
EXECUTIVE SUMMARY

Continuous Glucose Monitoring: Innovation in the Management of Diabetes



New England Healthcare Institute

NEHI Innovation Series

March 2005

Executive Summary

OVERVIEW

Continuous glucose monitoring (CGM)ⁱ is a rapidly developing innovation poised to improve the lives of millions of diabetes patients. Providing vastly more information than today's episodic monitors, CGM can help patients achieve and sustain tight blood glucose control, which is critical in reducing long-term complications associated with the disease.

First-generation CGM devices are already available today for limited uses. As the technology evolves, CGM is expected to become the new standard in daily monitoring, benefiting the almost three million diabetes patients on exclusive insulin therapy who must test their blood glucose levels several times per day (See Figure 1-1). CGM devices also have the potential to become an important assessment and diagnostic tool for the remaining 10 million diabetes patients who test less frequently.

This report provides an in-depth analysis of CGM as experts predict it will exist in five years: an unobtrusive, easy-to-use device that is FDA-

approved to replace episodic monitoring. This analysis includes an overview of the growing need for such a tool, a forecast of the technology's value, and a discussion of the barriers that could impede its timely adoption. The report concludes with action-oriented steps that stakeholders can take now to begin planning for the adoption of this emerging innovation.

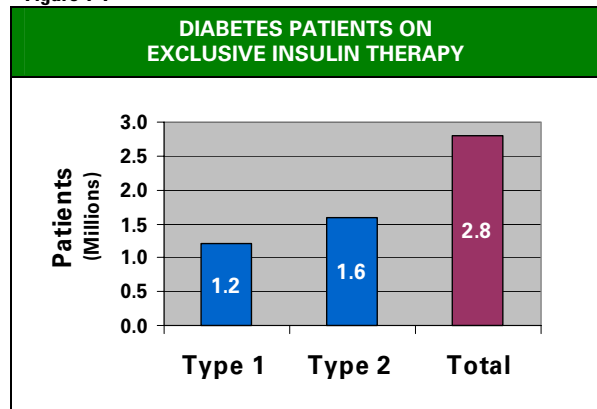
DIABETES: A GROWING BURDEN TO SOCIETY

Diabetes is widely acknowledged to be an immense and growing public health problem. Over 18 million Americans are afflicted with diabetes, and this number is expected to double by 2050.¹ A pernicious disease, diabetes is associated with decreased quality of life and costly, dangerous complications, such as blindness, damage to the lower extremities, kidney failure, heart disease, stroke and even death. At the root of most of these complications is the loss of the body's natural ability to use insulin in order to maintain normal levels of glucose in the blood.

INTENSIVE GLUCOSE MANAGEMENT IS CRITICAL...BUT CONTROL REMAINS POOR

ⁱ Using the initials CGM in this report as an acronym for "continuous glucose monitoring" is for purposes of convenience and brevity only. The designation is intended to signify a class of technology; it does not refer to any specific manufacturer's product.

Figure 1-1



Sources: NEHI; Expert Interviews

Landmark studies have demonstrated that tightly managing blood glucose levels to stay within a near-normal range can dramatically decrease the risk of serious complications and death.^{2,3} As a result, tight glucose management has become today's standard of care. To achieve glucose control, many patients are recommended to test their blood glucose frequently. This requires patients to pierce their skin with a lancet to draw blood, apply the blood to a test strip that is chemically sensitive to the presence of glucose, and then feed the strip into a meter that calculates their current blood glucose level. Patients then use this information to adjust their treatments if their blood glucose level is too high or too low.

Only 37 percent of patients with diabetes are achieving the level of control recommended by the American Diabetes Association.

Despite the serious consequences of poor blood glucose control, only 37 percent of patients with diabetes are achieving the level of control recommended by the American Diabetes Association (ADA).⁴ The reasons for poor control are myriad and complex; they include lack of patient motivation, denial of the disease, and difficulties caused by co-morbid conditions. Certainly, however, the inherent difficulty of glucose management stands as a central barrier to maintaining tight control.

Achieving good glucose control is especially demanding for patients who are exclusively on insulin therapy. Due to a variety of physiological factors, these patients' blood glucose levels fluctuate constantly throughout the day. A reading from an episodic monitor only provides patients with information on their glucose level at a single point in time. The reading does not indicate if a level is dropping or rising—information that could make a critical difference in the outcome of a therapy decision. Lack of information on trending of blood glucose also means that today's episodic monitors cannot actively warn patients of impending hypoglycemia, a potentially life-threatening complication that occurs more frequently as patients attempt tighter blood glucose control.

In addition, today's monitors are burdensome to use. Given the disruption and discomfort caused by existing glucose monitoring methods, even highly vigilant patients often find it difficult to test their blood glucose levels as frequently as recommended (i.e., typically three or more times per day for diabetes patients exclusively on insulin therapy).

EMERGING, CONTINUOUS MONITORING TOOL PROMISES HIGH IMPACT

A Developing Technology

Continuous glucose monitoring (CGM) devices have been in development for the past 30 years. First-generation devices are on the market today, but they are FDA-approved for adjunctive use only; i.e., they can only be used to supplement the information provided by episodic glucose readings. As a result, current CGM-generated data are not to be used as the sole basis of a treatment decision. They are primarily used in the clinician setting for glucose trend analysis and less so by patients for daily management.

Already, many forces are working to advance the development of CGM technology. Because it has the potential to overtake a large portion of the \$5 billion blood glucose monitoring market, both large and small companies are investing significant capital in research and development in CGM.^{5,6} The Juvenile Diabetes Research Foundation has also made CGM a top priority. In addition, the National Institute of Diabetes and Digestive Kidney Diseases and the National Institute of Child Health and Human Development are supporting a project called DirecNet, which is testing the clinical impact of CGM on type 1 patients.^{7,8}

On The Five-Year Horizon

Given the level of development activity, experts predict a viable product that can be used as a replacement for today's episodic monitors will likely gain FDA approval for commercial use within five years. These new devices will provide patients with important information not available today, such as the rate of change in glucose levels. They will also be designed with alarms that alert the patient when a glucose level is becoming too high or too low. Continuous data will allow clinicians to study a patient's glucose trends over time. Such trend analysis can be used to troubleshoot problems and titrate treatment. In addition, continuous data can be fed into a decision support tool that can—with a few inputs from the patient—provide a suggested insulin dose. Finally, the new devices will be compact and relatively unobtrusive to the patient, allowing them to be worn or carried more discretely than today's CGM models.

Advanced Devices Will Deliver High Value

Using cost-effectiveness methods and expert estimates of costs and capabilities of advanced CGM devices, we developed an economic model to forecast the likely value of the technology. Our calculations indicate that long-term, daily use of future CGM devices will result in a cost-effectiveness ratio of approximately \$51,000 per quality-adjusted life year (QALY), which is well within traditionally accepted standards for cost-effectiveness.⁹

Conservatively, this forecast of cost-effectiveness does not assume an improvement in daily patient quality of life from use of CGM devices (e.g., reduced hypoglycemia). If, as many expect, CGM demonstrates the ability to improve patient quality of life, the technology will present even greater value. For example, CGM may improve patient quality of life by providing a measure of freedom from blood glucose monitoring kits and minimizing disruption to daily activities. At the same time, CGM devices can ease stress by alerting patients before their glucose levels reach a dangerous point.

HOWEVER, SIGNIFICANT BARRIERS TO ADOPTION REMAIN

Despite the high potential value of this technology and the forces driving it forward, significant barriers remain that, if left unaddressed, will slow down the introduction of even the best CGM devices.

Replacement Labeling Critical, But Elusive

More patients are likely to use CGM devices if they are FDA-approved as a replacement for episodic monitoring. Yet to date, this labeling for CGM has

eluded the industry due to concerns over point-in-time accuracy when compared to today's episodic monitors.

It is possible that the additional information that CGM provides (i.e., rate and direction of change in glucose levels, along with continuous measurement) could redefine how accuracy is measured and enable patients to make more appropriate treatment decisions. While manufacturers must continue to improve the accuracy of CGM technology, the FDA must also be willing to consider a new accuracy standard, or risk delaying the approval of a CGM device that could greatly aid a significant number of diabetes patients.

Reimbursement and Administrative Challenges

For CGM to receive broad-scale coverage as an outpatient device, manufacturers must demonstrate CGM's value relative to current episodic monitoring methods. This requires significant investment in large, randomized clinical trials which can clearly isolate and quantify the improved patient outcomes that come from the use of CGM. Currently, these efforts are stymied due to a lack of clarity regarding the evidence needed to demonstrate such value. Moreover, even after value is demonstrated in clinical trials, the challenges associated with gaining coverage, coding and reimbursement could slow the deployment of a valuable CGM device.

Challenges to Clinician Adoption

Even if a CGM device is covered and properly reimbursed, it can still face significant challenges to clinician adoption. Clinician acceptance of CGM will be critical to its adoption since the devices will likely either be administered by clinicians or require a physician prescription. Yet in order to adopt the technology, clinicians will need sufficient resources and support from a health care system that is not currently positioned to provide coordinated chronic care. For CGM, the key issues to overcome are time limitations, payment-based limitations on care techniques, and poor adherence to clinical guidelines.

Need for Patient Involvement and Education

For CGM to be successful, patient acceptance is critical. As such, manufacturers must make efforts to ensure adequate patient input and involvement in the product design process. Once the device is ready for widespread use, patients will require extensive education on how to translate the valuable information CGM provides into beneficial treatment adjustments.

Patient adherence to clinician-recommended self-care has been a long standing problem in diabetes management. While CGM has the potential to reduce many barriers to improved patient adherence, it does not reduce them all. An improved monitoring technology will likely have little effect on societal problems such as lack of access to health insurance and poor socioeconomic status, or a range of other issues, such as a basic lack of motivation to manage one's disease or an inability to cope with the burden and complexity of multiple co-morbid illnesses. Because appropriate use of CGM will require active patient self-management, it is likely that these same factors will also impact the technology's adoption. Patients will need significant resources and incentives to overcome these fundamental barriers to quality health care.

PLANNING FOR INNOVATION: NEXT STEPS

Fortunately, stakeholders can take steps now that will both improve diabetes care and support the development, proper use and adoption of CGM. NEHI recommends that relevant stakeholders pursue the following course of action as soon as possible:

Coordinate Standards and Evidence for Regulatory Review

- Create a pragmatic consensus on accuracy standards for CGM, in order to enable the timely and appropriate evaluation by the FDA.
- Determine how evidence used in the regulatory approval process could also be used for the coverage decision process, leveraging any similarities in data requirements.

Take Steps to Improve Reimbursement

- Specify trial design, endpoints and the appropriate level of evidence that manufacturers must demonstrate for coverage, in order to speed the coverage review process.
- Improve reimbursement for new clinician services and diabetes support staff.
- Identify financial incentives that can realistically drive outcomes-focused diabetes care and improve patient self-management.

Set Stage for Efficient, Clinical Use

- Anticipate how CGM can be best integrated into the clinical setting and ensure ease-of-use by clinicians.
- Plan for the continued evaluation of CGM as it becomes more broadly deployed, to identify the most appropriate types of use and target subpopulations.

Lay Groundwork for Patient Acceptance

- Gather and evaluate patient input on CGM device designs to ensure greater appeal to patients.
- Create the infrastructure required to educate patients on the use of continuous data.

CONCLUSION

As an emerging innovation poised to help millions of diabetes patients manage their disease more effectively, CGM's future is extremely promising. NEHI's findings indicate that future CGM devices have the potential to be highly valuable and cost-effective tools in managing diabetes, particularly for long-term, daily management. While critical forces are working to advance CGM, significant barriers still remain. Given CGM's promise and, most importantly, its future benefit to patients, stakeholders must take up the call of action to pave the way for the successful and timely adoption of this innovation.

Endnotes

¹ U.S. Centers for Disease Control and Prevention. Diabetes: Disabling, Deadly, and on the Rise. Available at: http://www.cdc.gov/nccdphp/aag/aag_ddt.htm. Accessed on February 1, 2005.

² The DCCT Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine*. 1993;329:9770-986.

³ UKPDS Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes(UKPDS 33). *Lancet*. 1998; 352:837–853.

⁴ Saydah S, Fradkin J, Cowie C. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291:335-342.

⁵ Expert Interview

⁶ Jasper B. Abbott to acquire diabetes test maker. *Chicago Tribune*. 14 Jan. 2004: Business 1.

⁷ USAMRC Military Operational Medicine Research Program. The Technologies for Metabolic Monitoring (TMM) and Julia Weaver Fund (JWF) Research Program. Available at: <http://www.momrp.org/67.htm>. Accessed January 4, 2005.

⁸ DirecNet. Presentations. Available at: http://public.direc.net/slides/TamborlanePresentationSlides10-25-02_files/frame.htm. Accessed December 14, 2004.

⁹ “While there is no accepted standard for what constitutes good value, the range from \$50,000 to \$100,000 per QALY has often been used as a rough benchmark for the United States. Evidence from some quarters suggests that this is too low. The most common source supporting the \$50,000 threshold seems to be Medicare's decision in the 1970s to cover dialysis in patients with chronic renal failure at a C/E ratio within this range.” Source: Harvard School of Public Health. The CEA Registry: Standardizing the Methods and Practices of Cost-Effectiveness Analysis. Available at: <http://www.hsph.harvard.edu/cearegistry/faq.html#AcceptableQALYthreshold.htm>. Accessed February 21, 2005.