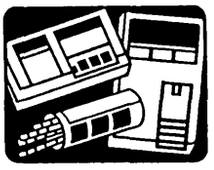
Technical Section



Personal Computer Programs to Assist with Self-Monitoring of Blood Glucose and Self-Adjustment of Insulin Dosage

NAT L. PERNICK, M.D., AND DAVID RODBARD, M.D.

We have developed computer programs in compiled BASIC for the IBM-PC and compatible microcomputers for use by physicians, paramedical personnel, and/or patients to assist with self-monitoring of blood glucose (SMBG) and self-adjustment of insulin dosage. The programs can potentially assist with patient education and motivation, and provide: (1) a customized "electronic notebook" for storage and retrieval of information on blood glucose, insulin dosage, hypoglycemic reactions, urinary ketones, diet, activity, weight, illness, apparent explanations for hypoglycemic reactions or glucose values outside target ranges, and comments; (2) graphic displays of glucose and insulin versus date, and of a "glucose profile" versus time of day or versus day of the week; (3) simple and detailed statistical analyses; (4) a legible summary of data; (5) a facility to permit the physician to prepare a "customized treatment plan" for each patient, involving a choice of six regimens, target levels for each of eight time periods, four supplement tables (when well or sick, before meals, or at bedtime), rules to reduce insulin in response to hypoglycemic reactions or documented hypoglycemia, rules to increase routine insulin doses in response to persistent unexplained hyperglycemia, and rules when the patient should call the physician; (6) suggestions regarding compensatory supplements and adjustments of routine insulin dosage; (7) explanations why various insulin dosages should or should not be altered, and why various glucose values should be tested; (8) comparisons of the insulin dosage administered by the patient and the recommendations of the program, together with explanations for discrepancies offered by the patient, to help evaluate compliance. The program is "user-friendly," easy to learn, and easy to use. A detailed plan for introduction of the program to the patient has been developed. Use of the program is flexible: it could be used several times a day (when monitoring glucose and adjusting insulin dosage), once a day (e.g., to enter the day's data and obtain suggestions for the following day), once every week or two (for data storage, evaluation of the recent degree of control, and analysis of patterns in the daily glucose profile), or once every 1–3 mo (before office visits, to prepare summaries, graphs, statistical analyses, and for retrospective comparison of patient's decisions with the program's recommendations). The advantages and limitations of the present program, approach, and design philosophy are discussed.
DIABETES CARE 1986; 9:61–69.

We have developed a set of microcomputer programs for patients with diabetes mellitus and their physicians to assist with self-monitoring of blood glucose (SMBG) and intensive insulin therapy or continuous subcutaneous insulin infusion (CSII) with or without self-adjustment of insulin dosage. The programs provide a convenient means of data collection, display, and analysis; suggestions about insulin dosage based on an individually customized algorithm; and explanations of the logic used in adjusting insulin dosage.

The programs, which represent a complete revision and considerable extension of our previous efforts,[1,2] are available in compiled BASIC for the IBM-PC or compatible personal computers. They require 128K of memory, a printer (to obtain a permanent copy of reports), and capabilities for display of high-resolution graphs on a graphics monitor or on the printer.

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One floppy disk holds the programs and data for one patient for several months. Machines with a standard (10 Mbyte) hard disk configuration can store data for 99 patients.

The programs, detailed user guides, instructions, and a reference manual are available to physicians on request. The programs have been designed for use by persons with minimal experience with the computer: one can, in principle, simply turn on the machine and be guided continuously by the program.

MATERIALS AND METHODS

Programs were developed using the IBM-PC, -XT, and PCjr models, and on the Compaq-Plus. They also operate on the AT&T personal computer (PC 6300) and on compatible machines produced by other manufacturers. PC-DOS 2.0, COMPAQ-DOS 2.02, and MS-DOS 2.02 were used as the operating systems. 128K RAM are required. A dot-matrix (or similar) printer is highly desirable to obtain permanent copies of summaries, graphs, statistical analyses, and interpretation.

Programs were first developed in interpreted BASIC, using the Basic Development System (SofTool Systems, Denver, Colorado) and compiled using the IBM BASIC Compiler. For models equipped with a 10-Mbyte hard disk, it is possible to store data for up to 99 patients. Alternatively, a separate double-sided, double-density 5.25-in. flexible (floppy) disk (360K bytes) holds the program and data for several months for each patient.

The file structure is as follows: a master file indicates the total number of patients and the active patient. A "parameter" file holds more than 100 parameters (e.g., target ranges, insulin regimen, and four separate supplement tables) selected by the physician to specify the customized treatment plan for each patient. These parameters are used by the program segment, which gives suggestions and explanations, and prints out the "prescription." The "patient data file" holds the patient identification data and program data for 4 mo. The data include the date most recently used, insulins, glucoses (and any apparent explanations for values outside the target ranges), hypoglycemic reactions (and explanations), illness, comments, weight, insulin doses recommended by the computer, and user-supplied reasons for discrepancies between actual insulin dosage and the values recommended by the computer.

TABLE 1
Features of the diabetes data management program

1. Educational
   (a) Printout of customized treatment plan
   (b) Distinction between routine and supplemental insulin
   (c) Concept of "negative" supplements in response to hypoglycemia
   (d) Advice (suggestions) about glucoses to check
   (e) Suggestions about insulin dosage (increases or decreases, supplements, or routine)
   (f) Recommendations when to call physician
   (g) Explanations for suggestions re glucoses to check, insulin doses
   (h) Comparisons of patient's actual insulin dosage with program's suggestions
   (i) Educational messages
   (j) For physician: a systematic approach to setting up customized treatment plan for each patient
2. Motivational: use of data in a timely manner
3. User friendly: easy to learn, easy to use, previous experience with a computer not required
4. Worksheets to facilitate data entry and minimize transcription errors
5. Menu driven
6. Use of special function keys to facilitate data entry
7. Data entry for insulin doses, glucose values, hypoglycemic reactions, ketones, illness, weight, comments
8. High-resolution graphics: insulin, glucose, glucose profile, pattern analysis
9. For use by physician, paramedical personnel, or patient
10. Physician can customize treatment goals and algorithms by modifying any one of several stock prescriptions
11. Both a simple and advanced version: physician can deactivate suggestion feature
12. Detailed interpretation of daily glucose profile
13. Graphic and statistical analyses by day of week
14. Detailed documentation and instructions

```
Diabetes Programs Version 85.1
Main Menu for

 1. DAILY ENTRY & Suggestions & Explanations

 2. Data Summary
 3. Suggestions for several days
 4. Comparison Report
 5. Graphs
 6. Worksheets
 7. Print computerized prescription

 8. Other Options
 9. Change from Advanced to Simple features

Enter option ( 1 - 9  or  RETURN to end )
```

FIG. 1. Main menu.

RESULTS

Program features. The program provides several user convenience features (Table 1).

(1) Simply inserting the disk and turning on the computer will automatically start the program.

(2) "Menus" of options are provided and the user simply enters a number to make selections (Figure 1).

(3) The 10 special function keys are used to facilitate rapid selection of options for data entry.

(4) For speed and accuracy, the routine insulin values from each day will be assumed to carry over to the next day unless otherwise indicated by the user. However, the program does not assume that the user has accepted the previous suggestions of the program and supplementary insulin doses do not carry over to the following day.

(5) Insulin values can be entered only for the times of day and types prescribed by the physician (Figure 2).

(6) The program automatically skips over glucose values that are not customarily checked, although these values can be entered when available.

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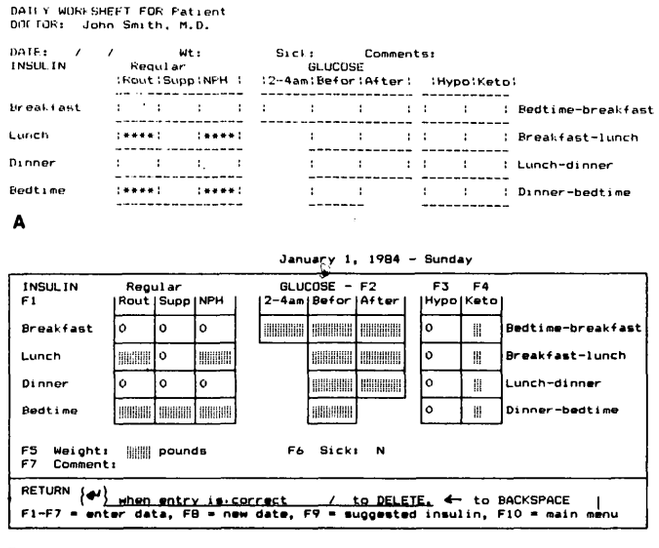

FIG. 2. (A) Worksheet for data entry. (B) Data entry screens. Identical format for both reduces the likelihood of transcriptional errors.

(7) We have attempted to minimize the number of keystrokes for data entry.

(8) Values are displayed on the screen as they are entered. The user can detect errors and make corrections immediately, using the backspace key. In one mode, data are accepted and saved only after the user presses the "Enter" key. Alternatively, the values can be accepted immediately by the program. Data are saved as soon as they are entered so that data will not be "lost" if program execution terminates inappropriately.

(9) The user is given a warning whenever a requested function would lead to loss of data or entail significant delay (e.g., to load other programs).

(10) Program segments for use by physicians only are protected by password. Alternatively, they can be removed from the disk given to a patient.

(11) Since most users are not in the habit of recording each food ingested or a count of food exchanges, we have devised a simple single-digit code for each meal and snack, rating each meal from 0 to 5 (3 = normal or customary value).

(12) A single-digit code (0–5, with 2 = customary) was also used to record morning, afternoon, evening, and nighttime activity.

(13) Scattergram of glucoses by time of day (glucose profile) is shown in Figure 3. The program will show each glucose value versus time of day. We have also provided an option to display a bar graph showing the lowest and highest values, and the 25th, 50th, and 75th percentiles. The median ±1 SE is shown when there are more than 10 observations.

(14) Detailed written interpretation of the glucose profile.

(15) A simplified version is provided for use by beginners to facilitate introduction to the program.

Data entry. Data entry is facilitated by using worksheets that closely resemble the data entry screen (Figure 2). Data entered includes routine and supplemental insulin doses, glucose values, and, if desired, hypoglycemic reactions and urine ketones, weight, illness, and comments (Figure 2). The user can indicate whether there was any obvious explanation (e.g., Diet, Insulin, Activity, Stress, Other, or None) for abnormal glucose values, urine ketones, or hypoglycemic reactions. Typically, it requires 30 minutes to enter data for 1 month, i.e., only about 1 minute per day.

Modes of use. The programs are designed for two principal modes of use. The first is the patient entering data every day and printing the computer's suggested insulin doses for the next 24 h. The second is entering data for several days at a time and printing the suggestions for several days. The latter method might be used initially to verify that the computer's suggestions are acceptable to the physician.

The program also displays suggested "glucoses to check" and can provide an explanation for all its recommendations. For supplements, the glucose value and its location in the correct supplement table are displayed. For routine insulins, the suggested dose calculation, as well as the criteria for hypoglycemia and hyperglycemia can be displayed. The explanations can show the specific criteria used next to the actual input data. Each of these criteria has been selected or specified by the physician (Table 2).

The user can compare the computer's suggested insulin doses with the actual doses taken, and indicate possible reasons for any discrepancy. A numerical code for this explanation appears on a comparison report, which displays all actual insulin doses that differ from the suggested dose by more than a specified number of units.

Graphic and statistical analyses. Other reports include a data summary with averages of glucose values and insulin doses, graphs, and statistics (Table 3). Graphs include glucose at selected times of day or mean daily glucose versus date (or day of the week), insulin doses by date, and a glucose profile by time of day or day of the week (Figure 3).

Glucose profile interpretation. The program can provide a detailed interpretation of the daily glucose profile for data from any selected range of dates. This includes an evaluation of the overall level of control, frequency, severity, and timing of hypoglycemia or hyperglycemia, and an analysis of patterns (e.g., magnitude of postprandial rises), variability, and adequacy of sampling followed by a prioritizing of problems. This program will evaluate: (1) whether preprandial values are similar, (2) whether postprandial values are similar, (3) the average rise in glucose after a meal, (4) whether there is a consistent trend throughout the day (or night), (5) whether there are two consecutive times of day that are out of range, (6) which routine insulins need to be adjusted (upward or downward) based on the long-term (2–3 wk) averages rather than on the basis of the past 2–3 days.

Logic and algorithms for adjustment of insulin. Our approach was to generalize the algorithms of Skyler[3–6] and others[6–9] into a "customized algorithm" or "computerized prescription" that the physician specifies. Each day is divided into four time periods (overnight, morning, afternoon, and evening) and

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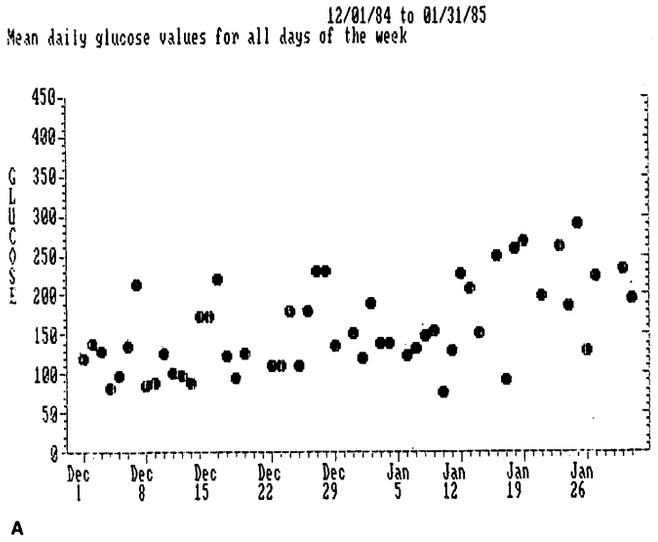

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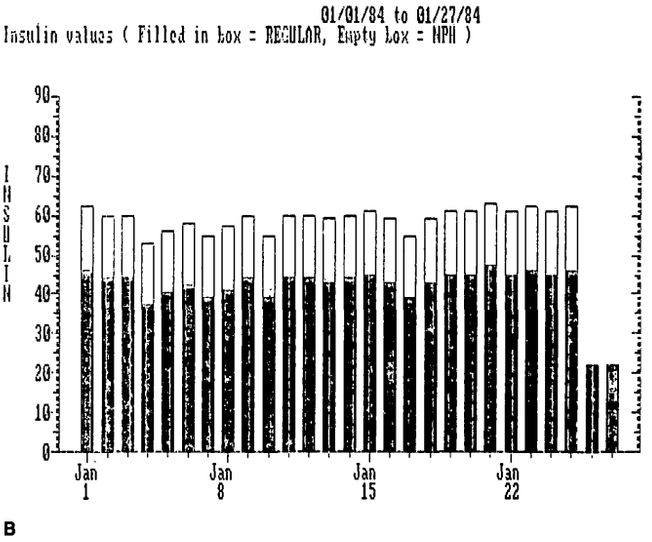

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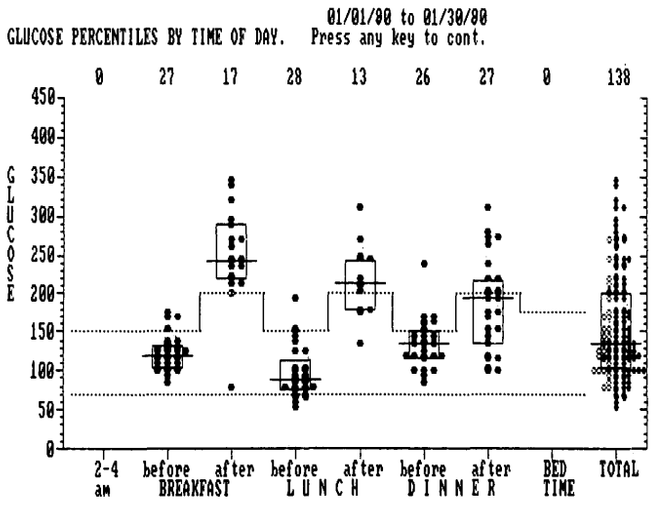

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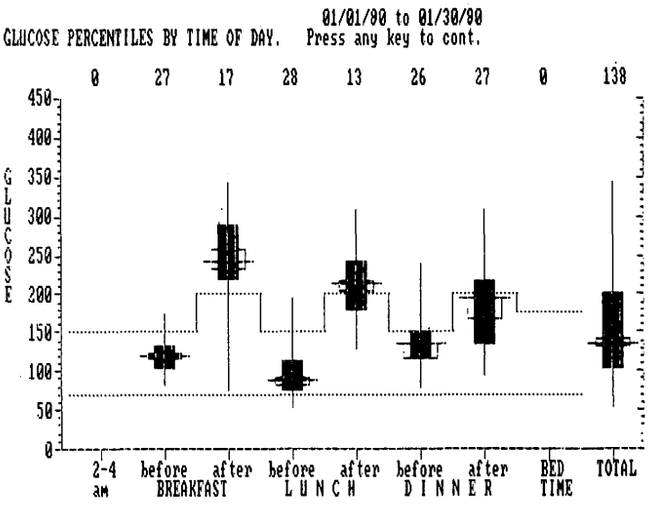

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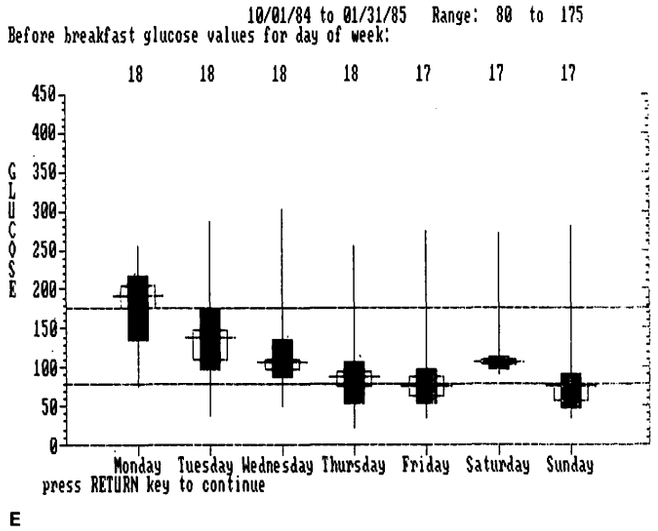

E

FIG. 3. Graphic displays. (A) Mean daily glucose versus date. (B) Insulin versus date, distinguishing short- and intermediate-acting insulin. (C) Daily glucose profile (by time of day), as scattergram superimposed on target range. (D) Daily glucose profile (as bar chart), showing range, median ± 1SE, and 25th and 75th percentiles. Heavy bar shows region containing 50% of the observations. (E) Glucose (as bar chart) by day of week.

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TABLE 2
Customized algorithm or computerized prescription

I. Physician:
Regimen: REGULAR and **NPH** at breakfast, **REGULAR** at dinner, **NPH** at bedtime. Insulin suggestions are available.

II. TARGET GLUCOSE LEVELS:

2–4 AM	95 to 150
before breakfast	80 to 175
after breakfast	80 to 200
before lunch	80 to 175
after lunch	80 to 200
before dinner	80 to 175
after dinner	80 to 225
bedtime	80 to 175

III. CALL THE DOCTOR IF:
glucose is Below 30
glucose is Above 400
glucose is Above 350 with medium ketones
4 hypoglycemic reactions in 7 days
2 nighttime hypoglycemic reactions in last 7 days
Sick 2 days in a row

IV. SUPPLEMENT TABLES

WELL - BEFORE MEALS		WELL - BEDTIME		SICK - BEFORE MEALS		SICK - BEDTIME	
Glucose	Supp.	Glucose	Supp.	Glucose	Supp.	Glucose	Supp.
below 69	−1	below 69	−1	below 109	0	SAME	
70 to 110	0	70 to 110	0	110 to 150	1		
111 to 150	1	111 to 150	1	151 to 200	2		
151 to 200	2	151 to 200	2	201 to 250	3		
201 to 300	3	201 to 300	3	251 to 300	4		
above 301	5	above 301	4	301 to 350	6		
				above 351	8		

V. CHANGES in ROUTINE INSULIN if UNEXPLAINED HYPOGLYCEMIA:
If unexplained hypoglycemia (low blood sugar) in the:

night-time	- REDUCE BEDTIME-NPH by 1 unit.
morning	- REDUCE BEFORE-BREAKFAST-REGULAR by 1 unit.
afternoon	- REDUCE BEFORE BREAKFAST-NPH by 1 unit.
evening	- REDUCE BEFORE DINNER-REGULAR by 1 unit.

VI. CHANGES in ROUTINE INSULIN if PERSISTENT UNEXPLAINED HYPERGLYCEMIA:
If all 3 conditions (1–3) are met, then follow the instructions (below) for the appropriate time of day.
1. Hyperglycemia is not due to obvious changes in meals, stress, illness, etc.
2. Do not change more than one type of routine insulin every 4 days.
3. NO Hypoglycemia reaction(s) in the past few days.

If hyperglycemic BEFORE BREAKFAST:
If 3 of the last 4 before breakfast glucose values, including the last one, were greater than 175 and unexplained, and if at least 1 of the last 4 2–4 am glucoses were checked and not less than 125, Then increase the BEDTIME NPH insulin by 2 units.

If hyperglycemic BEFORE LUNCH:
If 2 of the last 3 before lunch glucose values, including the last one, were greater than 175 and unexplained, and if at least 1 of the last 3 after breakfast glucoses were checked and not less than 110, Then increase the BEFORE BREAKFAST REGULAR insulin by 1 unit.

If hyperglycemic BEFORE DINNER:
If all of the last 3 before dinner glucose values, were greater than 175 and unexplained, Then increase the BEFORE BREAKFAST NPH insulin by 2 units.

If hyperglycemic BED TIME:
If 3 of the last 5 bedtime glucose values, including the last one, were greater than 175 and unexplained, then increase the BEFORE DINNER REGULAR insulin by 1 unit.

each period has two possible blood glucoses (2:00 to 4:00 a.m. and before breakfast, after breakfast and before lunch, after lunch and before dinner, after dinner and bedtime, respectively).

According to the principles underlying Intensive Insulin Therapy,[3–9] we adopt the important simplification that for each of the regimens, each type of insulin controls glucose at two different time points (e.g., before-breakfast short-acting insulin controls the after-breakfast and before-lunch glucoses for all regimens). Furthermore, we assume that any given glucose value is controlled primarily by only one kind of insulin for any of the six regimens. For example, the before-bedtime glucose is regarded as principally dependent on the before-dinner short-acting insulin for all regimens. Routine insulin is held relatively constant from day to day, while compensatory supplements of short-acting insulin are adjusted immediately in response to premeal or bedtime glucose values.

Customizing the algorithms. For each patient, the physician is guided through a program that sets up the computerized prescription or customized algorithm (Table 2). "Prescriptions" can be copied from one patient to another or from a series of standard or "stock" prescriptions. The physician spec-

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ifies the increments for insulin dosage. It is essential that the physician examine the prescription before the other programs are used to ensure that it reflects the desired treatment goals and strategy. Some of the values that must be entered by the physician are as follows: (1) Regimen—six are offered, corresponding to the four of Schade et al.,[6] with minor modification. (2) The suggestion feature can be "turned off" so the patient cannot obtain the suggested insulin doses. If "turned off," the programs can still be used for data collection, summaries, graphic and statistical analyses, and written "interpretation." (3) Supplement tables—these tables are used as the basis of suggestions for compensatory supplements of insulin before meals or at bedtime. Bedtime supplements may or may not be allowed when the patient is sick or well. (4) Hypoglycemia—in the event of an unexplained hypoglycemic reaction, the program will recommend an immediate reduction in the appropriate routine insulin and an immediate "negative" supplement. If hypoglycemia is severe or frequent (especially at night), the program will advise the patient to call the physician. (5) Hyperglycemia—since each routine insulin dose is assumed to influence glucose values at two times of day, the physician can specify how many elevations of each of the two types of glucose values are needed to recommend that the insulin be increased. For example, in regimen 1, the before-dinner NPH (or lente) insulin affects both the 2:00–4:00 a.m. glucose and the before-breakfast glucose. The physician might require that at least four before-breakfast glucoses must be elevated without a clearly explainable and preventable cause over a 5-day period and that at least one 2:00–4:00 a.m. glucose must have been checked and found not to be low. The physician also specifies the minimum number of days after an adjustment of routine insulin dosage before another increase of routine insulin will be permitted.

DISCUSSION

Design goals and philosophy of a program such as this require many compromises between cost, speed and performance, portability, computational power, simplicity, and complexity. No single computer program can be expected to appeal to all patients or physicians. Several groups[10–14] have attempted to develop small, inexpensive portable hand-held devices. These devices have a "reminder" value, much like a wristwatch with four alarms per day. For example, one device essentially requires the user to test glucose four times per day.[12] We will discuss the pros and cons of the present approach, as contrasted with these smaller portable systems. Advantages of the present approach include the following:

1. *General applicability.* We provide six regimens, with a flexible treatment plan that can be customized to the individual patient.
2. *Memory.* The disk file holds data for several months.
3. *Data analysis.* This program provides graphic and statistical analyses,[15] which are not possible on the small, portable devices with current technology.
4. *Suggestions.* Detailed and explicit recommendations regarding supplemental and routine insulin dosage.
5. *Explanations.* All recommendations by the program can be traced back to the original data. This provides an objective basis to help the user understand the basis for the recommendation, or detect errors in data entry.
6. *Comparisons.* The program produces a report of compliance.
7. *Flexibility of algorithms.* Consultation programs should be sufficiently flexible that the physician can "tell it what to do," and not vice-versa. We have attempted to do this using the "computerized prescription" or "customized algorithm." This requires the physician to be very explicit in his instructions. We have developed several standard "prescriptions" that physicians can select to provide a nearly continuous gradation of levels of tightness of control and aggressiveness of therapy.
8. *The program examines the data to determine when the last change in routine insulin was made.* It does not assume that the patient will heed its advice or that the patient is using the program in a routine or consistent manner.
9. *Cost sharing.* One can obtain a machine that will accommodate the present program for about the same cost as one of the hand-held calculator devices.[12] The larger machine will enable the user to run hundreds of available programs. Many other programs should soon be available for this class of machine for general education about diabetes,[16] diet education, diet planning, diet history, calendar and diary functions, and diabetes management simulators,[16,17] which should be useful for the personal management of diabetes. The present program could be cost effective in the physician's office, where microcomputers are used for billing and accounting, database management, programs for patient and physician education, and access to information services. Thus, the net or effective cost of the system described here can be less than the cost of a smaller machine dedicated exclusively to diabetes management.

The cost, size, and weight of microcomputer hardware is continuing to fall rapidly. Recent introduction of a 10-pound portable machine that is compatible with the IBM-PC indicates that a portable version of this kind of program with a full-screen display is possible.

10. *Fail-safe features.* With any computerized system for advice or consultation, one must always consider the possibility of erroneous or inappropriate advice due to a variety of factors, including errors in data entry, program errors, system errors, hardware errors, printer errors, and misreading or misinterpretation of output by the user. The larger, more powerful hardware permits introduction of many features to reduce the likelihood of such errors. These include: (1) a large, easily readable screen; (2) format for data entry that coincides exactly with the worksheets and is familiar to the patient to minimize the likelihood of transpositions or other errors of data entry; (3) a warning message if a value is extremely high or low, which should help to detect gross errors in data entry; (4) the program "beeps" and requests the user to indicate whether there is an explanation whenever a value is outside

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TABLE 3
Statistical analysis and summary of interpretation (01/07/85 to 01/27/85)

	Glucose statistics by time of day								
		Breakfast		Lunch		Dinner			
	2:00 to 4:00 a.m.	Before	After	Before	After	Before	After	Bedtime	Total
Values	0	20	14	21	10	21	20	0	106
Lowest		82	77	59	130	80	97		59
25th %		102	214	71	178	109	125		99
Median		115	237	82	208	134	183		131
75th %		125	267	100	241	147	203		198
Highest		165	344	142	266	238	261		344
Mean		116	235	89	204	131	171		148
SD		18	59	24	40	35	48		61
Limit									
Lower	70	70	70	70	70	70	70	70	70
Upper	150	150	200	150	200	150	200	175	150
Range									
Below (%)		0	0	5	0	0	0		5
Within (%)		19	2	16	4	16	14		61
Above (%)		1	12	0	6	5	6		40

Summary of interpretation

Total 106 Target range (mg/dl) 70 to 150
Median 131 mg/dl Very good!
In Range 58%
Low 5%
High 37%
Hypoglycemia: four in last 2 wk
Worst time: before lunch
Hyperglycemia: 14 in last 2 wk
Worst time: after breakfast
Level of monitoring: five per day
Overall score: 78, very good!

More than 20 additional pages of detailed interpretation can be obtained.

the target range; (5) tabular and graphic displays also help the user detect outliers and errors in data entry; (6) one can easily review and correct previously entered data and obtain new outputs; (7) there is no penalty if the user does not follow the advice of the program or if there are missing values for blood glucose; (8) the physician can modify the "customized algorithms" at any time; (9) the suggestions, explanations, and comparisons section of the program can be turned off by the physician (made unavailable to the patient); (10) after an episode of hypoglycemia or after a change in routine insulin, the program will not recommend an increase in routine insulin for several days, as specified by the physician; (11) the advice generated by the program is based on the same kind of algorithms as has been used and tested in practice by many physicians at several medical centers for many years.[3-9] The major features of the algorithms have been retained while the logic has been generalized to allow greater flexibility; (12) the explanations, comparisons, and graphics sections of the program can help to detect errors in data entry since all decisions can be traced back to input data; (13) the program should make special provisions for abnormal values for which there exists an obvious explanation (e.g., hypoglycemia after a skipped meal or after strenuous exercise, or hyperglycemia after a major dietary indiscretion). Such a feature has not been and cannot easily be implemented in small, portable units.[10-14] The present program allows the user to enter the abnormal values and indicate the explanation with a single keystroke and also permits the user to enter a more detailed comment. The abnormal value will still be included in the graphs and statistics, and is considered in regard to adjustment of compensatory supplements but it is not used to adjust routine insulins. The summary table makes it possible for the physician to see whether the patient is providing an excessive number of explanations for abnormal values; (14) the program can provide a printout of the "customized algorithms" at any time. This should help with patient education, and facilitate manual implementation of the algorithms.

Limitations of the present approach include:

1. Complexity and intimidation. The more features one adds (Table 1), the longer and more difficult is it for the typical

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user to learn, the longer is the start-up time and initial patient education, and the larger is the number of potential problems and pitfalls. Although we have sought to make the program simple, it is still too complicated for many users and some persons are intimidated by the present approach.

2. *Nonportability.* Others have used programmable calculators or hand-held microcomputers to make recommendations about insulin doses.[10–14] These calculators can be carried by the patient at all times. Our system uses microcomputers that, although claimed to be portable (e.g., the Compaq and IBM-Personal-Portable Computer), are at best "transportable." When away from their microcomputer, a patient could use a small wallet-size card to look up values for their supplements. If away for more than a day, he would have to make changes in the dose according to previous instructions.

3. *Potential errors.* No matter how many "fail-safe" features have been incorporated (see above), there is always the possibility that the program will give inappropriate or erroneous advice. The user should never place complete and total reliance on the program output. When in doubt, the patient should call the physician or available paramedical personnel.

4. *Rigidity of logic.* The program does not easily accommodate true changes in the structure of the logic. Although the numerical values in the prescription (Table 2) can readily be changed, additional features cannot be easily added.

5. *Physician and patient acceptance of computer-generated advice remains to be evaluated.* Many expert computer systems perform about as well as acknowledged specialists or "experts"[18,19] but most have not achieved widespread clinical use. Teach and Shortliffe[21] and Shortliffe and co-workers[20,21] have stressed the need for programs to mimic a typical "consultation" with a human expert or specialist: one needs to give advice and provide explanations and justifications at the desired level of detail. We have attempted to respond to this issue by explaining the logic used by the program (as specified by the physician), and by providing a printout of the "customized algorithms." The potential impact on the patient–physician relationship and possible psychological effects remains to be evaluated.

6. *The major problem, at the present time, is still getting the data into the computer.* While many physicians have a computer, they (and their secretarial/clerical staff) would not, in general, have the time to enter the data for all patients. Some patients are likely to have the time, but only a few patients have a suitable computer at home, and it remains to be seen how many would use this approach.

Use of "recording" or "memory" glucose meters[22] permits one to automatically enter glucose data for the past 3 months. Information regarding insulin doses, hypoglycemic reactions, urinary ketones, illness, comments, etc., must still be entered manually.

7. *Impact on habit and life-style.* Both physicians and patients change their standard modus operandi slowly and with great difficulty.

8. *(Un)reliability of data.* Mazze et al.[23] have documented that a remarkably large percentage of patients will falsify a remarkably high percentage of their measurements of capillary blood glucose. We speculate that use of computer programs such as the present one to provide meaningful and useful output (graphics, advice, explanations, and interpretations) in an ongoing and timely fashion could improve motivation for self-monitoring of blood glucose and hence improve accuracy.

Several lines for further evolution and refinement are immediately apparent. We may need to develop multiple "configurations" of the program for different sets of users (patients, medical students, housestaff, diabetes educators, nurses, etc.). Integration with modules for patient education, diet history, planning, etc., should improve the overall attractiveness of the approach. Game-like scoring systems may be helpful for some patients but could aggravate the problems of falsification of data for others. We recognize the need to incorporate algorithms to handle anticipatory supplements. We need to provide still greater flexibility for the physician in prescribing a regimen without increasing the complexity. Ultimately, the logic of the program might shift from arbitrary rules to an appropriate pharmacokinetic model, as used in programs to assist physicians with dosage for digitalis, aminoglycosides, coumadin, lidocaine, theophyllin, etc.[23–25]

The present programs have not been field tested for clinical acceptability, utility, or performance and the algorithms have not been tested for efficacy. We are currently designing prospective clinical trials to evaluate the practicality of the present approach. Use of computers to assist with management of diabetes is now in an early and experimental stage. We will need objective testing to evaluate this new approach. It remains to be seen if computer programs like the one described here will lead to improved control, and whether such approaches will be cost effective. Preliminary reports by others[10–14] using small, inexpensive portable and simple devices are encouraging.

The design considerations and our experience in the development of this program are reported in the hope that this prototype will be useful to others for evaluation and use in its present form and/or as a basis for designing alternative and improved systems.

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ufacturers. The program is available to physicians on request from David Rodbard, M.D.

From the Laboratory of Theoretical and Physical Biology, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland 20892.

Address reprint requests to David Rodbard, M.D., at the above address.

REFERENCES

[1] Pernick, N., Beveridge, M., Jaffe, M. L., Parker, R., and Rodbard, D.: A microcomputer consultation system for self-adjustment of insulin dosage. *In* Medical Management and Computing. Williams, B. T., Ed. Bethesda, Md., The American Association for Medical Systems and Informatics, 1983; 2:62–67.

[2] Rodbard, D., Jaffe, M., Beveridge, M., and Pernick, N.: A data management program to assist with home monitoring of blood glucose and self adjustment of insulin dosage for patients with diabetes mellitus and their physicians. *In* Proceedings, 1984 Symposium on Computer Applications in Medical Care. Cohen, G. S., Ed. Silver Spring, Md., IEEE Comput. Soc., 1984:321–24.

[3] Skyler, J., Skyler, D. S., Seigler, D., and O'Sullivan, M.: Algorithms for adjustment of insulin dosage by patients who monitor blood glucose. Diabetes Care 1981; 4:311–18.

[4] Skyler, J., Seigler, D., and Reeves, M.: Optimizing pumped insulin delivery. Diabetes Care 1982; 5:135–39.

[5] Skyler, J. S., Ed.: Insulin Update: 1982. Amsterdam, Excerpta Medica, 1982:306.

[6] Schade, D. S., Santiago, J. V., Skyler, J. S., and Rizza, R. A.: Intensive Insulin Therapy. Amsterdam, Excerpta Medica, 1983:341.

[7] Jovanovic, L., and Peterson, C.: Optimal insulin delivery for the pregnant diabetic patient. Diabetes Care 1982; 5 (Suppl. 1):24–37.

[8] Witt, M. F., White, N. H., and Santiago, J. V.: Roles of site and timing of the morning insulin injection in type I diabetes. J. Pediatr. 1983; 103:528–33.

[9] Dimitriadis, G. D., and Gerich, J. E.: Importance of timing of preprandial subcutaneous insulin administration in the management of diabetes mellitus. Diabetes Care 1983; 6:374–77.

[10] Newman, W.: A glucose home monitoring data base system on a pocket computer. Abstract. Diabetes 1983; 32 (Suppl. 1):65A.

[11] Newman, W.: Office based computerized insulin adjustment. Abstract. *In* Recent Advances in the Pathogenetic Mechanism and Treatment of Insulin-Dependent and Noninsulin-Dependent Diabetes Mellitus. New York, American Diabetes Assoc., Inc., 1984:113.

[12] Schiffrin, A., Albisser, A. M., and Mihic, M.: Optimizing conventional insulin therapy using an insulin dosage computer. Abstract. Diabetes 1984; 33 (Suppl. 1):39A.

[13] Schultz, G. H. A., Beyer, J., and Hohleweg, F.: A computerized program for intensified SC insulin therapy by diabetes self-adjustment. Abstract. Diabetes 1984; 33(Suppl. 1):26A.

[14] Chanoch, L. H., Jovanovic, L., and Peterson, C. M.: The evaluation of a pocket computer as an aid to insulin dose determination by patients. Diabetes Care 1985; 8:172–76.

[15] Wilson, D. E., and Clark, D. H.: Profiling self-monitored blood glucose results with the personal microcomputer. Diabetes Care 1983; 6:604–607.

[16] Ginsberg, B.: Diabetes 2.0: Simulation to Teach Insulin Adjustment. Iowa City, Computer Diabetes Educators, 1983.

[17] Mazzola, F., and Rowe, D. W.: Video diabetes: a teaching tool for children with insulin-dependent diabetes. Abstract. *In* Proceedings, Seventh Annual Symposium on Computer Applications in Medical Care. Dayhoff, R. E., Ed. New York, IEEE Computer Society Press, 1983:822.

[18] Duda, R. O., and Shortliffe, E. H.: Expert systems research. Science 1983; 220:261–68.

[19] Shortliffe, E. H., Buchanan, B. G., and Feigenbaum, E. A.: Knowledge Engineering for Medical Decision Making: A Review of Computer-Based Clinical Decision Aids. Proceedings of the IEEE 1979; 67:1207–26.

[20] Teach, R. L., and Shortliffe, E. H.: An analysis of physician attitudes regarding computer-based clinical consultation systems. Comput. Biomed. Res. 1981; 14:542–58.

[21] Shortliffe, E. H., Davis, R., Axline, S. G., Buchanan, B. G., Green, C. C., and Cohen, S. N.: Computer-based consultations in clinical therapeutics: explanation and rule acquisition capabilities of the MYCIN system. Comput. Biomed. Res. 1975; 3:303–20.

[22] Mazze, R. S., Shamoon, H., Pasmantier, R., Lucido, D., Murphy, J., Hartmann, K., Kuykendall, V., and Lopatin, W.: Reliability of home glucose monitoring by patients with diabetes mellitus. Am. J. Med. 1984; 77:211–17.

[23] Sheiner, L. B., Halkin, H., Peck, C., Rosenberg, B., and Melmon, K. L.: Improved computer-assisted digoxin therapy: a method using feedback of measured digoxin concentrations. Ann. Intern. Med. 1975; 82:619–27.

[24] Sawchuk, R. J., Zaske, D. E., Cipolle, R. J., Wargin, W. A., and Strate, R. G.: Kinetic model for gentamicin dosing with the use of individual patients parameters. Clin. Pharmacol. Ther. 1977; 21:362–69.

[25] Jelliffe, R. W.: Time-shared computer programs for therapeutic drug monitoring and adaptive control of dosage regimens. *In* Applied Therapeutic Drug Monitoring, Vol. 1. Moyer, T. P., and Boeckx, R. L., Eds. Washington, D.C., Am. Assoc. Clin. Chem., 1981:133–53.

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