Using Diabetes Therapy Management Software to Support Behavior Change—A Case-based Approach

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Abstract

The management of diabetes is complex and requires a team approach for optimal outcomes. This team is comprised of the patient, numerous healthcare providers, and various technologies to elicit the behavioral changes needed in the ongoing care of the disease. This paper uses a case-based approach to demonstrate the patient–healthcare provider relationship and the use of various technologies when managing diabetes. The use of diabetes therapy management software demonstrates enhanced patient–healthcare provider communication, provides data showing that behavioral changes can improve outcomes, and allows the patient to enact positive self-management practices.

Keywords

Type 1 diabetes, hypoglycemia, insulin pump therapy (IPT), continuous subcutaneous insulin infusion (CSII), diabetes therapy management software, sensor-augmented pump therapy (SATP)

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Diabetes outcomes are determined largely by self-management of complex behaviors.[1] People who use intensive insulin regimens, for example, are taught that healthy blood glucose levels depend on balancing the amount of energy in the food they absorb with the amount of energy they expend while adapting their insulin dose to both. This involves multiple interrelated actions—e.g., carbohydrate counting, adjusting the timing and/or dosing of insulin administration, and altering the frequency or method of blood glucose monitoring—which are, in turn, subject to emotional, cultural, and social influences. Today's healthcare environment rarely allows time to sort out these intertwining issues, making effective, long-term behavior change difficult for patients and practitioners alike.[2,3]

Diabetes technologies—namely, blood glucose meters, insulin pumps, and continuous glucose monitors—have evolved in response to this challenge. When used with compatible web-based therapy management software, data from these devices may be downloaded to personal or office computers for a quick, comprehensive view of how insulin timing or dosage, food choices and portions, exercise, and other behavioral factors interact to affect glucose control.[4] This visual feedback from customized reports can serve as a "road-map" during consultation for pinpointing barriers to effective self-care and eliciting practical solutions at the level of the individual patient.

Therapy management software for personal and professional use has benefits that may include:

- expediting data interpretation;
- enhancing patient–healthcare provider communication;
- motivating behavior change in real-world situations;
- showing the versatility of this clinical tool; and
- increasing patient and provider confidence in their ability to enact or induce positive self-management practices.

Therapy Management Software in Context

While there are, as yet, no evidence-based guidelines or best practices for using therapy management software, the recent STAR (Sensor-augmented pump therapy for A1C reduction) 3 trial was the first to formally document a self-management training protocol based largely on downloading and interpreting glucose data via a computerized diabetes management program (CareLink® therapy management software, Medtronic).[5–7] Study subjects who switched from multiple daily

Table 1: General Rules for Physicians when Looking at Therapy Management Software Reports with Patients

- Start with only a few reports
- Emphasize positives by noting strengths and/or improvements in control or behavior
- Identify patient's stated treatment goals and challenges, being mindful of common problem areas:
  - General: overtreating hypoglycemia, insulin stacking, timing of insulin delivery with respect to meals, meal composition, insulin sensitivity, hypoglycemia post-exercise, intentionally "running high" during the night, infrequent self-monitoring of blood glucose
  - If the patient is using an insulin pump: suspending pump, overriding bolus calculator, need for combination bolus, entering incorrect carbohydrates to get desired dose of insulin, infusion site integrity
  - If the patient is using real-time continuous glucose monitoring: alarm burnout, focusing on number rather than trend, not wearing the monitor
- Initiate actions starting with the overnight period, moving to pre-prandial glucose levels and then to post-prandial data
- Identify and treat hypoglycemia first
- Focus on one or two behavioral changes at a time

injection (MDI) insulin therapy to sensor-augmented pump therapy (SAPT)—which combines continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) in one device (MiniMed Paradigm® REAL-Time System, Medtronic)—were urged to download their pump and CGM data at least monthly, analyze selected reports with their healthcare providers to determine problem areas, and make pre-emptive therapy adjustments to improve glycemic control.[6,7]

Compared with patients who remained on MDI therapy, patients in the SAPT group experienced a marked decrease in glycated hemoglobin (HbA_{1C}) levels from baseline within three months, and these levels remained significantly lower for one year. Although this improvement could not be attributed specifically to the use of the therapy management software, the role of this technology for initiating SAPT and adjusting therapy was considered integral because it allows patients and providers to visualize the cause-and-effect relationships driving diabetes outcomes. Asking patients to download, print out, and interpret their preferred CareLink software reports before clinic visits was observed to enhance opportunities for:

- involving them in the care process;
- providing feedback; and
- reinforcing concepts of glucose pattern management as related to habits of everyday life.

Table 1 summarizes general rules of thumb for looking at therapy management software reports with patients using an insulin pump, CGM, or both. Reports commonly used by clinicians who have access to professional versions of therapy management software—for example, CareLink Pro—include:

- Sensor and Meter Overview Report—Displays sensor and meter glucose tracings in order to allow quick identification of patterns and excursions;

Table 2: Professional or Personal Continuous Glucose Monitoring (CGM)

Professional CGM	Personal CGM
• Owned by healthcare professional, clinic, or hospital • Minimal patient training/ set-up time • Worn temporarily (three days) by patients when: o they are not meeting glycated hemoglobin goals o they have recurrent hypoglycemia and/or hypoglycemia unawareness o they are pregnant • Data are not seen by patient in real time • Reimbursement: o Subject to national and local payer policies for CGM o Current Procedural Terminology (CPT) codes 95250 for data collection and 95251 for data interpretation o Cannot be billed more frequently than every 30 days • Therapy management software: o Accessible from clinician's computer only (CareLink iPro®, Medtronic) o Data downloaded and interpreted by clinician	• Owned by patient for adjunctive use with fingerstick testing • Entails intensive training and diabetes education • Typically used by patients with type 1 diabetes: o whose glucose levels are out-of-target, and who have the ability to interpret and apply the information and have hypoglycemia and/or hypoglycemia unawareness o who are pregnant o whose glycated hemoglobin is <7.0 % but could benefit from real-time feedback and/or alarms for hypo- or hyperglycemia • Real-time glucose results are continuously visible • Reimbursement variable, but more likely if patient is >25 years of age and has recurrent hypoglycemia • Therapy management software: o Accessible from clinician's computer o Separate versions available for patients (e.g., CareLink Personal) and healthcare professionals (e.g., CareLink Pro)

Source: adapted from Blevins et al., 2010.[17]

- Daily Detail Report—Provides detailed pump, sensor, and blood glucose meter data pertaining to specific days in order to elucidate daily glucose control, carbohydrate consumption, and insulin use;
- Logbook Report—Provides hourly information and daily averages in a traditional logbook format in order to help identify glucose management patterns;
- Adherence Report—Provides insights into patients' typical utilization of pump, meter, and/or CGM capabilities; and
- Device Settings Report—Shows the customized pump and CGM settings that were active at the time of a particular upload.

Moreover, a more recent version of the CareLink therapy management software program (CareLink Pro 3.0), designed for healthcare professionals treating patients with a minimum of five days of insulin pump and real-time CGM data, incorporates the following new reports:

- Therapy Management Dashboard—Provides a one-page summary of insulin and CGM data, including basal and bolus insulin use, estimated HbA_{1C}, overrides of the pump's bolus calculator, and time-specific patterns of hypo- and hyperglycemia; and

Figure 1: CareLink® (Medtronic) Sensor and Meter Overview Report Showing 24-hour Meter Blood Glucose (BG) Overlay—Patient's Readings and Means Over a 14-day Period at First Assessment

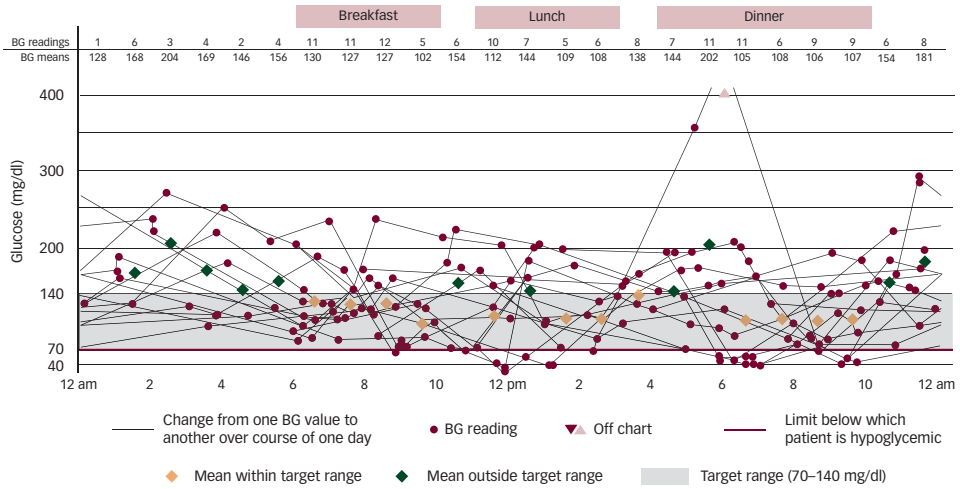
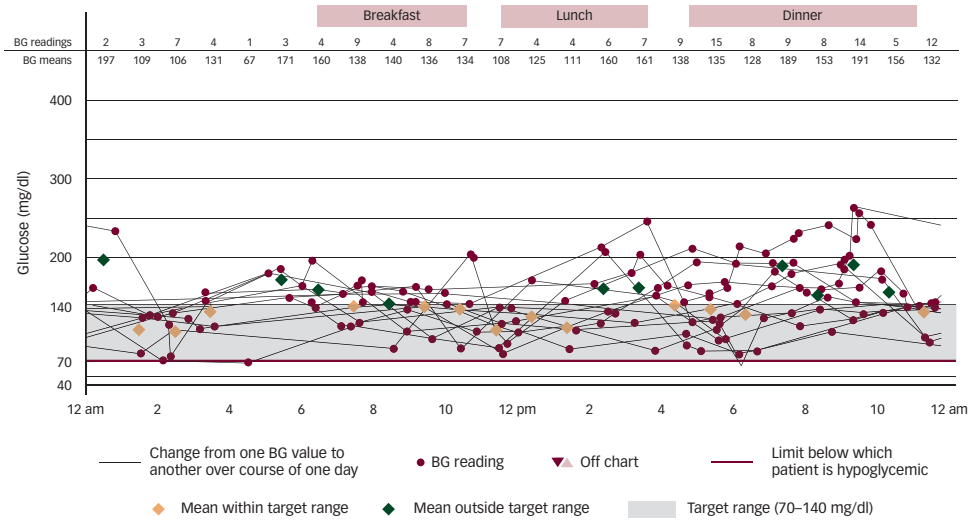


Figure 2: CareLink® (Medtronic) Sensor and Meter Overview Report Showing 24-hour Meter Blood Glucose (BG) Overlay—Patient's Readings and Means Over a 14-day Period at Six-Month Follow-up



- Episode Summary Report—Links key events surrounding episodes of hypo- and hyperglycemia with reasonable therapy considerations.

When used strategically, these reports provide advanced decision support, further reducing the demands of data interpretation, and freeing up time for problem-solving during consultation. *Table 2* outlines the respective characteristics of professional CGM (formerly known as retrospective CGM) and personal CGM (also called real-time CGM).

Case Study—An Anxious Patient with Severe Hypoglycemia Using an Insulin Pump and Standard Blood Glucose Monitoring

Case Description

Eric is a 37-year-old engineer who has had type 1 diabetes for 34 years. For the past 11 years, he has undertaken increasingly complex approaches to CSII therapy, often without the advice of an endocrinologist or another healthcare professional. Disappointed with his last two endocrinologists, he is doubtful that his current physician will be able to help him stabilize his glucose excursions as he strives toward his personal goal of near-normal glycemia.

At the outset of the clinic visit, he explains that his other doctors have not listened to him and that he knows more about diabetes than most healthcare providers. His psychiatrist, whom he sees regularly, is currently prescribing medications for obsessive–compulsive disorder and depression. He is also taking valsartan, triamterene, nebivolol, and diltiazem for high blood pressure and edema.

Eric lives alone, suffers from sleep apnea, and, at 5' 7" and 277 pounds, has "failed" numerous weight-loss programs. He is very concerned about both nocturnal and daytime hypoglycemia. Over the past several years, he has received emergency treatment for severe hypoglycemia on 12

occasions. Although Eric would like to try CGM, his insurance company will not provide coverage. He thus checks his blood glucose levels with a standard meter eight to 10 times per day to ward off hypoglycemia.

Eric's pump data reveal that he is using 10 different basal rates. His insulin:carbohydrate (I:C) ratio is 1:3 for both breakfast and dinner, and 1:4 for lunch; his insulin sensitivity factor is 10; and his HbA_{1c} is 6.5 %. His therapy management software report, downloaded from his pump at the time of the office visit, shows that his average blood glucose is 137 (±63) mg/dl, his mean daily carbohydrate intake is 322 (±67) grams, and his mean daily insulin dose is 269 (±27) units. Of his total daily insulin dose, 57 % (153.2 units) is administered as basal insulin and 43 % (118.4 units) as bolus insulin.

When asked about his excessive basal rate settings, Eric replies that being able to fine-tune his basal insulin dose throughout the day makes him feel more in control of his life and capable of meeting his two main treatment goals: avoiding hypoglycemia and maintaining pre-meal glucose levels between 70 and 90 mg/dl. Although this pre-meal target is lower than the ranges recommended by both the American Association of Clinical Endocrinologists and the American Diabetes Association (<110 and 90–130 mg/dl, respectively),[8,9] Eric is emphatic that he needs to "normalize" his blood glucose to avoid "having a heart attack."

He dismisses the suggestion that 10 different basal rates could increase the risk of hypoglycemia, but pauses when told that it can take several hours before changes in basal insulin infusion are reflected in the circulation, possibly causing overlaps in action (insulin stacking) that would not be accounted for by the pump's bolus calculator.[10] He admits that he has never thought about that before.

The physician directs Eric's attention to the therapy management software's Sensor and Meter Overview Report (see *Figure 1*), which has been printed out by the medical assistant and placed on the desk next to the computer in the examination room. Eric is surprised to see the high number of glucose excursions in the hyperglycemic range, which are often preceded or followed by hypoglycemia. He becomes visibly agitated, saying that there must be a mistake given all the work he puts into his diabetes self-management.

Physician's Recommendations

The physician, first, acknowledges the patient's conscientious approach to diabetes management. He adds that Eric is a good candidate for pump therapy given several important characteristics:[11]

- he monitors his blood glucose frequently;
- he is motivated to manage his blood glucose control; and
- he has shown the competence and commitment required to use the technology.

Eric is also a prime candidate because of his erratic glucose excursions and frequent episodes of severe hypoglycemia, which may be effectively reduced with well-guided CSII.[12]

In an effort to help Eric get what he needs and wants from pump therapy without putting him on the defensive or offering unsolicited advice,[13] the physician suggests that, together, they map out steps to adapt Eric's insulin regimen to his stated treatment goals. Refocusing the conversation on the therapy management software report, the physician asks Eric when his basal rates were last evaluated. When Eric replies uncertainly, the physician suggests a basal check test to gauge appropriate basal rates apart from interfering factors such as carbohydrate intake or exercise.[14] He explains that, although there is no exact formula for everyone or every blood glucose meter, in general, a basal rate that keeps blood glucose levels from rising or falling >30–50 mg/dl overnight or over a three- to four-hour period since the last meal is considered optimal.

Eric agrees to start with an overnight basal test to reduce the risk of night-time lows and morning highs, and to consider daytime basal-rate testing (i.e., omission of meals with glucose checks performed every hour for a specific duration of time, usually four to six hours) when he feels ready. He also accepts the suggestion to meet a diabetes educator/pump trainer to discuss specific adjustments to his current pump regimen. He writes the educator's name, number, and additional notes from the visit on the therapy management software print out, which he asks to take home with him.

Follow-up after Six Months

Returning to the physician's office six months later, Eric reports that he has been laid off and is under considerable stress. Nevertheless, he managed to have two sessions with the diabetes educator covered by his former insurance plan.

Working with the educator, Eric first looked at the ratio of basal:bolus insulin he used each day. In general, a higher percentage of basal insulin in patients with frequent hypoglycemia may indicate that basal rates are too high, whereas more than half of the total daily dose in patients with frequent hyperglycemia suggests that bolus doses are frequently being missed.[12] Concentrating first on hypoglycemia, Eric reduced the number of basal settings to six per day, with decreased basal insulin prior to times of hypoglycemia. His daytime basal rates were set to include a decrease in insulin to prevent hypoglycemia associated with regularly scheduled exercise. At the second session with the educator, Eric reviewed his bolus dosing strategy, including his target blood glucose level, insulin sensitivity factor, and I:C ratio.

The resulting adjustments allowed Eric to distinguish more easily between his basal and bolus insulin needs, reducing the risk of insulin stacking and resultant hypoglycemia seen in *Figure 2*. He also found that using a temporary basal rate 10–20 % lower after exercise helped stabilize his post-exercise glucose levels.[14] Although his average blood glucose is 148 mg/dl and his HbA_{1c} 6.7 %, up from five months ago but still within the acceptable range, the improvement in Eric's standard deviation (from 63 to 47) indicates that his blood glucose is less variable.

Eric tells the physician that he has been uploading his pump data at least monthly and is feeling generally more confident in his self-management decisions. The physician acknowledges Eric's success at "letting go" of his stringent definition of "control," even as he copes with uncertainty in other areas of his life.

Recognizing that this is a stressful period for Eric, the physician refrains from introducing new goals at this stage and, instead, offers several links to local peer support websites so that Eric can hear from people like himself, feel less isolated, and increase his chances of maintaining his current success.[15] He suggests, too, that Eric considers professional CGM, which may help reveal excursions often missed by fingerstick testing alone.[16,17] Eric responds favorably, but notes that he will have to wait to see whether he can remain on his former employer's group health plan before making any decisions. The physician ends the visit by offering to write a letter of medical necessity, if needed, for coverage of professional CGM or, if warranted, personal CGM when that time comes. ■

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