussed, and hurdles to implementation considered.

### COMPUTER APPLICATIONS—BACKGROUND

There has been in recent years increasing interest in the development of prototype computer systems to assist in a number of different areas of diabetes care. Figure 1 summarises the spectrum of IT applications—the acceptance scale indicating how widely such approaches have been adopted into routine clinical practice. For example, BG meters (either with or without electronic memories) are well-accepted tools. By contrast, at the other end of the spectrum, computerised decision-support is not at all widely used, at present.\(^7\)

The approaches applied to date can be broadly summarised: (a) as computerised out-
patient clinic databases that store patient clinical and biochemical data—in some cases also providing the physician with management advice; (b) as statistical and graphical analysis programs that help the clinician, diabetes educator, and/or patient detect patterns and trends in the patient’s home monitoring BG readings; (c) as dietary analysis programs that examine food composition and dietary exchanges and help devise meal plans; (d) as handheld insulin dosage adjustment computers that advise patients on a day-by-day or even meal-by-meal basis; (e) as simulators that allow patients to practice and gain experience with insulin dosage, dietary, exercise, and lifestyle adjustments—without actually exposing themselves to the risks of hypoglycaemia; (f) as expert systems and question and answer programs for patient education; (g) as integrated simulation and knowledge-based systems intended for possible therapeutic use; (h) as games for children with diabetes; and (i) as telemedicine or Internet/Web-based resources. Many of these approaches have been reviewed elsewhere. In this column attention will be focussed on the role of decision-support applications.

**DECISION-SUPPORT TOOLS**

The DCCT results, showing the significant benefits of tight glycaemic control in patients with IDDM, have increased interest in the utilisation of computer-based decision-support tools to assist in the transfer of diabetes-related knowledge from specialist hospital-based secondary and tertiary referral centres to primary care, as well as possibly directly to patients.

From the computing perspective both longer-term (basal) visit-by-visit therapy adjustments and shorter-term dose-by-dose insulin dosage adjustment strategies can be considered. A whole plethora of computational approaches have been tried. These have included rule-based approaches, algorithms, causal nets, neural nets, time series approaches, adaptive control, and fuzzy logic.

Academically and intellectually, up to now, diabetes has attracted a great deal of interest from computer scientists as a worthwhile area of medical informatics research. This interest has been fuelled by the relatively quantitative nature of diabetes care, which provides an unusually data-rich field within medicine. This makes the problem of how to improve glycaemic control amenable to a whole range of computational methodologies—which in itself can be intellectually rewarding for computer scientists—although to date perhaps not necessarily so rewarding for patients. Furthermore, “artificial intelligence” is in itself an appealing goal—all the more interesting if it might offer some medical benefit.

However, to reap the potential benefits that computers may have to offer in this field, we need to steer a rational course between informaticians’ enthusiasm and many clinicians’ widespread scepticism for such prototype decision-support applications. It is also necessary to recognise that insulin-dosage adjustment is only one component of the diabetes management “problem” and that while this particular component may be amenable to modern day IT techniques, many other aspects of diabetes care, such as patient motivation or compliance, may in the long term be of equal if not greater importance.

For instance, it may be argued that other relatively simple things can be done to improve standards of patient care, e.g., ensuring that patients actually measure their BG values, and take off their shoes and socks before coming into the consulting room (so their feet are checked). Such “low tech” things should not be forgotten in the rush to adopt novel technologies. However, an equally convincing case could also be made for proposing that patients might actually be encouraged to measure their BG more often if greater use was made of the data they collect. Similarly, computer prompts could offer a means to help ensure that relevant clinical checks were performed at clinic visits.

A commonly posed question is: “Can computers really advise what insulin injections to give?” The importance of knowing the proposed users, and knowing their real needs, cannot be overemphasised. The answer very much depends on for whom the system is being developed. The literature is full of novel computational prototypes that have been tried to gen-
erate insulin-dosage adjustment advice, but with limited success.\textsuperscript{9–18} Many earlier decision-support prototypes in the diabetes field appear to have addressed system developers’ perceptions of users’ needs more than the actual requirements of users.

For example, for clinicians there is little perceived need for a computer system to offer short-term insulin-dosage adjustment advice. Rather, if such tools are going to be developed they need to be offered to patients directly. By contrast, if computer systems are being built to transfer expertise and knowledge from diabetes specialist centres to less specialised settings and primary care—then necessarily there is a need for more general, longer-term advice to be given.

Decision-support prototypes for therapy planning in the past used to comprise either desk-top programs for use by non-expert primary care physicians who had to manage patients with IDDM away from specialist centres,\textsuperscript{19} or handheld devices for patients themselves to use.\textsuperscript{20} The former gave longer-term advice, whereas the latter offered short-term insulin dosage adjustment suggestions. More recently telemedicine-based systems, which use a telephone and the public telephone network, have been described.\textsuperscript{21–23} Also, the growth of the Internet, the World Wide Web, and mobile telephony has increased interest in the use of this medium for communication.\textsuperscript{24,25} Furthermore, with technological advances leading to miniaturisation, handheld computers are becoming more and more powerful and are increasingly being applied as mobile prototype computer platforms.\textsuperscript{26}

\textbf{Physician use}

One suggestion has been that until computer applications for clinicians are able to deal with complicated patients with “hypos” and poor compliance they are unlikely to help busy diabetologists in routine clinical practice. In the foreseeable future it is highly improbable that computers will be able to deal with such complex patients. Given that computers have not yet become widely accepted as advisors in medicine—it would be wrong to expect them to manage complicated patients any “better” than clinicians.\textsuperscript{27} Also, defining the “best” or even the “optimum” treatment is not a particularly straightforward task. This will vary from patient to patient and also depend on the inherent risks of hypoglycaemia that may result from an attempt to improve glycaemic control. For example, a preprandial BG of 250 mg/dL (13.9 mmol/L) may be perfectly acceptable for an 87-year-old man with IDDM living on his own, whereas for a 17-year-old patient recently diagnosed with diabetes attempts would be made to tighten glycaemic control.

Notwithstanding these issues, it is possible that semi-“intelligent” computer applications, including visit-by-visit insulin dosage adjustment, perhaps with the assistance of structured checklists, may well be able to help less experienced health-care workers deal with some of the “routine” patients seen in many primary care physicians’ offices (general practices) and diabetes clinics. The use of such applications might permit more highly trained staff to spend more time focusing on patients with poorer glycaemic control who we know from the DCCT are at greater risk of later life complications.

\textbf{Patient use}

An alternative way to support primary care physicians might be to provide selected patients with a handheld device to advise them directly on how to make insulin-dosage, dietary, and lifestyle adjustments on a meal-by-meal or day-by-day basis. However, to date the prototype handheld devices described in the literature\textsuperscript{28,29} have only received limited acceptance. Furthermore, they have not been able to explain their reasoning. In this age of medical-legal considerations\textsuperscript{30} it could be argued that the decision-making process really needs to be challengeable\textsuperscript{31} by both patients and physicians alike.

However, perhaps now the time is right for such attempts at computer-generated advice for patients. While earlier approaches, for example, one marketed as a “Pocket Doctor,” may have been viewed by some as a replacement for the physician—in the post-DCCT era it will now be apparent that physicians and other health-care professionals simply do not
have enough time or resources to devote to the provision of such intensive insulin therapy, much as they would like to. If computer/IT techniques can be provided to assist in this role, there is certainly a clinical need waiting to be filled.

A partnership approach

In business and industry, computerisation, in its early days, was in part viewed as a threat to jobs. In medicine this should not be allowed to be the case. Some may fear that computers might detract from the autonomy of the clinician—possibly making the clinician’s role superfluous. This is unlikely to happen. The discussion is not about replacing clinicians—but rather supplementing their input as resources and facilities are simply not in place at present to provide the benefits of the DCCT to the majority of patients with IDDM.

It might be considered that such an approach could lead to problems if patients with their device felt more knowledgeable or competent about controlling their diabetes than their primary care physician. However, this is no different from a patient who receives secondary or tertiary care from a hospital specialist, but who still remains under the joint care of a primary care physician (general practitioner).

Furthermore, it should be recognised that doctors and patients will always need to work together in partnership both with each other, as well as with dieticians, educators, nurses, and other health-care professionals. Given this, any techniques that might be able to help health-care professionals and patients optimise insulin therapy—at a reasonable cost—are likely to have great clinical utility. Advanced IT techniques may well be able to fulfil this role and therefore—rather than being perceived as any sort of threat—should be clearly embraced as another useful tool to be applied to improve current standards of patient care.

Evaluation issues

However, before we can get too excited by such approaches there is a very great onus on computer programmers and system developers to provide validation studies demonstrating reliability and safety, and randomised controlled clinical trials demonstrating efficacy. Such studies of clinical efficacy need to show in a large enough sample of subjects that a doctor, nurse, or patient with a decision-support tool can achieve tighter glycaemic control (with lower BG and haemoglobin A1c levels, without more “hypos”) than a doctor, nurse, or patient alone.

While many prototypes have been developed as advisory tools to assist in insulin-dosage adjustment, not enough time and resources have been devoted to the evaluation of such work. Furthermore, the resources required for this have often been underestimated—and the lack of validation/evaluation studies remains one of the main hurdles to the broad acceptance of such IT-based techniques.

Validation studies are time consuming and tedious to perform. However, to convince clinicians of the utility of an IT-based approach—such studies are imperative. Furthermore, computer systems are needed that can explain their reasoning in a clear manner, for both patients and doctors.

In this respect evaluation should be an essential and integral part of any computer program’s development. It helps programmers identify deficiencies in their software, thereby permitting modifications and improvements to be made, as well as also assisting in assuring end users of the quality and safety of the finished work. Any strategy for the evaluation of decision-support systems ideally needs to comprise at least four different levels of analysis: verification, validation, human factors assessment, and clinical assessment. While these distinct components can be identified, it is necessary for these to form an integral part of the software development process. Figure 2 shows one way in which such evaluation can ideally be tightly coupled with the actual development cycle of a decision-support system.

DISCUSSION

During many years spent doing research in the diabetes computing field a number of recurring themes have emerged, and become clearer over time.

It is vitally important to establish early on in
a software program's development for what sort of end user the program is intended. Apart from a common problem that the vast majority of prototypes do not work—clinically—an important issue remains as to who might actually make use of such decision-support software.

A conundrum that has not really been addressed is that most diabetes health-care professionals do not really need a computer program to advise them as to what insulin dosages their patients should take. Primary care physicians (general practitioners) in the community might find such a program of use—but for the most part probably will not see or have enough patients with diabetes to maybe make such a system so viable for general practitioner use alone. People with diabetes (and their relatives) would surely love to have access to a computer program or personal organiser that could offer advice about what insulin doses to inject, but such standalone use of a program by patients—without reference to a health-carer—is the sort of thing that gives health-care professionals cause for concern, because of issues over patient safety. Also, such standalone use of a decision-support tool by patients is usually the very situation that can be the most taxing to validate and of course the situation that raises the greatest issues over responsibility. For instance, who would actually be medically and legally accountable for the advice issued by such a computerised insulin-dosage advisor?

In addition to this, there are all the issues of remuneration and reimbursement—will insurance companies and managed care plans reimburse patients for the costs of purchasing/leasing/using such devices?

The answers to many of these questions lie in rigorous and comprehensive validation and clinical evaluation studies. However, at present very few prototypes have been rigorously tested in a bench or lab setting, or objectively evaluated in clinical randomised controlled trials.

In this respect, the basic tenets of evidence-based medicine must not desert us in the rush to computerisation. In this era of evidence-based medicine, decision-support prototypes, like any other approach intended for patient management, should be subjected to the scrutiny of independent, well-conducted evaluation studies. Without proper validation studies the potential for the application of IT techniques to improve glycaemic control in patients with IDDM remains unproven—more a hope for the future rather than a reality.
FURTHER TOPICS

If you would like to suggest further topics or Websites for future “Diabetes Information Technology & WebWatch” columns, please e-mail 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.

REFERENCES


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