Realizing Proactive Diabetes Care in the 21st Century.

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Diabetes care has become busier and more complex than ever before. Provider time to collect and analyze patient self-reported data has never been more restricted. If advances are to be made in realizing optimal glycemic control in the majority of patients with diabetes, the analysis of patient collected data must be streamlined and enhanced to provide the necessary feedback to the patient in a time sensitive fashion that balances the needs of the patient and the health care team. The GlucoMON and its GlucoDYNAMIX™ care management system elegantly address these concerns and will become the standard for technology-enabled intervention for persons engaged in patient-centric care models.

Since the discovery of insulin over 80 years ago, medicine has struggled to improve not only the longevity, but the quality of life for all persons with diabetes. With the advent of home blood glucose monitoring in the 1970's and its dissemination through the end of the last century, the need for a patient-centric approach to diabetes care became apparent. The results of the Diabetes Control and Complication Trial in 1993 highlighted the potential benefits of intensive diabetes management on reducing the risk of long-term diabetes complications and in turn increasing the odds of a long and happy life for millions of people with diabetes. For detailed information regarding DCCT see http://diabetes.niddk.nih.gov/dm/pubs/control.

However, DCCT was based on a physician-protocol-directed model where the patients were in frequent contact with the research team at least weekly, combined with monthly encounters with the specialist physician. Study participants were required to record and transfer blood sugar data to a research nurse, who in turn would apply predetermined algorithms to determine need for any changes in the diabetes management plan. Specifically, large amounts of numerical data needed to be relayed from the patient to the care team in a time sensitive fashion. The methods of data gathering included verbal feedback or fax of log books, a very time consuming undertaking. Ultimately, all care was overseen by a specialist physician with expertise in the goals set forth by the study protocol, namely attainment and maintenance of a hemoglobin A1C value as close to normal as possible. The need for frequent decision making based on ongoing review and analysis of blood glucose levels was discovered to be absolutely essential if optimal blood glucose control was to be achieved.

Following publication of these landmark findings, translation of DCCT results into real world practices has remained elusive for all but a small percentage of highly motivated persons with diabetes. In addition to a motivated patient or family, optimal metabolic outcomes have required an aggressive health care provider or team with experience in interpretation of blood glucose data, access to the necessary equipment and financial resources required to achieve and sustain these results. Even the DCCT screened all its participants for the ability to comply with the rigors of intensive diabetes self-management programs and excluded high risk patients; an option not available to practicing physicians in the real world setting.

The world of diabetes has certainly been changing in many ways. With the increasing cost and complexity of diabetes care, rates of new diabetes cases continue to increase while physician reimbursement for delivering care has declined. Furthermore, self-management education remains poorly reimbursed in spite of its value in improving patient adherence and competency with prescribed care regimens.

Self-collected blood glucose data remains the key for maintaining optimal glycemic control in patients with any form of diabetes at any age. Properly organized and interpreted, blood glucose data is the most powerful method for attaining and maintaining tight blood glucose control. However, prompt and transparent acquisition of this data has not been practical until only recently.

Over time, methods for home blood glucose monitoring have become faster, requiring smaller blood samples, even utilizing devices which time stamp and record data in a memory chip within the meter itself. With the advent of the personal computer, patients can download and attempt to analyze their own data.

Observation of patients over the past 15 years shows that while these tools are capable of improving patient outcomes, they are grossly underutilized. Research presented at ADA Scientific this year finally documents the fact that glucose meter internal clocks are set incorrectly up to 50% of the time, often by many hours or even years. Many patients are never instructed to analyze their own test data by their physicians, who may also lack experience in analyzing the data. The end result for many patients is a meter replete with carefully collected blood sugar data, but without any attempt to analyze the overall pattern of control, outside the acute reaction to extreme high or low blood sugar values (typically performed by the patient or caregiver).

A rapidly expanding population of patients with diabetes, combined with reduced provider time to spend addressing patient problems, and more patient collected data to collect and analyze than ever before, creates a "perfect storm" scenario. The tools for attaining optimal blood sugar control exist in great abundance, yet the time and expertise to apply to the problem remains severely limited. A solution must be reached which includes transparent acquisition of reliable and accurate patient-collected data, combined with rapid and ongoing data analysis in a time-sensitive fashion without excessively burdening the patient or the health care provider. Such a solution is now in reach.

The collection of accurate patient reported self-test blood glucose data in real time is a reality with the GlucoMON™ device by Diabetech. Immediately following collection of a blood sugar test result, the time-stamped glucose data is effortlessly and immediately transferred to the patient's virtual log book without the need for connecting the meter to a personal computer or manually logging and forwarding the data. Depending on the clinical scenario, the data can also be directed to any member of the patient's "diabetes care community", including family members, friends or various members of the diabetes care team itself. The log book can be viewed by the patient anytime, online. Various trend views of the data may be sent via e-mail for review at any frequency, customized for each member of the care team, including the patient.

The real time alert feature provides an immediate text message to members of the patient's family or health care team (as directed). Profiles may be set to transmit only results above or below a threshold level, or to queue the data to be sent at a specific time or date for review by family, diabetes support group partners or providers (e.g., 8AM). Parents of children who may be away from home and perform blood sugar testing (school, trips) now have the ability to know not only if the test was done, but also the result, and in real time. Family management has benefited in some cases by removing the need for confrontation required by some parents in order to review the data locked up in their teen's meter.

Thoughtful application of this real-time intervention system to clinical practice has opened a whole new range of options for attaining optimal blood sugar control, plus addressing acute metabolic emergencies as they might arise. In my four years of clinical experience with proactive diabetes care in children using this technology, I can attest to a wide array of applications for achieving improved patient outcomes based on direct observations within my patient population in South Texas at Driscoll Children's Hospital. This close involvement with the technology includes working with Diabetech as a member of their advisory board.

Real time glucose monitoring combined with automated patient feedback has numerous applications, including but not limited to treatment and follow through of moderate to severe hypoglycemia, early diabetic ketoacidosis, blood sugar pattern management, and initiation of insulin pump or multi-dose insulin therapy, among others. The following case studies demonstrate the realization of proactive intervention:

Case 1. Remote Patient Monitoring Following DKA

A 14-year-old boy on insulin pump therapy developed an insulin pump malfunction resulting in severe hyperglycemia and ketosis. He was participating in the earliest trials of the GlucoMON and also had an inexpensive, two way text messaging device (GlucoMESSENGER™) as part of his proactive toolkit. He was seen in our hospital emergency department and discovered to be in early diabetic ketoacidosis. The pump problem was readily correctable and he was capable of oral intake and frequent blood glucose and ketone monitoring at home. Instead of a direct inpatient admission to the hospital, he was instructed to monitor glucose and urine ketone levels frequently. The blood sugar levels were transferred to me in near real time via the GlucoMON and ketone levels manually transmitted to me via the GlucoMESSENGER. I instructed him via my study issued GlucoMESSENGER and within 6 hours his blood glucose levels had returned to controlled levels and his urine ketones became negative. By circumventing an admission, overall cost savings were in the thousands of dollars. In addition, the patient, his family and I experienced an improved quality of life since they didn't have to spend a day in the hospital and I was able to continue my usual weekend activities with minimal interruption.

Case 2. Proactive Intervention and Associated Decrease in A1c
A 12 year old girl with type 1 diabetes has consistently had elevated hemoglobin A1C values. She presents with a value of 9.8%, indicating poor glycemic control. She agreed to use the GlucoMON device to record, log and share her blood sugar data with my management team as part of a research protocol. Her blood glucose data was reviewed by prior agreement every two weeks by the diabetes team. The team only needed to review a color-coded log sheet with all data displayed. Values outside target range were highlighted red or yellow (high or low). Feedback was made to her family regarding her care regimen based on bi-weekly data review, or if calls were initiated from the patient to the team. After 3 months, her follow up hemoglobin A1C had fallen to 7.3%. Patient satisfaction with this method of management was entirely positive. Data review was transparent to the family and required no phone calls to gather and organize the data prior to review. The time savings for the diabetes team were dramatic compared to traditional methods and the improved control was directly associated with the use of the uniquely proactive methods based on earlier recognition of aberrant blood sugar patterns and proactive intervention by the diabetes team.

Case 3. Improved Safety and Effectiveness During Initiation of Insulin Pump Therapy
A 7-year-old boy wishes to start insulin pump therapy. Following the pre-pump training, the process of pump initiation is undertaken. This process takes several hours and involves setting numerous rates and ratios into the software of the pump. These settings are estimates based on the child's prior insulin schedule and other patient-specific factors. An essential aspect of quality pump starts is rapid acquisition of blood glucose values in the days and weeks following start up. Using the GlucoMON, the family was able to relay blood sugar data to the child's virtual log book, which could then be reviewed as needed by the pump trainer. Rapid feedback to the family allowed a safer and more effective pump initiation than what would have been possible with frequent faxes, in clinic visits and phone calls. Patient satisfaction was significant.

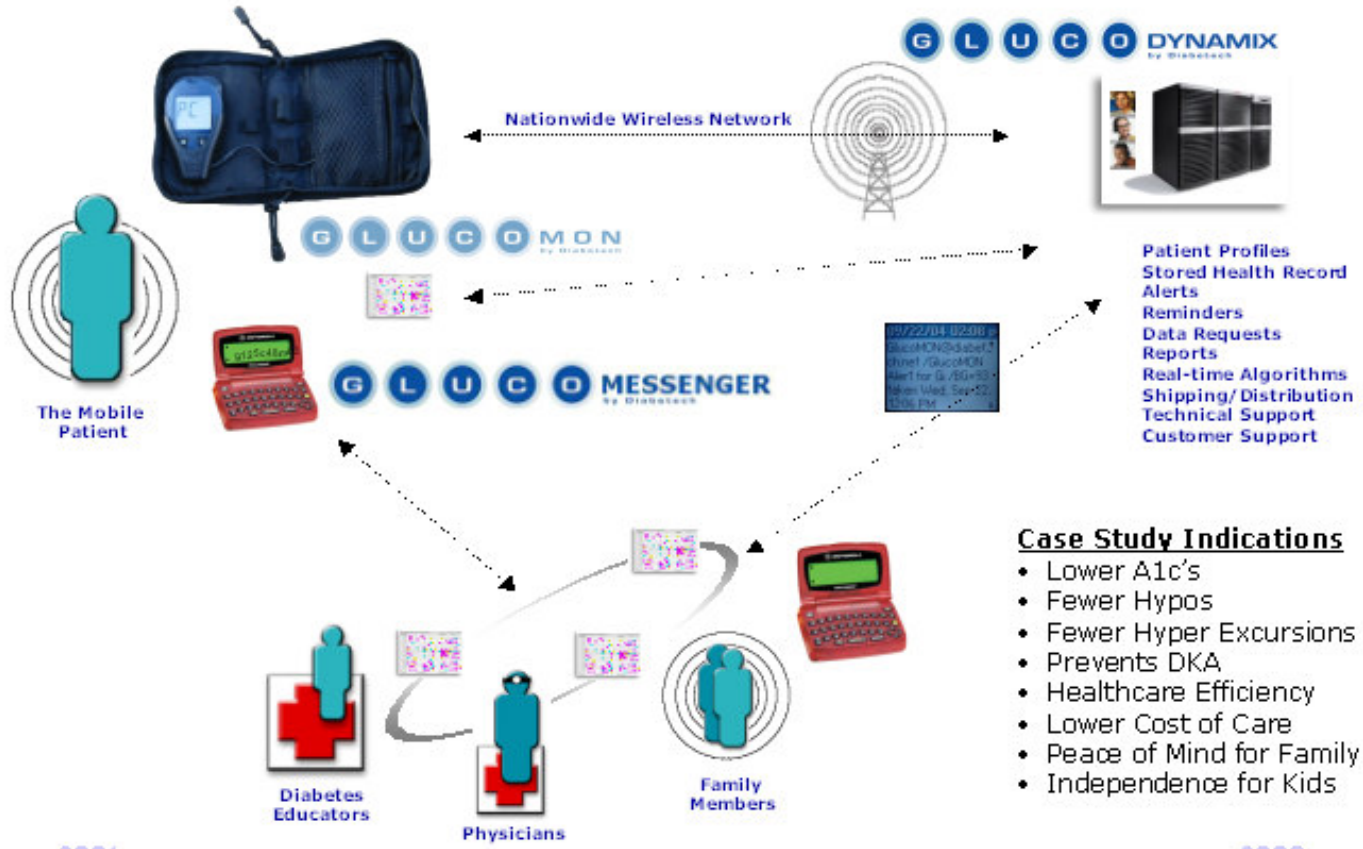
Case 4. A Better Way to Manage Type 1 Diabetes at School
An 8-year-old girl with type 1 diabetes managed by multi-dose insulin therapy starts her first day in a new school. The school has a nurse who is not familiar with pediatric diabetes care. The parents meet with the nurse to orient her to the GlucoMON, which takes only a short time. Over the next few weeks, the parents receive immediate notification of the girl's blood sugar results and contact the nurse to advise her on what actions to take with her insulin dose based on the data received. The parents develop tremendous peace of mind and the nurse rapidly develops expertise in the care of a child with intensively managed diabetes in the school setting.

There are an infinite number of ways to apply this technology. For example, inpatients with diabetes may need to have blood sugar data forwarded to their attending physician outside the facility, based on preset thresholds ordered by the physician. The physician can review and decide whether action is needed, but avoid the need for frequent calls to the nurse's station and requests for the information. Family of elderly people with diabetes can know how their family member is doing from virtually anywhere in the world. Research studies depend on carefully collected blood sugar data as part of the outcomes analysis. The GlucoMON manages this data with the accuracy of the atomic clock and stores the information for ongoing review and archiving as needed. In an upcoming large-scale deployment of the technology, the system will support research into automated risk-management of a diverse population of children and adolescents with all types of diabetes. By issuing devices without the typical tech-savvy requirements, thousands of patients will now participate in intensive management without any change in behavior on their part. This study includes forwarding patient-specific aberrant data clusters as needed for review and intervention by the primary investigator, the patient or any other member of the authorized patient-centric team. A proactive diabetes care network is illustrated on the following page.

In conclusion, diabetes care has become busier and more complex than ever before. Provider time to collect and analyze patient self-reported data has never been more restricted. If advances are to be made in realizing optimal glycemic control in the majority of patients with diabetes, the analysis of patient collected data must be streamlined and enhanced to provide the necessary feedback to the patient in a time sensitive fashion that balances the needs of the patient and the health care team. Furthermore, any method needs to be transparent to the patient and provider. The GlucoMON and its GlucoDYNAMIX™ care management system elegantly address these concerns and will become the standard for technology-enabled intervention for persons engaged in patient-centric care models.

proactive diabetes care network

Diabetes Intervention Technology™



Case Study Indications

- Lower A1c's
- Fewer Hypos
- Fewer Hyper Excursions
- Prevents DKA
- Healthcare Efficiency
- Lower Cost of Care
- Peace of Mind for Family
- Independence for Kids

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