



## Fixing the Black Hole in Diabetes Management



POSITIVEID CORPORATION

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## 1. Diabetes: The Disease and its Health Burden

Diabetes is a disease in which the body does not produce or properly use insulin. Its cause continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles.<sup>1</sup> According to the American Diabetes Association (ADA), there are an estimated 23.6 million children and adults in the United States, or 7.8% of the population, who have diabetes, 18 million of which have been diagnosed with diabetes and 5.7 million people (24%) who are undiagnosed.<sup>1</sup> Worldwide, the figure is much more daunting, with diabetes affecting 246 million people and expected to affect 380 million by 2025.<sup>2</sup> On a global level, the percentage of undiagnosed cases is much higher (50%), and in some countries this figure may reach 80%.<sup>2</sup> The International Diabetes Federation (IDF) estimated that diabetes caused 3.8 million deaths worldwide in 2007, or about 6% of total global mortality -- about the same as HIV/AIDS. This makes diabetes the fourth leading cause of global death by disease. Using the World Health Organization (WHO) figures on *years of life lost* per person dying of diabetes, this translates into more than 25 million years of life lost each year. An additional 23 million years of life are lost to disability and to reduced quality of life caused by the preventable complications of diabetes.<sup>2</sup>

Five to ten percent of Americans diagnosed with diabetes have type 1, a product of the body's failure to produce insulin, the hormone that "unlocks" the cells of the body. More common (90-95%) is type 2, which results from insulin resistance (a condition in which the body fails to properly use insulin), combined with relative insulin deficiency.<sup>1</sup> Those with type 2 diabetes are over twice as likely to have a heart attack or stroke as those who do not have diabetes, with cardiovascular diseases being the major cause of death in diabetes, accounting for 50% of all diabetic fatalities. Type 2 diabetes has become the most frequent condition in people with kidney failure in Western countries. The reported incidence varies between 30% and 40% in countries such as Germany and the U.S.

## 2. Diabetes: The Economic Burden

Needless to say, the disease and its health complications amount to huge health care costs. A study commissioned by the ADA in 2002 examined the direct medical and indirect productivity-related costs attributable to diabetes, and calculated the total and per capita medical expenditures for people with and without diabetes. In this study, direct medical expenditures alone totaled \$91.8 billion -- \$23.2 billion for diabetes care, \$24.6 billion for chronic complications attributable to diabetes, and \$44.1 billion for excess prevalence of general medical conditions.<sup>3</sup> In addition, 51.8% of direct medical expenditures were incurred by people >65 years old (\$47.6

billion), all or most of whom are Medicare or Medicaid recipients. Attributable indirect expenditures resulting from lost workdays, restricted activity days, mortality, and permanent disability due to diabetes totaled \$39.8 billion. <sup>3</sup>

A more recent study published in a leading pharmacoeconomics journal found that U.S. hospitalizations numbered approximately 30.8 million and individuals with diabetes accounted for over 6.4 million (20.9%) of these admissions.<sup>4</sup> For every 1000 individuals without diabetes, with type 1 diabetes or type 2 diabetes, the corresponding numbers of hospitalizations equaled 89, 418, and 303, respectively. In 2005, hospital charges alone and medical costs for individuals with diabetes exceeded US\$171 billion and US\$90 billion, respectively.<sup>4</sup> Total U.S. health expenditures according to this pharmacoeconomics study were \$865 billion, of which \$160 billion, or 18.5%, was incurred by people with diabetes. Per capita medical expenditures totaled \$13,243 for people with diabetes and \$2,560 for people without diabetes. <sup>4</sup>

This figure is in line with those of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which states that diabetic Americans have per capital medical expenses and out-of-pocket expenses two to five times higher than people without diabetes.<sup>7</sup> According to the NIDDK, the above mentioned costs are higher because diabetics visit physician's offices, hospital outpatient departments, and emergency rooms more frequently than their non-diabetic counterparts and are more likely to be admitted to the hospital.<sup>7</sup>

Government-funded programs are responsible for health care coverage for 57.4% of adults with diabetes, including 26.4% of those age 18-64 years and 96.0% of those age 65 years. Virtually all (97.2%) diabetic people who are covered by Medicare have both Medicare Part A and Part B2. Coverage for prescription medicines occurs for 62.9% of people with diabetes through private insurance, Medicaid, and military sources, including 71.2% of those age 18-64 years and 52.6% of those age 65 years.<sup>5</sup>

As aforementioned, 23.6 million Americans in 2007 had diabetes; this is a 13.5% increase from the 20.8 million in 2005. Another 57 million have pre-diabetes. Many factors contribute to this rise, including higher prevalence of overweight and obesity, changes in diagnostic criteria, improved or enhanced detection, decreasing mortality, a growing elderly population, and growth in minority populations in whom the prevalence and incidence of diabetes are increasing. By 2050, the CDC predicts 48.3 million Americans will have diabetes - an *epidemic* that shows no signs of abating.<sup>8</sup>

Diabetes health complications, the associated loss of productivity and the enormous health expenses of the disease have a grave impact not only on diabetic patients and their families, but on federal and state governments and society as a whole.<sup>8</sup>

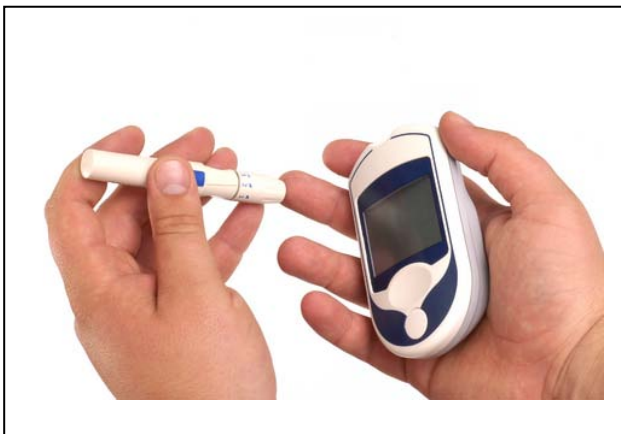
**«By 2050, the CDC predicts that 48.3 million Americans will have diabetes – and epidemic that shows no signs of abating»**

### 3. Disease Management Today

Therapy for both type 2 diabetics (T2D) and type 1 diabetics (T1D) includes pharmacological agents in addition to medical nutrition therapy and increased physical activity. Pharmacological agents are oral antihyperglycemics, synthetic hormones and/or insulin. These medications are frequently changed and/or adjusted depending on a patient's response to therapy and blood glucose levels.

There are two basic tests for monitoring diabetes: (1) the A1C test -- a blood test performed in a physician's office or laboratory that reflects the average blood glucose level over the last three months, and (2) the SMBG (self-monitoring blood glucose) test -- which is performed by the patient before meals, after meals, and/or at bedtime. Frequency of the latter depends on the severity of the disease on the insulin dependency. In general, the ADA recommends testing three to four times daily for type 1 diabetes, and once daily for type 2 diabetes treated pharmacologically. All therapy is geared toward reaching target A1C goals (normal to lower levels), which correlate to the average plasma blood glucose in a person's body.

According to all diabetic stakeholders -- organizations, associations, healthcare practitioners, providers and patients -- the SMBG is a cornerstone of self-management for the person with diabetes, regardless of whether they have type 1, type 2 or gestational diabetes.



However, this test is only useful when health care providers and patients utilize the results of SMBG to improve glycemic control and achieve long-term goals through pharmacotherapy changes and lifestyle decisions.<sup>12</sup> The SMBG is also helpful for patients in detecting acute hypoglycemia or hyperglycemia. More importantly, however, this test allows patients to better manage their disease, promoting disease education and thereby motivating patients toward healthier behavior.<sup>11</sup>

Unfortunately, this test is not performed or utilized effectively. In a large cross-sectional study examining SMBG practice patterns and barriers in 44,181 diabetic adults in a managed care setting, 60% of patients with type 1 diabetes and 67% of those with type 2 diabetes reported practicing SMBG less frequently than recommended by the ADA.<sup>13</sup> These testing figures have been corroborated by other studies in diabetic patients.<sup>13</sup> One of the reasons cited for the infrequent testing was financial as some of these patients incurred high out-of-pocket expenditures for test strips. The authors of this study concluded that removal of financial barriers by providing more comprehensive coverage for these costs may enhance adherence to recommendations for SMBG.<sup>13</sup>

Recently there has been debate as to the optimal frequency of SMBG testing. One study examined the effect of measuring SMBG once weekly as opposed to four times weekly in T2D patients treated with oral antihyperglycemics. This study found that the once-a-week testing was

not associated with any deterioration in metabolic control (HbA1c) or therapeutic safety as compared to testing four times a week. The authors concluded that compliance for this low frequency of SMBG was surprisingly high and that implementing the study results in clinical routine would result in considerable cost-savings and convenience for T2D patients.<sup>14</sup> Not surprisingly, these conclusions are not shared by the major medical societies such as the American Association of Clinical Endocrinology (AACE), medical groups, patient groups, diabetes foundations or other major players such as the ADA, all who advocate testing once a day or four times a day for T1D and T2D patients, respectively.<sup>15</sup>

Thus far, this debate has not extended to insulin-treated T1D and T2D patients, whose glucose levels are more fragile. For these patients, extensive and accepted national and international guidelines on testing frequency exist. Moreover, there has been sound evidence as to the benefits of regular and frequent SMBG testing in T1D and T2D patients on insulin treatment as well as for T2D patients who are not on insulin therapy. Davidson and colleagues demonstrated an inverse correlation between frequency of SMBG and A1C values in T1D patients; the more times per day that patients tested their blood glucose levels, the lower their A1C. The frequency reaches levels of diminishing returns after six to seven tests per day. Strowig and colleagues reported similar results; specifically, a 0.25% decrease in A1C for each SMBG test per day, with a leveling off at eight tests per day. In a retrospective study of more than 24,000 insulin-treated patients, Karter and colleagues found that increased frequency of SMBG correlated strongly with improved A1C regardless of the type of diabetes or therapy used. A more recent study with 5,862 veterans found that more frequent testing was associated with a significantly lower A1C and that this effect ranged from -0.22% to -0.94% for every 10 glucose test strips per week.<sup>16</sup>

The studies above show that frequent testing results in statistically and clinically significant improvements in A1C (reductions ranging 2.5-4.0%). These reductions correlate to better glycemic control, better health and, eventually, fewer health care costs. Nesser and colleagues performed a health economics study assessing the clinical impact and related costs when SMBG is performed by non-insulin treated patients. For their study, they assumed a slight to moderate improvement in A1C (0.39%). According to their model, this correlated to a slight increase in life expectancy and a reduced cost of complications, 70% of which was attributable to reductions in microvascular events. Nesser and colleagues concluded that the cost per life-year gained was approximately \$39,650, a cost-effective intervention from a health economics perspective.<sup>17</sup> One can conclude from the body of scientific evidence that following established SMBG testing guidelines not only promotes better health in diabetic patients, but also results in lower health care costs.

Nevertheless, barriers to more frequent testing are many, among these educational, financial and motivational. Patients are also supposed to log the results of their daily tests and present this log to their physician for proper disease management (a macro view). However, as cited before, the majority of T1D and T2D patients do not check their blood glucose with optimal frequency (*non-compliant* patients) and most of these do not keep test logs. The same holds true for *compliant* patients (those that test with optimal frequency). Thus, the results of one of the most

frequent tests performed nationwide (SMBG) are figuratively going into a “black hole” as they are not being used in an effective way to manage the disease.

#### 4. Medications and Supplies: Facts, Figures & Fraud

As previously mentioned, diabetes poses a heavy economic toll on the U.S. healthcare system. It accounts for approximately 21% of hospital admissions, with an accompanying price tag for hospitalizations alone of \$160 billion – with the government funding 60% of these expenditures in adults. These figures do not include the costs of outpatient medications and supplies.

In 2002, the costs for insulin and delivery supplies, oral agents to lower blood glucose, and other outpatient medications in the United States attributable to diabetes were estimated at \$7.0 billion, \$5.0 billion, and \$5.5 billion, respectively. This represented 13% of the total health care expenditures attributable to diabetes in 2002. With the prevalence of diabetes in the US expected to more than double by 2050, the cost for diabetic supplies alone will exceed \$40 billion.<sup>8</sup>

Besides screenings, physician visits, exams and other, Medicare Part B covers diabetic supplies for all beneficiaries, including blood glucose testing monitors, blood glucose test strips, lancet devices and lancets, regardless of whether the patient is insulin-treated. However, the amount of supplies that are covered varies. Insulin-treated patients are eligible for up to 100 test strips and lancets every month, and one lancet device every 6 months. Non-insulin treated patients may be able to get 100 test strips and lancets every 3 months, and one lancet device every 6 months if the patient’s physician deems it is medically necessary.<sup>19</sup>



For Medicare, “medically necessary” means that services or supplies are needed for the diagnosis or treatment of that patient’s medical condition and meet accepted standards of medical practice. Patients are responsible for a 20% co-payment of the Medicare-approved amount after the yearly Part B deductible. Medicare Part D covers certain medical supplies for administration of insulin (like syringes, needles, alcohol swabs, gauze, and inhaled insulin devices). Coinsurance or copayment Part D deductible may also apply.<sup>19</sup>

Medicaid patients are eligible for the same benefits, with the difference being that Medicaid bears 100% of the cost as the beneficiaries are, in most cases, below the poverty level (as defined by the government). Invariably, the large amount of patients, coupled with the large expenditure – principally borne by the two government programs (Medicare and Medicaid) - has led to a vast amount of healthcare fraud. Healthcare fraud is defined as the deliberate

submittal of false claims to private health insurance plans and tax-funded public health insurance programs such as Medicare and Medicaid.<sup>20</sup> Since the early 1990s, healthcare fraud has become a serious and escalating nationwide crime.

In 1997 Congress established the Health Care Fraud and Abuse Control Program (HCFACP) dedicated to fight Medicare and Medicaid fraud and abuse. One of the key areas identified by the HCFACP is criminal fraud cases for durable medical equipment (DME) suppliers, prosthetics, orthotics and suppliers (POS), especially in South Florida and California.<sup>17</sup> Due to the amount of fraud, the fiscal year budget for HCFACP in 2008 was \$1.3 billion – allocated to strengthening program oversight and reducing improper payments in Medicare and Medicaid.

In one example in late 2006, the HCFACP, working with the Department of Justice (DOJ), formed a Medicare Fraud Strike Force to combat fraud through the use of real-time analysis of Medicare billing data by DMEPOS suppliers, many of these for diabetic supplies. In just three months, 56 individuals were charged in South Florida alone with fraudulently billing Medicare for more than \$258 million.<sup>6</sup> Nationwide, the amount of fraud is staggering – in 2007, the National Healthcare Anti-Fraud Association (NHCAA) estimated that at least 3% of the nation's healthcare expenditures, or \$68 billion, was lost to outright fraud. Other estimates by government and law enforcement agencies place the loss as high as 10% of our annual expenditures, or as much as \$226 billion each year.<sup>21</sup>

**«Fraud accounts for as much as 10% of the nation's annual healthcare expenditures, or as much as \$226 billion per year»**

In one of the many efforts to combat fraud, the Centers for Medicare and Medicaid Services (CMS) enacted in December 2008 Medicare Part B Utilization Guidelines for local coverage determination (LCD) for Glucose Monitor (L196) and Policy Article for Glucose Monitor (A33673). These guidelines establish who is covered, what is covered (accessories & supplies), how much is covered (utilization & over-utilization guidelines) and what documentation is required.<sup>31</sup> These new guidelines mandate that if quantities of supplies dispensed exceed guidelines, documentation in physician's or supplier's records must indicate that: (1) patient *testing frequency corroborates with* quantity dispensed, (2) narrative statement or beneficiary's log, (3) new documentation at least every six months for patients that regularly use quantities exceeding guidelines. Other important mandates were requirements for additional documentation evidence such as:

- > Diagnosis
- > Reason for prescribed frequency of testing
- > Physician's evaluation closest to date of service
- > Documentation indicating actual testing frequency
- > Beneficiaries testing log or physician's records

- › Evidence supplies nearly exhausted prior to refill<sup>31</sup>

Stricter requirements alone will only go so far in combating fraud. For that reason, programs such as the HCFAACP, the Medicaid Integrity Program and associations such as the NHCAA (funded by private and government), are increasingly turning to technology, specifically electronic medical records (EMRs), as a means of combating fraud – preventing, detecting as well as minimizing opportunities for fraud. <sup>22</sup>

## 5. Electronic Medical Records and its Role in Patient Care & Fraud

In 2004, the Office of the National Coordinator for Health Information Technology (ONC) was created to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure with the goal of improving the quality and efficiency of health care. This office resides within the Office of the Secretary of Health and Human Services.<sup>24</sup> The ONC has worked to develop a Federal Health IT Strategic Plan to achieve the nationwide implementation of this technology infrastructure throughout both the public and private sectors within the 2008-2012 timeframe. The ultimate goal of this plan is for most Americans to have an electronic health records (EHR) by 2014. The HHS defines an EMR as a “computer-based electronic health record containing a wide range of documentation, including multimedia elements (e.g., EKG output, heart and lung sounds) and digitized photographs (e.g., rashes, retina changes).” <sup>28</sup>

Other definitions include EMR as encompassing: “(1) longitudinal collection of electronic health information; (2) immediate electronic access to person- and population-level information by authorized users; (3) provision of knowledge and decision-support systems; and (4) support for efficient processes for health care delivery.”<sup>29</sup> The terms EMR and EHR are now used interchangeably. This is not the same for electronic patient records (EPR) which have been defined as encapsulating a record of care provided by a single site, in contrast to EMR/EHR which are longitudinal and carried out across different institutions and sectors.<sup>29</sup>

In, 2005 the HHS formed a national collaboration, the American Health Information Community (AHIC), a public-private body, to aid with the transition of the nation to EHRs in a smooth, market-led way. Given the rising tide of fraud, the top priorities of the AHIC were to study how to use health information technology (HIT) to enhance and expand fraud management and to examine the state of automated coding software and its development to enhance anti-fraud activities.<sup>26</sup> Two separately commissioned AHIC studies concluded that technology can play a critical role in detecting fraud and abuse and “help pave the way toward prevention.” The studies found that technology will not be able to eliminate fraud; but it can “significantly minimize fraud and abuse, and ultimately help improve the bottom line.”<sup>26</sup>

According to the studies, effective healthcare fraud management requires:

- AHIC certifying EHR software features and functions that are required or prohibited in the healthcare technology infrastructure such as:
  - a. Standardized reference terminology
  - b. Up-to-date classification systems that facilitate the automation of clinical coding
- Incorporating fraud management functionality into software programs
- Defining and enabling interoperability standards between multiple EHRs
- Linking claims with corresponding documentation from an EHR
- Ability to access information in other EHRs regarding the same patient
- Applying advanced analytics to aggregate clinical and financial databases <sup>25,26</sup>

This last point has proven very effective for the financial services industry and could be applied to the health care industry. Financial entities use automated systems to monitor behavioral spending patterns, identify anomalies, verify consumer identities, and gather data about the individual to continue to strengthen the consumer's profile.

The economic stimulus passed in early 2009, will create important national HIT interoperability standards. These standards are essential to achieve the promise HIT holds to help increase patient safety, improve care coordination and reduce unnecessary paperwork.<sup>23</sup>

In many respects EMRs are still in an infancy stage, and the OMC's goal of having an EMR for most Americans by 2014 may not be realized. However, it is recognized that technology, specifically EMRs, have an enormous potential of addressing the issue of healthcare fraud through real-time tracking, monitoring, and auditing health data electronically. Ultimately, and more importantly, technology will provide better patient care through the management of medical information and its secure exchange between patients and providers.

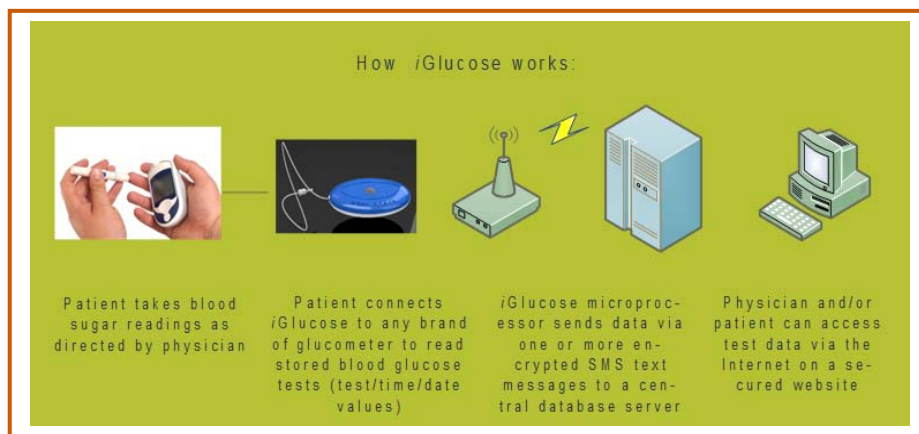
## 6. iGlucose: Managing Diabetes, Managing Fraud

It is no surprise that many healthcare studies have found that patient care and overall health improves when there is a high quality of patient-clinician collaboration. In the area of diabetes, the Diabetes Attitudes, Wishes, and Needs (DAWN) study showed that suboptimal patient-clinician relationships and limited access to coordinated care correlated with poor self-management and control.<sup>30</sup> The DAWN study was a qualitative, cross-sectional survey of 5,000 patients with type 1 or type 2 diabetes in 13 countries. The study also found that the opposite was true (i.e. better regimen adherence in all domains) when there were optimal patient-clinician relationships.

As mentioned in Section 2, most diabetics do not follow recommended SMBG testing guidelines. Moreover, those that do may not share the SMBG test results with their healthcare providers. While the results may be useful for detecting acute hypoglycemia or hyperglycemia, they are not being used to improve glycemic control and achieve long term

goals. Thus, the results of one the most frequent worldwide daily tests, are effectively being lost in a “black hole.” Further, the lack of monitoring or oversight of these patient test result logs continue to contribute to healthcare fraud, specifically for overbilling or false billing diabetic testing supplies by DME suppliers – until now.

The *iGlucose* is a wireless, seamless device which connects to any glucometer to send blood glucose data to a central database where it can be accessed by physicians and patients to better manage their disease. *iGlucose* works automatically – there is no downloading, dialing, computer, software or cell phone needed to complete the transmission. Patients simply connect the *iGlucose* to their glucometer and the test results stored on the glucometer are transmitted as SMS messages to a central server (see figure below). Patients can choose the frequency and destination of glucose data and reports. An important feature of *iGlucose* is its compatibility with any data-capable glucometer, making it device or manufacturer independent.

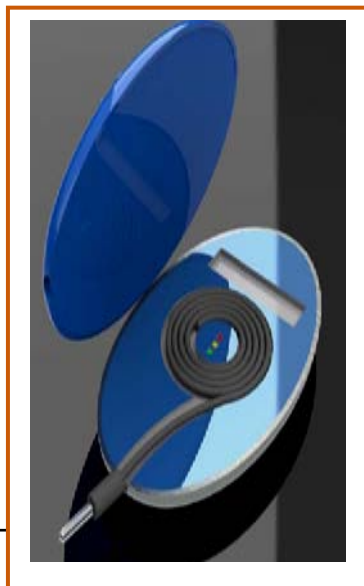


Physicians can easily access these accurate test logs online through a user-friendly website. They can provide better patient care by implementing best practices in medication therapy management (MTM). This in turn can generate significant savings to the health system through better disease management. An essential component of *iGlucose* is that practitioners can now be fully compliant EMRs for Medicare Part B Utilization guidelines.

The obvious benefits of *iGlucose* are improved health through real-time disease management. Patients can simplify their lives by eliminating logs and glucose record keeping. Frequently,

increased monitoring – in this case by the patient’s physician -- might lead to better self-management of diabetes through more frequent testing.

Payors enjoy significant savings through better management of diabetes and its complications. More importantly, *iGlucose* can serve as an anti-fraud measure as it provides a real-time system for accessing patient EHRs and linking DME supplier reimbursement claims of glucose monitoring suppliers with corresponding documentation.



## 7. Conclusion

Diabetes is a growing epidemic in the U.S. and worldwide, carrying with it an enormous economic and health burden. As disease prevalence grows, so do associated healthcare costs including physician visits, testing, hospitalizations, medications and diabetic testing supplies. Unfortunately, this has given rise to billions of dollars of healthcare fraud, particularly from DME suppliers. Although the government has taken many steps to counter fraud, the sheer amount of fraud outweighs any agency's ability to effectively combat it on a large scale.

Healthcare technology has been cited as a means to improve patients' health and combat fraud. Specifically, EMRs are believed to play an important role in the latter through the ability to electronically monitor reimbursement claims, identify anomalies and gathering data.

The *i*Glucose device provides a system for real-time diabetes management and as an anti-fraud measure. The device can lead to improved patient compliance, fewer disease complications, better overall health and lower healthcare costs.

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## *i* Glucose

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