HAZARD SUMMARY

Blood Glucose Monitors (BGMs) also Known as Glucometers

Scope of this Hazard Summary

- This Hazard Summary addresses portable Blood Glucose Monitors (BGMs) that are used by diabetic patients to self-monitor glucose levels.
- This Hazard Summary is a supplement; it DOES NOT replace latest revisions of existing guidelines and directives for proper handling, storage and operation of BGMs, their accessories and/or test strips.
- This Hazard Summary references the "systems approach" to delineate vulnerabilities in a system, where the patient is identified as part of the system.

VA National Center for Patient Safety

Introduction

Portable Blood Glucose Monitors (BGMs), also known as Glucometers, are portable, battery operated medical devices that measure the blood glucose concentration from a small drop of capillary blood (from finger sticks or alternate sites) using methodologies such as: reflectance photometry, absorbance photometry, or electrochemistry.[1]

Benefits: Some of the benefits of this device are convenience and safety to the patient on many levels:

1) Since patients can check and monitor their own blood glucose levels at their leisure, they do not have to travel to a healthcare facility to have their venous and/or arterial blood drawn.

2) Therapy/treatment can be rendered quickly at their homes.

3) Since the blood sample these portable devices require is smaller than that needed for automated laboratory/chemistry analyzers, BGMs can reduce patient blood loss due to laboratory testing.

4) Cost is greatly reduced for the care and treatment of diabetic patients for all parties involved: the patient, the healthcare facility, insurance providers and the physician.

Vulnerabilities

I. Nature of portable battery-operated medical devices

- Dropping and breakage: As compared to stationary (those that are heavy or bolted down) medical devices, there is higher incidence of dropping portable devices and the result may lead to a broken, malfunctioning device, changed unit of measure [from milligrams per deciliter (mg/dL) to milli-moles per liter (mmol/L)] [2] or an inaccurate device.

- Liquid intrusion: It is a common problem with patient owned, portable, medical devices that they are often dropped in toilet bowls, sinks, bath tubs, etc. which in turn may lead to a broken, malfunctioning device or an inaccurate device.

- Battery powered: As batteries drain, the devices could become inaccurate and malfunction. Depleted batteries or replacement of batteries may lead to loss of memory in some devices.

II. Patient Interaction

- Unsuitable patient selection and matching of the device to the patient can lead to improper use, erroneous results and poor outcomes. Patients with dementia or memory loss are contraindicated for this device. Patients must have manual dexterity to be able to perform the tests themselves, otherwise a partner will have to be assigned and trained. Care givers must accurately assess the patient's underlying physiologic conditions to make sure that the patient is capable of self monitoring.

- The operators' manual must be clear concise and must be written in layman's terms without medical jargon. Care givers must provide initial instructions, demonstrations, and training on how to use the device correctly and accurately. Periodic reviews on how to use the device should occur to assure that the patient is using the device properly. Audio visual aids such as video tapes, CDs and DVDs are good examples of cognitive aids.

- Contaminants such as food, chemicals, and dirt at the site of puncture can interfere with the test results. It is important to wash the puncture site and allow it to dry, especially if rubbing alcohol is used to clean the puncture site.

- Body fluids other than blood can interfere with the test results. Avoid squeezing the puncture site: Patients must have adequate circulation at the proposed puncture site or sites to be able to use these devices effectively and accurately.

III. Accuracy

- Methodology: Certain products, such as those containing maltose, galactose, or oral xylose, interfere with specific glucose testing methods and will result in inaccurate readings.[3]

- Electronic malfunction: Manufacturing errors and general wear of the electronics can cause the device to become inoperable or display erroneous results (missing digits). Often no feedback of the malfunction is relayed to the patient.

- Terminology: When the patient's glucose level was less than 10 mg/dL, the display of the meter shows "Bad Strip" without mentioning the possibility of a critically low glucose reading [4] NOTE: Manual has new inserts on what "bad strip" means. However this is not as effective as the meter displaying a warning of "critically low values".

IV. Strips

- Undesired exposure to temperature, altitude, and humidity can cause abnormal/erroneous readings. Reports of cracked or deformed vials have prevented a proper seal and resulted in exposure to humidity. Strips should be stored in their original vial to avoid deterioration.

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- Third-party test strips may not be compatible and may lead to incorrect results. Meter manufacturers are apt to change their meters and strips without relaying this information to third-party strip manufacturers. [5]

- Strips improperly placed in the meter may lead to inaccurate results.

V. Lancets

- Sharing lancets can spread communicable diseases[6].

- Lancets must be discarded as a biohazard in sharps-disposal containers.

VI. Information System Data Interface

- Erroneous downloads may lead to inappropriate error messages and memory problems.[7]

VII. Manufacturers' Issues

- Systems approach incorporating the user/patient into the equation. This is accomplished

Hazards: Recent FDA and manufacturers' notifications and recalls of these devices have proven that there are associated vulnerabilities in the use of glucometers.

FEATURE	VULNERABILITY
Portable battery operated medical device.	Dropping, breaking, liquid intrusions, inaccuracies.
Patients' underlying physiologic conditions, illness and puncture site preparation.	Improper site/sample preparation, contaminations, squeezing, improper operation of device, inaccuracies.
Methodology.	Interference with test results, inaccuracies.
Test Strips and containers (vials).	Storage issues, cracked or deformed vials, increased humidity, inaccuracies.
Lancets.	Biohazards and source of cross contamination.
Information system data interface.	Misidentifications and inaccurate downloads.
Manufacturing and systems design issues. Patient not considered as part of the system.	Poor user interface, not user friendly, poor manuals, difficult for the lay person to understand.

Note: Not every brand of portable blood glucose monitor is affected by the identified vulnerabilities. Some manufacturers have modified their devices to improve safety by applying certain forcing functions; e.g. when changing the time of day, to observe daylight savings time for instance, patients cannot inadvertently change the unit of measure. Some brands of devices sold in the Unites States will now display in milligrams per deciliter (mg/dL) only.

by actually observing true diabetic patients use a specific brand, specific model of device and eliciting their feedback and incorporating it into the design of the specific model.

- Operator's manual must be written in layman's terms in large enough print with short step-by step procedures, facilitated with clear diagrams and pictures of the buttons and displays. Cognitive aids are strongly recommended.

- Device operator/patient interface related problems. Refer to Jakob Nielsen's "Ten Usability Heuristics." http://www.useit.com/papers/heuristic/heuristic_list.html

- Software to software interface issues. Data transfer should not corrupt identifiers and measured values. Follow industry standard protocols. Devices that are compatible (interface able) with the VA patient information (VistA) and computerized medical records system (CPRS) are highly recommend, assuring that patient identifiers and tests results are recorded efficiently without human error.

Recommendations to Mitigate the Identified Vulnerabilities

I. Matching Device to Patient

The decision to provide the glucometer and its accessories, to patients for self monitoring of glucose, must be carefully evaluated, following Clinical Practice Recommendations (CPR), where the indications and contraindications for use of the device are identified. Pharmacy Benefits Program (PBM) is in charge of distributing BGMs.

Patients must be selected carefully, to assure that they are physically and mentally capable to self monitor. If this is not possible, a partner will have to be assigned and trained.

II. Instructing Patients on Use

1. Care givers must provide initial instructions and demonstrations on how to:
   a) Prepare the puncture site, and clean and dry it properly before the sample is collected, especially if alcohol is used.
   b) Not squeeze the puncture site.
   c) Assure adequate circulation at the proposed puncture site or sites.
   d) Take special precautions to not drop portable, battery operated medical devices and to keep them away from bathrooms, kitchens and showers to prevent liquid intrusion.
   e) Use the device correctly and accurately, retesting the glucose level if a result differs from how the patient feels and calling their healthcare professional if the problem persists.
   f) Properly store the device and dispose of lancets, test strips, and other waste as a result of testing.
   g) Replace batteries two times per year at time change.

2. Users must be informed of the implications for alternate site testing:
   a) Results may differ significantly from fingertip testing, especially when blood glucose levels are rapidly changing. Rapid change typically occurs after a meal, insulin dose, or physical exercise.
   b) Testing should follow the above activities by at least 2 hours.
   c) Alternate site testing is NOT recommended if testing for hypoglycemia or the patient suffers from hyperglycemic unawareness.
   d) Vigorous rubbing, until the test site feels warm, should precede lancing to better match results from the fingertip.

3. Care givers must conduct periodic reviews, with their patients, on how to use the device to assure that the patients are using the devices properly.

4. Use of audio visual aids such as video tapes, CDs and DVDs are good examples of cognitive aids that will augment the training.

III. Purchasing

1. Specifications for purchasing new glucometers should address these identified vulnerabilities. A good medical device company will design their device and products following the "systems approach" and will provide many resources to train the patient, and conduct usability testing to identify and mitigate human factors and device/user interface issues.

2. In addition to addressing the patient within the system, the company will also need to address the other components of the system such as the device, the strips, the lancets and control solutions.

3. Pre-purchase evaluation should be conducted by VA facilities that are planning to purchase the device. Standardization of the device and its accessories is highly recommended.

4. Devices that are compatible (interface able) with the VA patient information (VistA) and computerized medical records system (CPRS) are highly recommended to assure that patient identifiers and tests results are recorded efficiently without human error.

5. Audio/visual displays and prompts for the patient must be clear, concise and use layman's terms, and not medical jargon.

References

1. ECRI Healthcare Product Comparison System. Blood Glucose Monitors. April 2003.
2. VA National Center for Patient Safety Alert AL 05-11 May 31, 2005.
3. http://www.fda.gov/cber/safety/maltose110405.htm
4. VA National Center for Patient Safety SPOT database RCA JL0081.
5. http://www.fda.gov/diabetes/glucose.html. January 9, 2006.
6. ECRI Health Devices Alerts Special Report Accession Number: S0067 April 1, 2005.
7. ECRI Health Devices Action Item Accession Number: A4748 June 28, 2002.