

On the bus or under the bus? Is the current healthcare system is endangering elderly diabetes patients

Abstract

A large percentage of the diabetes population in the U.S. is over the age of 65. Elderly individuals with diabetes are at the greatest risk for hypoglycemia. Two U.S. regulatory agencies, the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS), are responsible for protecting the safety of these individuals by providing access to safe and effective diabetes treatment. Self-monitoring of blood glucose is a key component of diabetes management; however, neither the FDA nor CMS are meeting their obligations to ensure access to accurate glucose monitoring systems. This article presents an overview of these failings and discusses how medical associations and patient advocacy groups are working to address this troubling situation.

Keywords: diabetes, medicare, glucose monitoring, competitive bidding program, hypoglycemia

Volume 2 Issue 1 - 2015

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Received: December 17, 2014 | **Published:** January 20, 2015

Abbreviations: AACE, american association of clinical endocrinologists; AADE, american association of diabetes educators; ACE, american college of endocrinology; CBP, competitive bidding program; CE, conformite europeenne; CMS, centers for medicare and medicaid services; EASD, european association for the study of diabetes; FDA, food and drug administration; MDR, medical device reporting; NDVLC, national diabetes volunteer leadership council; SMBG, self-monitoring of blood glucose; T1DM, type 1 diabetes; T2DM, type 2 diabetes

Introduction

Elderly patients are at high risk for hypoglycemia

Among the estimated 29.1million people in the United States with diabetes, 11.1million (25.9%) are 65years of age or older.¹ Although achievement of optimal glycemic control has been shown to prevent or slow the development of the microvascular and macrovascular complications associated with diabetes,²⁻⁴ efforts to prevent hypoglycemia in elderly diabetes patients should be a priority among healthcare providers, payers and regulatory agencies.

Studies have shown that the risk of severe or fatal hypoglycemia associated with the use of oral agents or insulin increases exponentially with age.^{5,6} A recent report found that insulin-treated patients 80years or older were more than twice as likely to visit the emergency room and nearly five times as likely to be subsequently hospitalized for insulin-related hypoglycemia than patients age 45 to 64years.⁷ Although severe hypoglycemia in individuals with insulin-treated type 2 diabetes (T2DM) is not as common as in individuals with type 1 diabetes (T1DM), duration of insulin treatment is a key predictor of severe hypoglycemia in this population.⁸

Importance Of Self-Monitoring Of Blood Glucose (SMBG)

A key strategy for preventing or reducing the occurrence of

hypoglycemia is use of self-monitoring of blood glucose (SMBG). Widely recognized as a core component of effective diabetes self-management, SMBG provides immediate information about current blood glucose levels, which enables patients to take immediate action to address current or impending hypoglycemia, guide pharmacologic therapy and support health behaviors.

The American Diabetes Association recommends that diabetes patients treated with MDI or insulin pump therapy should perform SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose and prior to critical tasks such as driving.⁹ The American College of Endocrinology (ACE) recommends that individuals with type 2 diabetes who are on any medications that can cause hypoglycemia (e.g., basal insulin, sulfonylurea), especially the elderly, who are more prone to hypoglycemia, should also perform frequent monitoring; 3-5times per day for this population.¹⁰

Although use of SMBG facilitates improved glycemic control in individuals with type 1 diabetes (T1DM)² and type 2 diabetes (T2DM),¹¹⁻¹³ the benefits of SMBG can only be realized when patients have unimpeded access to accurate and blood glucose monitoring systems. Unfortunately, the recent changes in Medicare reimbursement for blood glucose testing supplies and failure of the U.S. Food and Drug Administration (FDA) to enforce its own regulations regarding product performance not diminish the use and clinical value of SMBG but actually threaten the safety of our most vulnerable diabetes population.

The dangers of inaccurate SMBG systems

Because SMBG data are used in clinical decision-making, it is critical that the data are consistently accurate. Inaccurate glucose information can lead to severe and even deadly consequences, either by failing to detect hypoglycemia or over-correction with insulin based on an erroneous high glucose result.¹⁴ Although several factors can impact SMBG accuracy, the inherent accuracy of SMBG systems

has gone unquestioned because the FDA must determine that all SMBG systems are safe and effective before they can be marketed in the US. Thus, it is assumed that these systems will provide accurate test results. However, this is not always the case.

Several recent studies have revealed significant inaccuracy and lot-to-lot variability in up to 45% of the SMBG systems currently marketed.¹⁵⁻¹⁸ Importantly, most of these systems are manufactured offshore and marketed at much lower prices than branded systems. Moreover, most of the manufacturers of these systems provide inadequate or no medical device reporting (MDR) of adverse events associated with the use of their systems. This is in direct violation of FDA requirements.¹⁹ Due to this lack of information, the clinical impact of the SMBG systems demonstrated to be inaccuracy of is unknown.

Because of similar concerns with accuracy and safety, the European Association for the Study of Diabetes (EASD) recently called for an urgent overhaul of the current Conformite Europeenne (CE) marking procedure for the evaluation and approval of SMBG systems and other medical devices, proposing comprehensive evaluation of such devices by independent research institutions (including *in-vitro* and real-life studies) and continuous post-marketing surveillance of the SMBG systems that are approved.²⁰

The reason why the FDA allows the known manufacturers of these inaccurate systems to continue marketing their products in the US is unknown. The FDA has publically stated that they have tools to effectively ensure that SMBG perform within labeled levels, including a number of enforcement options such as product recalls, seizures, safety alerts, warning letters, injunctions, civil money penalties and the authority to prevent distribution of such meters. Yet, virtually no action has been taken to remove these unsafe SMBG systems from the market.

Impact of the competitive bidding program on access to quality SMBG systems

In January 2011, the Centers for Medicare & Medicaid Services (CMS) initiated its Competitive Bidding Program (CBP) in nine test markets that included 2.3million Fee-for-Service Medicare Part-D beneficiaries. According to CMS data, approximately 475,000 beneficiaries with insulin-treated diabetes resided in those markets at that time.²¹ The goal of the program is to reduce beneficiary out-of-pocket expenses and save Medicare money while ensuring beneficiary access to quality items and services. In 2012, CMS reported that “beneficiaries’ access to necessary and appropriate items and supplies was preserved and that the rate of use of hospital services, emergency room visits, physician visits, and skilled nursing facility care remained consistent with the patterns and trends seen throughout the rest of the country”.²²

However, results from a survey conducted by the American Association of Diabetes Educators (AADE) found that access was, in fact, disrupted.²³ According to the AADE, the mail-order providers of diabetic supplies offered only 38% of the branded SMBG systems claimed to be offered on the www.medicare.gov website, which meant that beneficiaries had restricted (or no) access to the diabetes test strips they had previously been using. When the CBP was launched nationally in July 2013, CMS reimbursement for test strips was reduced from approximately \$35 to \$10 per bottle of 50 strips, which likely will dissuade many pharmacies from even serving Medicare beneficiaries. As a result, many beneficiaries may be forced to locate

(and secure transportation to) another pharmacy. It remains to be seen whether this potential disruption of access impacted patient adherence to their testing regimens. We suspect that it has.

It is also troubling that clinicians are often unaware of the SMBG systems their patients are using due to “switching” branded to low cost products either by the mail order distributor or pharmacy. This results in a “disconnect” between clinicians and patients, which increases the potential for inadequate patient training, resulting in even greater and more frequent inaccuracies due to user error.²⁴

What we know and don’t know

We know that the FDA and an increasing number of clinicians are now aware that many of the SMBG systems do not meet the minimum standards for accuracy and precision. We know that use of inaccurate glucose information can lead to severe and even deadly consequences, particularly among elderly patients, the people who are most at risk for acute complications such as hypoglycemia. We know that these SMBG systems of questionable accuracy are being marketed to elderly patients without face-to-face instruction in how to properly use their systems or how to appropriately use their blood glucose data.

From a clinical perspective, this is clearly unacceptable. From a cost perspective, this is both wasteful and expensive. If patients perceive no value from their testing, they will stop testing. But they may continue to receive their 60day supply of test strips. If they do test, but receive an inaccurate result that prompts an inappropriate treatment decision, we all pay for expensive emergency care and subsequent hospitalization.

What we don’t know is the ultimate impact of this perfect storm on patients, the healthcare system or society. Given that there are over 11million elderly diabetes patients in the US, we suspect the impact is large. In essence, we have placed millions of vulnerable elderly Americans in the direct path of a “perfect storm”, made of inaccurate SMBG systems, regulatory failures and a Medicare system that appears to more focus on cost than quality care.

Moving forward

Recognizing the need to address these issues and others, and to build consensus on glucose monitoring, the American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) convened a conference September 28-29, 2014, in Washington, D.C.¹⁰ Conference participants included members of healthcare associations, insurance companies, regulatory agencies, patient advocacy groups, pharmaceutical and equipment manufacturing companies, healthcare systems, physicians, educators and allied health care professionals. Based on findings from the conference, AACE submitted a letter to Congress, urging them to “conduct follow-up hearings to those previously held on the FDA Safety and Innovation Act to examine the FDA’s pre and post marking surveillance and enforcement activities and also on the Medicare Competitive Bidding Program to ensure congressional intent is being followed with respect to patient access to a range of diabetes testing supplies that meet and maintain FDA quality standards”.²⁵

The National Diabetes Volunteer Leadership Council (NDVLC) supports the legislative recommendations from the AACE consensus conference and encourages the FDA to:

- i. Enforce its current regulations to remove the inaccurate, unsafe SMBG systems from the market.

- ii. Critically review its current criteria for approval of SMBG systems.
- iii. Require more comprehensive testing of the accuracy and precision of these systems by independent laboratories/institutions.
- iv. Continuously monitor the accuracy/precision of these systems once they are in the market. Moreover, the NDVLC strongly urges that these new FDA criteria be applied retroactively to include all SMBG systems currently marketed in the US in order to better ensure patient safety, facilitate improved long-term glycemic control and help reduce the financial burden of diabetes.

Conclusion

Diabetes is a significant and growing international health concern. An estimated 11.1 million elderly Americans have diabetes, representing approximately 26% of the total US diabetes population. A key component of effective diabetes management is SMBG, which enables individuals to detect current or impending glycemic events (e.g., hypoglycemia, hyperglycemia). Although elderly individuals with diabetes are greatest risk for hypoglycemia,^{5,6} the FDA's failure to enforce existing requirements for SMBG meter accuracy poses an additional threat to the safety of our most vulnerable diabetic population. This threat is further exacerbated by the recent CBP, which has disrupted access to SMBG supplies among Medicare beneficiaries.

Although further discussions are ongoing regarding the tightening the international accuracy standard for glucose testing, which may lead to more accurate meters, stricter requirements would not improve access to SMBG systems with adequate training or ensure that glucose testing will be used frequently enough to ensure better outcomes in elderly populations. Therefore, CMS must halt its "grand experiment" and find a better way to provide quality care to Medicare beneficiaries. It is time that we put elderly Americans with diabetes back on the bus.

Acknowledgements

Roche Diagnostics, Indianapolis, Indiana, USA, provide funding to Christopher Parkin for the development of this manuscript.

Conflict of interest

Christopher Parkin has received consulting fees from Animas, Asante, CeQur, Dexcom, Intuity and Roche Diagnostics. Larry Ellingson has conflicting interests to report. The authors are solely responsible for the content of this manuscript.

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