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EDITORIAL

Improving the Safety of Blood Glucose Monitoring

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Performance and accuracy of blood glucose (BG) monitoring devices are currently being scrutinized by regulatory agencies and professional societies.[1,2] For medical devices to receive regulatory clearance and be adopted by the public, they must be both effective and safe. Although the accuracy of BG monitoring technology, which is a reflection of its effectiveness, has received much attention recently, it should be noted that the safety of this practice is also important.

Safety

Six aspects regarding the safety of BG self-monitoring must be considered, including: (1) transmission of blood-borne viral pathogens from patient to patient; (2) community exposure to sharps and other medical waste; (3) finger trauma due to lancing; (4) extraction of an adequate specimen to make a measurement; (5) achievement of adequate clinical accuracy; and (6) achievement of favorable postanalytical accuracy. These issues affect the safety of self-testing patients, other diabetes patients, and the entire community including others without diabetes.

Transmission of Blood-Borne Pathogens

In 2009, the Centers for Disease Control (CDC) in Atlanta, Georgia reported 18 outbreaks, since 1990, of hepatitis B due to unsafe BG monitoring practices.[3] These incidents involved at least 147 hospitalized inpatients or long-term care patients. Two outbreaks of the hepatitis B in assisted-living facilities were subsequently reported by CDC in 2010.[4] The pattern of these epidemics since 1990 is that the sites have been gradually migrating from hospitals to nursing homes to assisted living facilities. It was concluded that blood was passed from hepatitis B virus (HBV)-positive patients with diabetes to HBV-negative patients with diabetes in the course of BG monitoring through improperly shared paraphernalia. Regarding the types of unsafe BG monitoring practices associated with these hepatitis B outbreaks, the vectors of transmission were typically spring-loaded lancets for individual use. No outbreaks were due to reused lancets. In some cases, disposable endcaps for lancets were reused or used and unused endcaps were stored together. Apparently, in some instances, blood from used caps was physically transferred to unused lancets, which were later used on patients. In all cases BG monitors were shared and not cleaned between measurements.[3] In this issue of *Journal of Diabetes Science and Technology*, Thompson and Schaefer[5] report four additional HBV infection outbreaks involving 29 patients who were associated with assisted monitoring of blood glucose (AMBG).

In a survey of 68 ambulatory surgery centers in three states, which was reported in 2010, 46% had lapses in infection control practices in their handling of BG testing equipment. These lapses consisted of either failing to clean and disinfect BG monitors after each use or sharing

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Abbreviations: (AMBG) assisted monitoring of blood glucose, (BD) Becton, Dickinson and Company, (BG) blood glucose, (CDC) Centers for Disease Control, (HBV) hepatitis B virus, (FDA) Food and Drug Administration, (US) United States, (SMBG) self-monitoring of blood glucose, (T2DM) type 2 diabetes mellitus

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spring-loaded penlet devices among multiple patients.[6] A survey of 48 nursing homes and assisted-living facilities in Florida for factors that facilitate blood-borne pathogen transmission was reported in 2010. This survey found that 4 facilities (8%) used personal-use finger stick devices on multiple residents; 20 (42%) did not always perform BG monitoring by staff members who were wearing gloves during this procedure; 22 (46%) used shared BG monitors; and 6 (12%) admitted that monitors were not cleaned after each resident used them.[7]

Based on epidemiologic findings of blood-borne viruses being inadvertently transferred, a new term was coined in 2010 to describe the practice of assisting others in the practice of BG monitoring and to serve as a focus for new clinical and regulatory guidelines for this practice. The new term for this practice is AMBG.[8] A list of settings in which patients receive AMBG is presented in **Table 1**. Both the Food and Drug Administration (FDA)[9] and CDC[10] published guidelines last year about the risks of using reusable blood-lancing devices and point-of-care blood testing devices on more than one person. The FDA also published a notice of a modification in their regulatory review for all BG monitoring systems to ensure that adequate labeling and instructions for use are provided to health care workers so that they may respond adequately to the recommendations on avoidance of reusable BG monitoring paraphernalia.[11] Per these two agencies, necessary practices for safe performance of AMBG include: (1) restricting the use of finger stick devices to one individual; (2) disposing of used lancets; and (3) no sharing of BG monitors; but if it is necessary to share, then cleaning and disinfecting them after each use.

Table 1.
Settings Where Patients Receive Assistance with Blood Glucose Monitoring

1	Hospitals
2	Nursing homes
3	Assisted living facilities
4	Prisons
5	Home health care
6	Medical practitioners' offices or clinics
7	Diabetes research laboratories
8	Health fairs
9	Schools
10	Children's camps
11	Shelters

Community Exposure to Waste

Used needles, syringes, and lancets are commonly incinerated or treated and disposed of in landfills.[12,13] The CDC has estimated that 63.4% of adults with diabetes in the United States (US) test at least once daily[14] and that there are over 25 million adults in the US with diabetes.[15] This means that almost 16 million BG strips are used daily, assuming one test per day per testing patient. Lancets are used in similar quantities. The CDC has also estimated that, in the US, approximately 26 million people total have diabetes and approximately 26% of these people use insulin,[14] which is typically injected 1–4 times daily. Assuming two injections per patient per day, approximately 13 million injections are administered daily to insulin users, which is an additional daily environmental burden of approximately 13 million needles and syringes. As insulin pens become more popular, the number of syringes used per time period will decline. It is estimated that 1 in 12 households in the US use a syringe and needle for a medical condition, and that total needle and syringe use in the US is 7.5 billion per year.[16] What happens to these lancets, syringes, and needles? Two sharps recycling programs are the Coalition for Safe Community Needle Disposal, an organization of community groups, businesses, and government to promote increased awareness, and the Becton, Dickinson and Company (BD) ecoFinity Life Cycle Solution, a joint private program between BD and Waste Management that recycles medical waste and uses the material to manufacture new sharps containers. In this latter program, sharps wastes are sanitized and separated into plastic and metal, which are recycled, and into other materials, which are disposed of. The motto of this program is "turning a waste stream into a revenue stream."[17]

Finger Trauma

Regarding finger lancing to obtain a blood specimen for BG monitoring, there has been little research published on safe lancing. Alternate site testing to obtain blood from the forearms, thighs, and palms causes less pain.[18] This sampling method is not widely practiced, however. If a self-monitored BG test is needed immediately after a meal or if rapid fluctuations in glycemia are suspected, then this procedure should not be performed on the forearm or thigh (although the palm is not a problematic site),[19,20] because a lag is introduced when BG levels are rising or falling quickly. Laser lancets have been poorly

received and all-in-one lancing and testing devices do not appear to decrease pain. The best way to decrease pain from lancing is to optimize the lancet and the lancing process.[21] This approach will minimize trapped blood (which forms black dots), calluses, and decreased sensation in the fingertips.

A study of lancing devices to assess features that mitigate lancing pain reported six factors that mitigate pain.[22] These factors are listed in **Table 2**. In addition to pain, wound healing is an important factor that can diminish motivation for self-testing. Both pain and poor wound healing can be decreased if patients could receive instruction from a diabetes educator on: (1) skin preparation; (2) site selection; (3) adequate blood acquisition; (4) discomfort reduction; and (5) alternative site utilization.[21] No standalone motorized lancing product is currently available. One such product with depth and velocity control to minimize pain was marketed a few years ago, however, sales were poor and the product was discontinued. Two reasons patients might choose not to switch to a specific pain-free lancing system include: (1) added cost of switching to a new product instead of reusing lancets; and (2) inconvenience of carrying a separate device.[23]

Adequate Blood Sampling

Infrequently, a patient self-lances to obtain a blood sample for self-monitoring of blood glucose (SMBG), but fails to obtain an adequately sized blood sample or any sample whatsoever (i.e. has a dry tap). In such a case, it is debatable whether this type of event creates a safety concern. Furthermore, there is no clear consensus as to what the minimum percentage of adequate samples in an occasionally failing sampling system is safe for a patient. This percentage would be the likelihood of not obtaining desired information about the glycemic level and then being left in a potentially dangerous state of not being able to self-determine such a level. Little has been published about the phenomenon of inadequate sampling in terms of: (1) frequency of occurrence; (2) associated human factors contributing to the outcome; or (3) patient perceptions of health following such an outcome. In one series of adults with type 2 diabetes mellitus (T2DM), successful sampling occurred 98.3% of attempts for finger stick sampling, whereas three alternate sites (thigh, forearm, and palm) were successfully sampled in 92.7%, 93.4%, and 94.4%, respectively.[24] The sampling success of any lancing device should be formally evaluated and, if an excessive failure rate of adequate sampling should be noted, then the device or the directions should be redesigned. The redesign process needs to include a human factors analysis to improve the product and/or its directions, and in some cases, specific product labeling about this risk will be needed.

Table 2.
Six Factors Which Mitigate Lancing Pain

1	Shallow lancet penetration
2	Fast lancing speed
3	Sharp tip and cutting edges
4	Smooth lancet surface
5	Steady motion (no vibrations/jolts)
6	Skin fixation at lancet interface

Clinical Accuracy

Blood glucose monitors can be classified both by their analytical accuracy or their clinical accuracy. These devices are currently approved by the FDA if they meet analytical accuracy criteria as defined by International Organization for Standardization 15197.[25] This standard is currently being revised. The FDA has also announced plans to revise its own guidelines for analytical accuracy of BG monitors. The other type of metric for accuracy, clinical accuracy, is currently measured by using the Clarke error grid, published in 1987,[26] or the Parkes error grids (for type 1 diabetes mellitus and T2DM),[27] developed in 1994 and published in 2000. An error grid is a metric of clinical accuracy of BG monitors. Each data point, representing both the BG monitor value and the reference value, can be classified into a performance zone, which permits data sets to be defined on the basis of the percentage of data points that fall into each category. Clinical accuracy metrics are intended to describe outlier data points in terms of whether their degree of inaccuracy will lead to untoward clinical consequences and if so, how severe the consequences might be. These error grids assign a performance zone for each data point based on whether there is an effect on the clinical action and if so, how the clinical outcome will be affected. There are, however, many clinical conditions that might impact the target ranges for clinical accuracy and the magnitude of tolerable analytical inaccuracy with either type of diabetes. These conditions include hospitalization in an intensive care unit, hospitalization in a ward, outpatient insulin pump therapy, pregnancy, and corticosteroid therapy.

Error grids are useful for interpretation of the seriousness of outlier data points that result in altered clinical action and for regulatory classification of the performance of

specific BG monitors as clinically acceptable or unacceptable. Unfortunately, there is no generally agreed upon standard for any of the current error grids as to what percentage of data points must fall into the highest performance zone or zones to be defined as providing adequate clinical accuracy.[28] This type of tool can potentially ensure safe performance of BG monitors because only highly performing monitors with respect to clinical accuracy should be allowed on the market.

Postanalytical Accuracy

A postanalytical error of a BG monitor is an error in presentation or interpretation of a glucose value following measurement. No matter how accurately a BG monitor measures a sample in terms of analytical accuracy, if the result is presented incorrectly, then an error in the response to this value, with respect to therapeutic action, can follow. Examples of postanalytical errors include presentation of incorrect units of glucose concentrations (e.g., substitution of mmol/liter for mg/dl or vice versa); incorrect recording of data into a diary, faulty transmission of data into a handheld device, computer, or server for Web viewing; faulty storage of glucose data in a glucose monitor; or display of unintended incorrect instructions if the monitor contains decision support software.[29] In these instances, even if a BG monitor itself is analytically highly accurate, its usage will still be unsafe for patients. The FDA MedWatch program monitors reports of adverse events and other problems with approved BG monitors and alerts health care professionals and the public, as needed, to ensure proper use of these devices and protect the safety of patients.[30]

Conclusions

As the number of patients with diabetes continues to increase in various populations, it is likely that the numbers of patients who self-monitor their BG levels and who receive assistance with monitoring of their BG levels will also increase. More BG testing, whether by way of SMBG or AMBG, will likely necessitate increasingly strict safety measures to protect the public from blood-borne pathogens. This risk is due to inappropriate exposure to used lancets and other testing paraphernalia, and these exposures must be eliminated as much as possible. The public health programs by Coalition for Safe Community Needle Disposal and BD ecoFinity Life Cycle Solution have improved public health safety in this area for everyone in the US. The recent public health guidelines on lancing from the CDC and the FDA have improved public health safety of BG monitoring for patients with diabetes who are undergoing testing as a group in an AMBG setting. Additional research is needed on how to minimize both the pain and trauma from lancing and also on how to decrease the incidence of inadequate sampling so that these sampling barriers that prevent some diabetes patients from performing adequately frequent SMBG will be overcome. Monitors can be designed and regulated to demonstrate acceptable clinical accuracy and avoid problems with postanalytical accuracy.

Blood glucose monitoring is currently an overwhelmingly safe practice. This practice is becoming even safer each year thanks to public health initiatives for avoiding exposure to blood waste and used lancets, clinical research for adequate sampling volumes, metrics for meaningfully describing clinical accuracy, and surveillance mechanisms for maximizing post analytical performance. With sustained focus on the importance of avoiding exposure to blood waste, sampling problems, and monitor errors, the safety of BG monitoring will continue to increase.

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References:

1. Klonoff DC. The food and drug administration is now preparing to establish tighter performance requirements for blood glucose monitors. J Diabetes Sci Technol. 2010;4(3):499–504.
2. May 2010 Clinical Laboratory News: Blood Glucose Meters. http://www.aacc.org/publications/cln/2010/may/Pages/CoverStory1May2010.aspx. Accessed October 9, 2011.
3. Thompson ND, Perz JF. Eliminating the blood: ongoing outbreaks of hepatitis B virus infection and the need for innovative glucose monitoring technologies. J Diabetes Sci Technol. 2009;3(2):283–8.
4. Counard CA, Perz JF, Linchangco PC, Christiansen D, Ganova-Raeva L, Xia G, Jones S, Vernon MO. Acute hepatitis B outbreaks related to fingerstick blood glucose monitoring in two assisted living facilities. J Am Geriatr Soc. 2010;58(2):306–11.
5. Thompson N, Schaefer, T. "Never Events": Hepatitis B Outbreaks and Patient Notifications Resulting from Unsafe Practices during Assisted Monitoring of Blood Glucose, 2009-2010. J Diabetes Sci Technol. 2011;5(6):1396–1402.
6. Schaefer MK, Jhung M, Dahl M, Schillie S, Simpson C, Llata E, Link-Gelles R, Sinkowitz-Cochran R, Patel P, Bolyard E, Sehulster L, Srinivasan A, Perz JF. Infection control assessment of ambulatory surgical centers. JAMA. 2010;303(22):2273–9.
7. Thompson ND, Barry V, Alelis K, Cui D, Perz JF. Evaluation of the potential for bloodborne pathogen transmission associated with diabetes care practices in nursing homes and assisted living facilities, Pinellas County. J Am Geriatr Soc. 2010;58(5):914–8.

8. Klonoff DC, Perz JF. Assisted monitoring of blood glucose: special safety needs for a new paradigm in testing glucose. J Diabetes Sci Technol. 2010;4(5):1027–31.
9. Fingerstick Devices to Obtain Blood Specimens: Initial Communication - Risk of Transmitting Bloodborne Pathogens. Reusable fingerstick (blood lancing) devices and point of care (POC) blood testing devices (e.g., blood glucose meters, PT/INR anticoagulation meters, cholesterol testing devices). http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm224135.htm. Accessed October 9, 2011.
10. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html. Accessed October 9, 2011.
11. Letter to Manufacturers of Blood Glucose Monitoring Systems Listed with the FDA. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm. Accessed October 9, 2011.
12. Pfützner A, Musholt PB, Malmgren-Hansen B, Nilsson NH, Forst T. Analysis of the environmental impact of insulin infusion sets based on loss of resources with waste. J Diabetes Sci Technol. 2011;5(4):843–7.
13. Krisiunas E. Waste disposal in the 21st century and diabetes technology: a little coffee (cup) or beer (can) with that insulin infusion (set). J Diabetes Sci Technol. 2011;5(4):851–2.
14. Self-Monitoring of Blood Glucose Among Adults with Diabetes—United States, 1997--2006. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5643a3.htm#tab1. Accessed October 9, 2011.
15. National Diabetes Fact Sheet, 2011. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf. Accessed October 9, 2011.
16. Gold K. Analysis: the impact of needle, syringe, and lancet disposal on the community. J Diabetes Sci Technol. 2011;5(4):848–50.
17. 1BD eco Finity™ LifeCycle Solution. Turning a waste stream into a resource stream. http://www.bd.com/ecoFinity/flash/slide-show-14260.htm. Accessed October 8, 2011.
18. Jacoby JM. An analysis of alternate site tests to improve patient compliance with self-monitoring of blood glucose. J Diabetes Sci Technol. 2010;4(4):911–2.
19. Ellison JM, Stegmann JM, Colner SL, Michael RH, Sharma MK, Ervin KR, Horwitz DL. Rapid changes in postprandial blood glucose produce concentration differences at finger, forearm, and thigh sampling sites. Diabetes Care. 2002;25(6):961–4.
20. Kempe KC, Budd D, Stern M, Ellison JM, Saari LA, Adiletto CA, Olin B, Price DA, Horwitz DL. Palm glucose readings compared with fingertip readings under steady and dynamic glycemic conditions, using the OneTouch Ultra Blood Glucose Monitoring System. Diabetes Technol Ther. 2005;7(6):916–26.
21. Heinemann L, Boecker D. Lancing: quo vadis? J Diabetes Sci Technol. 2011;5(4):966-81.
22. Kocher S, Tshiananga JK, Koubek R. Comparison of lancing devices for self-monitoring of blood glucose regarding lancing pain. J Diabetes Sci Technol. 2009;3(5):1136-43.
23. Lekarcyk J, Ghiloni S. Analysis of the comparison of lancing devices for self-monitoring of blood glucose regarding lancing pain. J Diabetes Sci Technol. 2009;3(5):1144–5.
24. Bina DM, Anderson RL, Johnson ML, Bergenstal RM, Kendall DM. Clinical impact of prandial state, exercise, and site preparation on the equivalence of alternative-site blood glucose testing. Diabetes Care. 2003;26(4):981–5.
25. ISO 15197. http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=54976. Accessed October 9, 2011.
26. Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. Diabetes Care. 1987;10(5):622-8.
27. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care. 2000;23(8):1143–8.
28. Krouwer JS, Cembrowski GS. Towards more complete specifications for acceptable analytical performance - a plea for error grid analysis. Clin Chem Lab Med. 2011;49:1127–30.
29. Carraro P, Plebani M. Post-analytical errors with portable glucose meters in the hospital setting. Clin Chim Acta. 2009;404(1):65–7.
30. Medical Device Safety. http://www.fda.gov/MedicalDevices/Safety/default.htm. Accessed October 9, 2011.