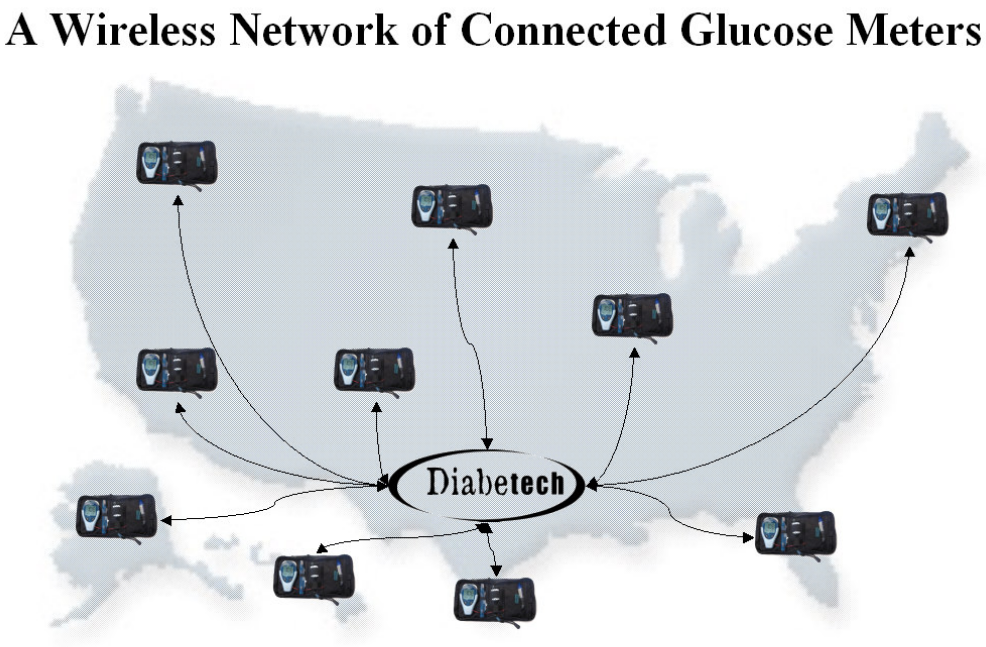
The Real Time Virtual-Loop™: Collection through Intervention

Utilizing specialized communications devices, glucose meters, insulin pumps and relevant biometric sensors to deliver automated proactive diabetes care management to people with diabetes.

Introduction

There have been several attempts to close the gap between knowledgeable clinical resources trained in diabetes management and patients working for better control of their diabetes. Technologies which have already been applied to assist both individuals and teams include handheld computers, desktop PCs, internet connectivity, web-based applications, and specialized glucose meters that physically integrate with PDAs & Cell Phones via cables and short range wireless connections. However, barriers to improved patient self-management remain. The tools deployed to date have only demonstrated limited effectiveness due to built-in dependencies on people to embrace cumbersome and oftentimes expensive technologies… and to change. All of the various tools available today have underestimated the critical dependency on patient behavior except for one.

The GlucoMON™ wireless device and the forthcoming GlucoDYNAMIX™ proactive diabetes care management system are unique in their inherently transparent method of collecting self-management blood glucose (SMBG) data. The GlucoMON design, as well as the technology underneath the surface, transforms an ordinary glucose meter into a network of "always-connected" glucose meters.



Within the larger network, reliable connections to other services include electronic medical records systems, analytical programs which constantly process high risk and predictive algorithms against data in real-time, patient management systems for easy to understand charts and graphs and for documenting clinically relevant actions, other wireless devices such as cellular telephones and pagers and essentially any technology which has a trusted connection to the internet.

More importantly, this paper attempts to define a connectivity roadmap, infrastructure requirements and a new model for bringing together the best of medical device manufacturers, informatics researchers, clinical practitioners and most importantly, patients and their day-to-day caregivers left primarily to their own resourcefulness as they navigate a lifetime of diabetes management.

The following diagrams illustrate the complexity of diabetes management today and how technology offerings continue to promise but rarely deliver. Finally, the concept of a Virtual-Loop is introduced as a way to bring together all of the relevant resources under a single umbrella, regardless of where they live. Also described are the benefits that come with a distributed technology architecture and one that is open to innovation by many.

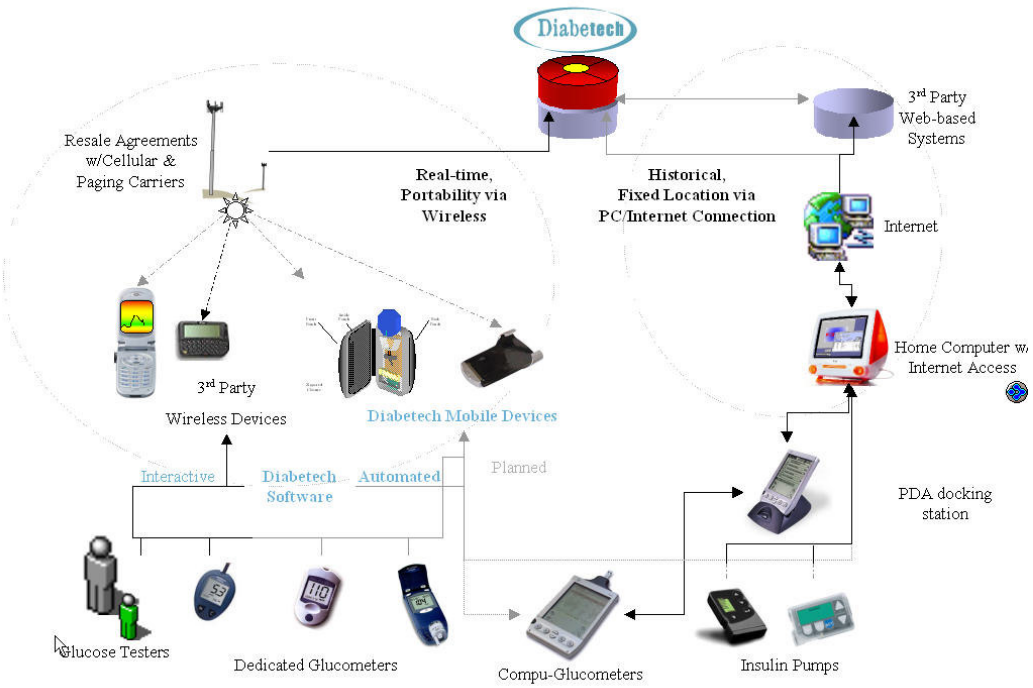
The Diabetes Self-Management Education Challenge

According to National Standards for Diabetes Self-Management Education (NS-DSME) as published in Diabetes Care; Vol. 26, Supplement 1, January 2003, “Clinical Practice Recommendations 2003", pgs. S149-S156, Diabetes Self-Management Education (DSME) is the cornerstone of care for all individuals with diabetes who want to achieve successful health-related outcomes. Within the comprehensive definition of DSME, the Task Force describes DSME as being "interactive, collaborative and ongoing". Within this process exists the need for assessment, identification, intervention and evaluation.

In that the NS-DSME Task Force does not define "how" to implement these Standards, it is up to clinical practice to advance the delivery of care in relation to the relevant technologies available to assist in the delivery of DSME. Under the banner of "creative interventions" within the Process subset of the DSME Standards, this technology will demonstrate a creative way to cost-effectively and efficiently enable proactive interventions at the teachable moment resulting in improved outcomes.

In the world of information management, a recently recognized concept in the field of diabetes, there is a truism that weaves its way through every step of the process. This truism is that without accurate and available data, the gears that drive information technology come to a screeching halt. A more commonly heard truism is, “Garbage in, garbage out”. In the world of patient self-management, the challenge is to first, get the data if you can, and second, how do you know that it’s not garbage? No wonder progress has been slow.

Step 1: Get the Data



By looking at the most prevalent self-management technologies in use today, we see that glucose meters are widespread thanks to the groundbreaking work of the DCCT trial group.

What we see by looking across the board at information technology, outside of the medical devices themselves, are a million different programs for displaying charts and graphs and none of them really do a very good job of addressing glucose analysis training. I suppose that if these systems actually had a sufficient number of interested parties, clinicians as well as patients, screaming for enhancements, the technology would be closer to delivering real benefit than it is today. Due to the incredibly low adoption rates of these systems dependent on manual, tech-savvy operators, it's obvious that the torches and pitchforks never gathered to make their demands.

Step 2: Use the Data

Once the data has been collected, and there is a level of assurance that the data is accurate, the next step is to use it. Within self-management devices, the FDA goes to great lengths to protect the consumer by ensuring that the data is in fact accurate within tolerance and when combined with training and medical guidelines, the person with diabetes or their caregiver will be able to effectively and safely administer the appropriate care based on that data.

If diabetes were in fact a self-managed disease, which only required isolated management decisions on each spot check of the blood glucose, the current meter technology would probably

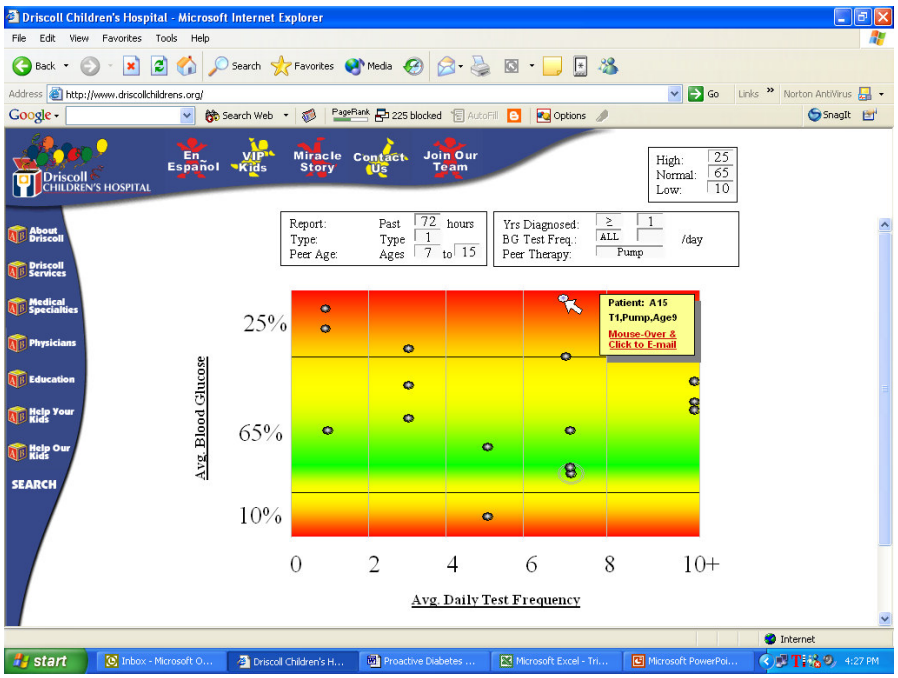
be sufficient. However, diabetes is neither a self-managed disease nor should decisions be limited to individual SMBG test results.

This is pretty much where the current state of the art leaves off. With the exception of manual logs, occasional faxing to the medical team and phone calls in the middle of the night, tools for people with diabetes are limited to the pace at which medical device manufacturers can build them into their medical devices.

Medical devices are medical for at least two very good reasons; Reliability and Accuracy. I'll take an insulin pump that just gets the job done over one that touts color screens and alarms with custom ring tones any day. However, as many clinical studies have recently brought to our attention, the psychology of diabetes management is an incredibly important part of patients successfully managing their chronic disease.

Steps 2, 3 and 4: Transform, Use & Share the Data

In the future, which one is Step 2? Which is Step 3 or Step 4? The lines are blurred when you consider the introduction of intelligent systems assisting people in the management of diabetes. The following system view illustrates how an intelligent patient management system can automatically segment a patient population based on risk parameters and easily identify patients with the highest probability for an oncoming crisis.



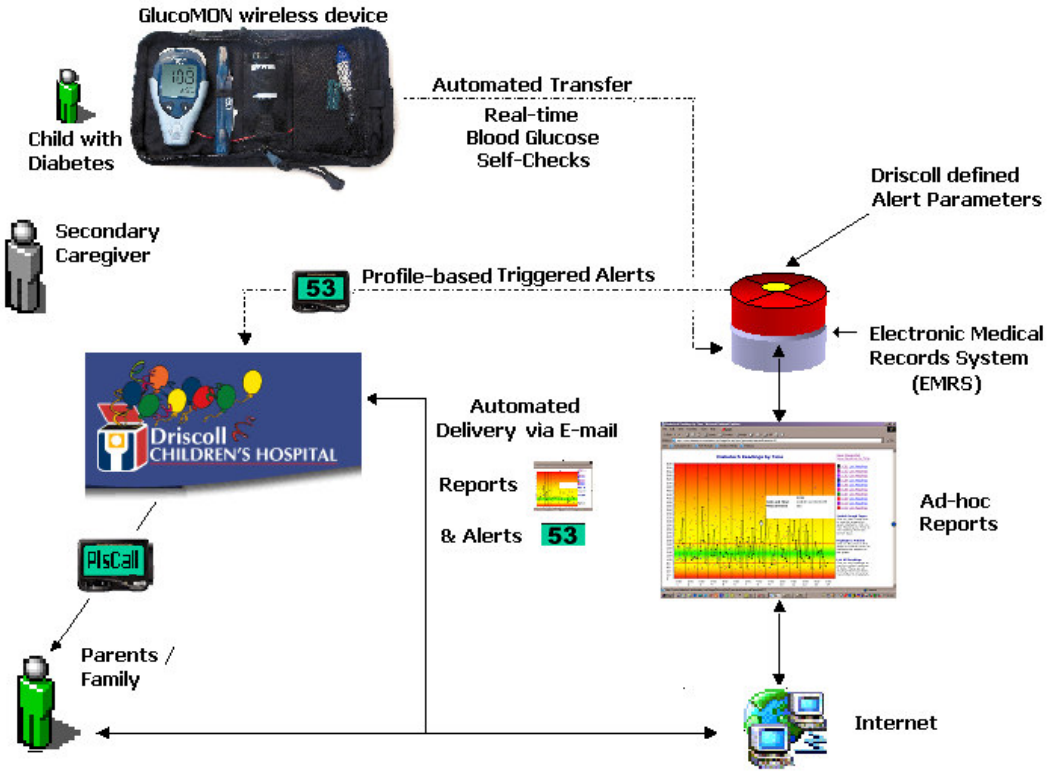
The impact of connecting accurate and reliable data to third party analysis, complex predictive algorithm design, development, testing and deployment will be to revolutionize the intelligent management of diabetes and promises to go far beyond a simple comparison of blood glucose data and test frequency. Even so, this simple example illustrated above is only now a possibility due to Diabetech's unique technology.

The DCCT Study and its use of resource intensive monitoring for proactive care and early interventions paved the way toward improved control through frequent testing of the blood glucose among other facets of intensive care. The *Virtual-Loop* follows on a similar path, however, with a practical and potentially cost-effective way to accomplish the same goals but with technology that was not available at the time of the DCCT Study. Rather than weekly telephone consultation as a standard intervention, clinical research based on the Virtual-Loop concept will illustrate the effectiveness of intervention *as appropriate* based on automated risk-based triggers suggesting proactive intervention and the *need* for a phone call. This is also perhaps a model for care that bridges the gap between intensive management today and the wide-spread adoption of intelligent on-body systems being developed for the future. Findings from this brand of research may also be useful in discovering telemedicine-style clinical processes not presently in place yet essential to the safe and effective use of intelligent systems in the future.

In the research performed at Children's National Medical Center in 2003, the researchers, Griffin and Henderson, report that in-office meter uploads using PC software transfers 8 to 9 minutes of time typically spent tabulating manual glucose logs instead of interacting with the patient team. Given that this phase of the office visit only totals 15 minutes, they were able to demonstrate the value of computer technology used in the delivery of DSME. However, this study was limited to a historical perspective on the SMBG data as opposed to any form of real-time review and proactive intervention.

In another body of research conducted in 2003, Klein, Malasanos and Patel at the University of Florida Department of Pediatrics studied "An Integrated Technology Approach Providing Education, Monitoring, and Communication for Children with Diabetes" as part of the Florida Initiative in Telehealth and Education (FITE). In contrast to the proposed research, this study required the patients to either possess or have ready access to an internet-connected PC, an aptitude to use the technology, and the motivation to manually and periodically upload their SMBG data. While the U of F study was novel in its use of interactive communication with the patient, it fails to address the possibility of timely interventions at the "teachable moment" This means simply that much of the context around SMBG data is lost after some short period of time thus diminishing the effectiveness of the intervention.

Therefore, research incorporating the *Virtual-Loop* will enable an entirely new form of clinical protocol, which considers the use of an automated real-time reporting mechanism telemetrically tied to the patient. Through a mobile two-way communications infrastructure, patient-specific, provider defined, proactive patient interaction will be automatically and cost-effectively enabled. This concept is illustrated below:



Summary

In summary, intelligent assistive technologies will have a great impact on clinical research as proactive intervention helps in the delivery of better outcomes across a wider demographic of patients, especially those with less access and aptitude to and for technology. Furthermore, this research will illustrate the value of timely interventions that permit the clinician to educate while leveraging the context of the situation.

In the short term, wide scale adoption of these technologies, including the GlucoMON, will help to create a cost-effective diabetes data repository and method to assist research in developing more effective medical devices and clinical processes. Collecting, managing and analyzing patient data can be an extremely time-consuming and expensive use of limited research funding and skilled personnel.

Should the search for the cure remain elusive, ultimately, Diabetech's remote monitoring and control capability will also be used to accelerate the deployment of pending advancements in the field by providing the assurances of remote control and a “Virtual-Loop” enhancement to the industry’s proposed Closed-Loop artificial pancreas.

About the Author

Kevin McMahon is the President, CEO of Diabetech, LP and Executive Director of the Diabetech Foundation. In May of 2001, his then 27-month-old daughter was diagnosed with type 1 diabetes.

Coincidentally, between 1997 and early 2002, Kevin led several international teams in the areas of healthcare, telecommunications and process integration technologies. As the Director of Mobile Commerce for Compaq then later with Vitria Technologies, he led sales, solution and business development teams in the area of Wireless Voice, Data and E911 Location Services. Also during this time, he was Vice President of Sales & Marketing for Elagent Corp., a Richardson, Texas based startup with a next-generation distributed computing platform.

Prior to November of 1997, Kevin was instrumental in building the deregulated phone company arm of GTE. In the early 90s, he reorganized financial and software development processes of the MedSeries4 hospital information system (HIS) now offered by Siemens Medical and also the Qcare mainframe managed care administration system. Kevin began his corporate career working on a transaction-based system as part of a pre-internet physician's office medical claims processing service bureau.

He holds a B.Sc. in Business Administration from Arizona State University and is a former member of the CDMA Steering Committee within the wireless industry.

About the Company

Diabetech® is a Dallas, Texas based biomedical technology company offering specialized wireless devices within a proactive diabetes care management system. These services are available to individuals, healthcare and employers to connect the patient's extended management team through a variety of tools designed to reliably collect, share, transform and use diabetes relevant data and information.

More Information is available on our website and by contacting Diabetech directly at:

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Website: www.diabetech.net

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The system illustrations included herein are examples only. Driscoll Children's, located in Corpus Christi, Texas and more specifically Dr. Stephen Ponder MD, CDE, have a close relationship with Diabetech. Dr. Ponder and Diabetech have worked together to pilot the technology and have conducted early feasibility studies since 2002. He is currently the Chief Medical Officer for Diabetech and actively provides guidance to the Company as we continue the design of formal trials for evaluating the clinical efficacy of the system called GlucoDYNAMIX™.