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EDITORIAL

Assisted Monitoring of Blood Glucose: Special Safety Needs for a New Paradigm in Testing Glucose

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A New Paradigm

The term "assisted monitoring of blood glucose" (AMBG) is a new paradigm in blood glucose testing and is introduced in this editorial. Assisted monitoring of blood glucose is similar to self-monitoring of blood glucose (SMBG), but unlike SMBG for which patients perform the monitoring, AMBG is performed for a patient with diabetes by a health care provider or other caregiver. Assisted and self-monitoring both have had long traditions in practice, but it is important that AMBG be recognized more broadly as a distinct concept in order to address safety concerns. In many instances, the equipment and processes that are appropriate for an individual performing SMBG are not appropriate in an AMBG setting. The primary reason for this is the ever-present risk of transmitting bloodborne viruses between individuals who are having capillary blood sampled and tested. This risk is heightened when finger-stick lancing devices, blood glucose meters, or other equipment are used for multiple patients.

Self-Monitoring of Blood Glucose

The practice of SMBG is a basic intervention for all patients with diabetes and generally is considered very safe. Patients with diabetes stick themselves routinely with a lancet to obtain a blood sample with which to perform SMBG. Basic diabetes education programs teach and promote this practice, and have emphasized safe disposal of sharp paraphernalia as a means to avoid contaminating others with blood waste. To transmit a bloodborne virus, a susceptible patient must come in contact with blood from another person. If a diabetes patient never shares equipment, supplies, or insulin with anyone else and safe waste disposal practices are followed, then there should be no risk of transmission from one person to another.

Most blood glucose monitoring equipment has been designed for self-use. In the context of personal use for SMBG, device design emphasizes features such as comfort, convenience, and portability. However, an important, growing, but inadequately studied setting for blood glucose monitoring is the environment where patients are not monitoring themselves, but rather receiving assistance with their monitoring from a caregiver or health care provider (i.e., AMBG). Types of settings [e.g., assisted living facilities (ALFs)] where patients receive assistance with blood glucose monitoring are shown in **Table 1**.

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Abbreviations: (ALF) assisted living facility, (AMBG) assisted monitoring of blood glucose, (CDC) Centers for Disease Control and Prevention, (HBV) hepatitis B virus, (SMBG) self-monitoring of blood glucose

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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

Outbreaks and Other Evidence of Unsafe Assisted Monitoring of Blood Glucose

Dating back to the introduction of insulin for the treatment of diabetes in the 1920s, hepatitis outbreaks have occurred in settings where multiple patients with diabetes underwent AMBG with shared equipment.[1-3] Documented outbreaks have occurred in hospitals, nursing homes, and other long-term care facilities. As reported last year in this journal, state and local health departments in the United States investigated 18 hepatitis B virus (HBV) infection outbreaks between 1990 and 2008 that were associated with the improper use of blood glucose monitoring equipment.[1] At least 147 persons were found to have acquired HBV infection during these outbreaks, 6 (4.1%) of whom died from complications of acute HBV infection. It was noted that outbreaks appear to have become more frequent since 2000, primarily affecting long-term care residents with diabetes; similar outbreaks have been investigated and documented in just the past year [Centers for Disease Control and Prevention (CDC), unpublished data]. Each outbreak was attributed to glucose monitoring practices that exposed HBV-susceptible persons to blood-contaminated equipment that was previously used on HBV-infected persons.

The predominant unsafe practices were the use of penlet-style spring-loaded finger-stick devices on multiple persons and the sharing of blood glucose testing meters without cleaning and disinfection between uses. Similar outbreaks have also been reported in several European countries.[1,4,5] In summary, HBV outbreaks associated with blood glucose monitoring have occurred with increasing regularity and may represent a growing but underrecognized problem.

Evidence from surveys indicates that unsafe AMBG practices may be more widespread than previously recognized. For example, Thompson and colleagues[6] at the CDC performed a survey of 48 licensed long-term care facilities in Pinellas County, Florida, to characterize routine blood glucose monitoring practices in nursing homes and assisted living facilities. They surveyed 15 nursing homes and 33 ALFs (17 of which were small with ≤50 beds and 16 of which were large with >50 beds). Data on facility characteristics, infection control policies, staff practices, and equipment used for blood glucose monitoring were collected. Respondents from small ALFs were less likely than those from nursing homes and large ALFs to report that their facility had a copy of the Occupational Safety and Health Administration's Bloodborne Pathogen Standard; to provide staff with infection control or bloodborne pathogen training; or to have a system for reporting sharps injuries or blood and blood fluid exposures. Most (80%) nursing homes reportedly had a facility policy for blood glucose monitoring, compared with only 33% of large and 0% of small ALFs. Glove use by staff during blood glucose monitoring was lowest at small ALFs. Reusable penlet finger-stick devices—that are intended for personal use by a single patient in the context of SMBG—were being used in some of the surveyed facilities, most often at ALFs; 4 of 18 facilities (including 1 nursing home) were inappropriately using them for multiple residents. At 22 facilities (including all the nursing homes), multiple residents were tested with shared blood glucose meters; only 6 (27%) facilities reported cleaning them after each use. This study identified practices that could put residents and caregivers at risk of bloodborne pathogen transmission during blood glucose monitoring in these community-based facilities. The authors concluded that better training and oversight of blood glucose monitoring in long-term care is needed to prevent transmission of bloodborne pathogens. Findings similar to those described in the report by Thompson and colleagues[6] were reported from a survey of ALFs in Virginia.[7] In addition, acute HBV infection outbreaks related to finger-stick blood glucose monitoring were reported in two ALFs in Illinois.[8]

Unsafe AMBG practices are not limited to long-term care settings. A survey of infection-control practices in a sample of ambulatory surgical centers was conducted in three states.[9] The survey found that the same spring-loaded

lancing penlet device was used for multiple patients in 21% (11 of 53) of the surveyed centers. In 32% (17 of 53) of facilities, the blood glucose meter was not cleaned and disinfected after each use. In addition, shared use of penlet finger-stick devices during diabetes screening events has been reported in the media. These incidents resulted in patient notifications advising bloodborne pathogen testing for exposed persons.[10]

Performance of Assisted Monitoring of Blood Glucose

In many instances, blood glucose monitoring equipment that is appropriate for SMBG may not be appropriate for AMBG. First, multiuse finger-stick devices should not be used for AMBG. By their nature, finger-stick devices come in close proximity to blood with every use. Even if the lancet is changed between patients, the potential for carryover of blood contamination of the inner or outer surfaces of the device makes sharing and reuse of these devices unsafe. Some designs place caregivers at potential risk of a needlestick injury during the manipulations that are required to change lancets within the body of the device. Labeling and packaging of these products do not always explain clearly that these devices are not suitable for use by more than one person. For AMBG to protect both patients and their caregivers, single-use disposable finger-stick devices featuring lancets that permanently retract after activation should always be used for diabetes screening and other forms of AMBG.

Blood glucose monitors are susceptible to blood contamination.[11] They should be shared only when absolutely necessary and with absolute adherence to cleaning and disinfection protocols. Even microscopic amounts of blood on glucose monitoring equipment may contain infectious viral particles that can serve as a reservoir for inoculation into a patient's finger-stick wound. Likewise, there is risk of patient exposure via transfer of virus from a health care provider's hands or gloves after contact with a contaminated monitor. It follows that each patient who regularly undergoes AMBG should have a blood glucose monitor assigned to them for their exclusive use. However, this recommendation will not be practical at health fairs or in a medical practitioner's office because many patients will be tested only one time. When sharing of blood glucose monitors cannot be avoided, it should be minimized and blood glucose monitors should be consistently cleaned and disinfected between each use. In these situations, the monitors should be of a type designed specifically for AMBG applications, including clear, well-validated instructions from the manufacturer for both cleaning and disinfection between uses.

Insulin Pens

Insulin pens must not be shared by more than one patient. The risk of transmission of bloodborne diseases from shared insulin pens is essentially the same as from shared syringes and similar to the risks from shared lancets. Blood or other contaminants can be transferred up into the pen cartridge during injection and mix with the insulin in the pen.[12] Changing needles after use will not prevent this type of contamination. If insulin is administered from a pen that has previously been used to deliver insulin to another patient, the downstream patient is at risk for exposure to infectious pathogens. Large-scale patient notification advising bloodborne pathogen testing has occurred in hospital settings where insulin pens were reused for multiple patients.[1,13]

Looking Forward

In May 2010, the CDC Foundation, in collaboration with the CDC's Division of Healthcare Quality Promotion, Division of Viral Hepatitis, and Division of Diabetes Translation hosted a meeting with industry representatives, the Food and Drug Administration, Centers for Medicare and Medicaid Services, and other partners to address the issue of safe performance of AMBG. The Diabetes Technology Society assisted in the planning of the meeting, which was entitled, "Sticking with Safety: Eliminating Bloodborne Pathogen Risks during Blood Glucose Monitoring."

An overview of the meeting is posted on the CDC Web site.[14] Speakers at the meeting called attention to three safety practices: (1) use only autodisabling single-use lancet devices for AMBG; (2) insulin pens are for single-patient-use only; and (3) glucose meters should be assigned to individual patients whenever possible; if a meter must be shared, then device selection should take infection prevention into account and thorough cleaning and disinfection should be ensured after every use. These points are emphasized in infection prevention recommendations for assisted blood glucose monitoring and insulin administration that have been developed by CDC, as shown in **Table 2**.[15] A recent clinical alert from CDC and a related advisory from the Food and Drug Administration have also reinforced these points.[16,17] Future consensus practice

Table 2.
Recommended Practices for Preventing Bloodborne Pathogen Transmission during Blood Glucose Monitoring and Insulin Administration in Health Care Settings[15]

BLOOD GLUCOSE MONITORING
Finger-stick devices
• Restrict use of finger-stick devices to individual persons. They should *never* be used for more than one person. Select single-use lancets that permanently retract upon puncture. This adds an extra layer of safety for the patient and the provider.
• Dispose of used lancets at the point of use in an approved sharps container. Never reuse lancets.
Blood glucose meters
• Whenever possible, blood glucose meters should be assigned to an individual person and not be shared.
• If blood glucose meters must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions, to prevent carry-over of blood and infectious agents. If the manufacturer does not specify how the device should be cleaned and disinfected, then it should not be shared.
GENERAL
• Unused supplies and medications should be maintained in clean areas separate from used supplies and equipment (e.g., glucose meters). Do not carry supplies and medications in pockets.
INSULIN ADMINISTRATION
• Insulin pens should be assigned to individual persons and labeled appropriately. They should *never* be used for more than one person.
• Multiple-dose vials of insulin should be dedicated to a single person whenever possible. » If the vial must be used for more than one person, it should be stored and prepared in a dedicated medication preparation area outside of the patient care environment and away from potentially contaminated equipment. » Medication vials should always be entered with a new needle and new syringe.
• Dispose of used injection equipment at point of use in an approved sharps container. Never reuse needles or syringes.
HAND HYGIENE (hand washing with soap and water or use of an alcohol-based hand rub)
• Wear gloves during blood glucose monitoring and during any other procedure that involves potential exposure to blood or body fluids.
• Change gloves between patient contacts. Change gloves that have touched potentially blood-contaminated objects or finger-stick wounds before touching clean surfaces. Discard gloves in appropriate receptacles.
• Perform hand hygiene immediately after removal of gloves and before touching other medical supplies intended for use on other persons.
TRAINING AND OVERSIGHT
• Review regularly individual schedules for persons requiring assistance with blood glucose monitoring and/or insulin administration.
• Provide a full HBV vaccination series to all previously unvaccinated staff persons whose activities involve contact with blood or body fluids.
• Establish responsibility for oversight of infection control activities. Provide staff members who assume responsibilities for finger sticks and injections with infection control training.
• Assess adherence to infection control recommendations for blood glucose monitoring and insulin administration by periodically observing staff who perform or assist with these procedures and tracking use of supplies.
• Report to public health authorities any suspected instances of a newly acquired bloodborne infection, such as HBV, in a patient, facility resident, or staff member.
• Check with state authorities for specific state and federal regulations regarding laboratory testing.

guidelines, educational initiatives, and regulatory activities may also be expected to address safe AMBG practices.

In summary, AMBG must become recognized as a practice similar to but distinct from SMBG in order for diabetes testing products to become labeled as intended for use with SMBG or AMBG. Likewise, additional safety standards should be established for AMBG, including whether, and under what conditions, specific devices may be used or shared. Blood glucose monitoring has evolved to encompass a variety of technologies.[18] Many of these involve sampling body fluids, which must be performed safely to protect both the caregiver and the patient. Self-monitoring of blood glucose is an established technology. The reality of AMBG is now also upon us and presents another series of challenges for diabetes science and technology.

Disclaimer:

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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