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Hygiene and Disinfection of Blood Glucose Meters in Multi-patient Setting

O. Schnell[1], B. Kulzer[2], M. Erbach[3]
Oliver.Schnell@lrz.uni-muenchen.de

[1] Forschergruppe Diabetes e.V., Helmholtz Center Munich, Munich-Neuherberg, Germany; [2] Research Institute of the Diabetes Academy Mergentheim (FIDAM), Bad Mergentheim, Germany; [3] Sciarc Institute, Baierbrunn, Germany

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Abbreviations: ABGM, Assisted Blood Glucose Monitoring; ASTM, American Society for Testing and Materials; BG, Blood Glucose; CDC, Centers for Disease Control and Prevention; CFU, Colony Forming Units; FDA, Food and Drug Administration; HBV, Hepatitis B Virus; SMBG, Self-Monitoring of Blood Glucose

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Summary

Blood glucose (BG) meters are approved for usage in different settings: they may be used for multi-patient settings or for use by a single patient. For some meters, approval applies to both single and multi-patient settings. In multi-patient settings, negligence in the appropriate handling (= disinfection / hygiene) has been identified as a potential risk factor for the transmission of infectious diseases such as hepatitis B or C. Failure to clean and disinfect BG meters after each use has been reported to be common in multi-patient settings. Proper cleaning and disinfection of BG meters after every usage are therefore a prerequisite for the prevention of transmission of blood borne pathogens during BG measurement; however, this does not only require clear and well-validated instructions by the manufacturers. Meters which have the option of out-of-meter dosing may provide an additional benefit in this regard.

Riassunto

I glucometri (BG) sono omologati per l'utilizzo in contesti diversi come, ad esempio,per un utilizzo multi-paziente oppure per l'uso da parte di un singolo paziente. Per alcuni glucometri, l'omologazione è valida per entrambe le impostazioni,singola e multi-paziente. Nelle impostazioni multi-paziente, una negligenza nella gestione (= disinfezione / igiene) è stata identificata come un potenziale fattore di rischio per la trasmissione di malattie infettive come l'epatite B e C. Scarsa igiene e mancata disinfezione del BG dopo ogni utilizzo sono stati segnalatifrequentemente in ambienti multi-paziente. Una corretta pulizia e disinfezione di BG dopo ogni uso è quindi un prerequisito per la prevenzione della trasmissione di patogeni per via ematogena; tuttavia, tutto ciò richiede istruzioni chiare e validate da parte dei produttori. Glucometri che hanno la possibilità di dosaggio out-of-metro possono fornire un ulteriore vantaggio in termini di sicurezza.

Introduction

While performing self-monitoring of blood glucose (SMBG) all handling steps are conducted by the patient himself; the testing in assisted blood glucose monitoring (ABGM) is performed by e.g. healthcare professionals[1]. ABGM is frequently performed in multi-patient settings. Negligence during ABGM with respect to cleaning and disinfection of the meter has been identified as a potential risk factor for the transmission of infectious diseases such as hepatitis B from one patient to another[2,3]. Such a lack of adherence to regulations on hygiene and on disinfection of blood glucose (BG) meters in multi-patient settings has been reported several times[4,5]. Inadequate hygiene not only promotes dissemination of infectious agents, it also may incur substantial costs due to acute infections.

The aim of this paper is to highlight the role of hygiene and disinfection of BG meters in multi-patient settings. Additionally, recommendations regarding hygiene and disinfection procedures have been compiled.

The need for adequate hygiene and disinfection in blood glucose monitoring in multi-patient settings

Due to compromised immune function, patients with diabetes are at an increased risk of developing a range of infectious diseases such as pneumonia, sepsis or viral hepatitis[6]. Since transmission of the hepatitis B virus (HBV) results from exposure to infectious blood or body fluids, HBV deserves special consideration in view of ABGM. Adults with diabetes in the age range of 23–59 years

have a twofold risk of acute HBV infection compared to people without diabetes; while patients ≥60 years have a 50% increased (but not significant) risk of acute HBV infection[7]. These findings are consistent with data from the 1999–2010 National Health and Nutrition Examination Survey which demonstrated a 60% increase in the seroprevalence of current or past HBV infections among adults with diabetes, and a 30% increase for adults ≥60 years – which was significant (CDC, unpublished data)[8]. The need for adequate prevention of HBV transmission is not least derived from the remarkable costs incurred by the treatment of HBV infections, which have been identified for a cost-effectiveness simulation model for HBV vaccination in patients with diabetes. As an example, mean costs per year for a patient with compensated cirrhosis are $ 7,402[8].

In the US, in settings where multiple persons require ABGM (hospitals, skilled nursing homes, and assisted-living facilities), 18 outbreaks of HBV due to unsafe BG monitoring practices were identified between 1990 and 2009[2]. During these outbreaks, at least 147 persons acquired HBV infection, six of whom died from complications of acute HBV infection[2]. For each outbreak, sharing of blood-contaminated equipment was identified as a source for transmission. The use of lancing devices intended for single-patient use in multiple persons and the multi-patient usage of BG meters without cleaning and disinfection between measurements in different patients were found to be the predominant unsafe practices leading to transmission of contaminated blood[9].

A multi-hospital study found 30% of BG meters to be contaminated with blood[10]. Meters were inspected visually and sampled for testing with a reduced phenolphthalein test to detect the presence of blood. Contamination was identified at the test strip insertion site as well as on the outside surfaces of meters. Meters used by intensive care units were 2.2 times more likely to be contaminated than meters on the general medicine floors[10].

Due to a report from 2010, failure to clean and disinfect BG meters after each use are common in nearly every second ambulatory surgery center[11]. According to a survey of 48 nursing homes and assisted-living facilities, 46% shared BG meters and 12% did not clean meters after each use. 42% stated that staff members did not consequently wear gloves while performing BG monitoring[4]. Thus, hygiene and disinfection procedures play a key role in the prevention of transmission of blood borne pathogens during BG measurement.

Suitability of glucose meters for usage in clinics and practices

BG meters are approved for usage in different settings: for multi-patient settings (most often in clinics or nursing homes) or for use by a single patient. Interestingly, some meters are approved for both, single and multi-patient settings. It appears to be obvious that when BG meters are used in multi-patient settings, the device must be cleaned and disinfected after every use. However, our knowledge about the reality of usage in daily care is limited. One important requisite is that clear and well-validated instructions for cleaning and disinfection are provided by manufacturers[1].

BG meter disinfection procedures

If BG meters are used in a multi-patient-setting, they must be cleaned and disinfected after every use, in accordance with manufacturer's instructions[12]. Manufacturers are required by the FDA to validate cleaning and disinfection procedures with a focus on the intended use of the meter[13,14] (see above). Evaluation must take the following into account:

- Cleaning and disinfection solutions and procedures must not lead to physical deterioration of the overall device or of any device component. The disinfection solution should be effective against HIV, HBV and hepatitis C. For example, 70% ethanol solutions are not effective against viral blood borne pathogens and the use of 10% bleach solutions may lead to physical degradation of the meter.
- As HBV is the most difficult to kill of the hepatitis viruses, efficacy of the disinfection protocol is recommended to be verified through viral challenge of the material used to manufacture the housing of the meter (viral challenge studies with the actual meter are not required).
- BG meter must be proven to withstand cleaning and disinfection procedures after multiple cleaning and disinfection cycles without compromising the analytical performance of the meters. The related tests should simulate the actual lifetime of the BG monitoring systems.
- The meter port (i.e. where the test strip is inserted) is highly susceptible to blood contamination. Thus, the port requires special attention by cleaning and disinfection procedures.
- Disinfectants should not cloud the face/display of the BG meter and should not corrode or erode the plastic housing or buttons.

In Europe, however, specific requirements for disinfection of medical devices do not exist. Manufacturers of reusable medical devices are only requested by the *in-vitro* diagnostic directive (98/79/EEC) to supply clear decontamination instructions[15]. Appropriate cleaning and disinfection methods shall be clearly described.

Examples of disinfection procedures

Two studies carried out on the Accu-Chek Active BG meter may serve as a model for the evaluation of cleanability and disinfectability. The studies were performed to assess the effectiveness of a manual cleaning and, respectively, disinfection process in scope of the

validation of reprocessing processes of reusable medical devices. First, potential areas for blood contamination of the meter were evaluated. Based on the type of use, different patterns were found. In the course of the studies, a challenge suspension was transferred to the identified "critical" areas.

The first study was performed to analyze cleanability. It was based on the ASTM (American Society for Testing and Materials) standard test method E-2314-03[16]. Test meters were contaminated with a mixture of >10^6 Colony Forming Units (CFU) of Bacillus atrophaeus spores and organic soil, simulating thereby contamination caused by the intended use of the device. Subsequently, 5 test meters were processed according to the manufacturer's cleaning instructions. Two devices served as controls. They were not subjected to the cleaning process instruction. For cleaning, after separating the test strip holder from the device, a lint-free tissue was moistened by applying 12 ml of demineralised water. In the next step, the entire outer surface was wiped ≥3 minutes until no residues were visible. The inner part was wiped carefully with respect to potential damage to sensitive parts. The efficacy of the cleaning process was assessed by determining the reduction of bacterial load (= bioburden) on the test meters subjected to the cleaning process in comparison to the bioburden on the control instruments. The procedure was expected to produce a $\log_{10}$-reduction of 2 to 4 in bioburden. Beyond that, apparent organic soil contaminations had to be removed efficiently from the test item[16].

In the cleaning study, in all tested Accu-Chek Active BG meters, the visible organic contaminations were removed efficiently. In 4 of 5 test meters, cleaning resulted into a $\log_{10}$-reduction between 2.16 and 2.91. One meter, however, narrowly missed the goal of a $\log_{10}$-reduction of 2 to 4 in bioburden (1.91 $\log_{10}$-reduction).

The second study investigated disinfectability. It was conducted based on ASTM E1837-96[17] and the FDA guideline "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff"[18]. Accu-Chek Active test meters were contaminated with a mixture of >10^6 CFU of bacteria and organic soil, simulating thereby contamination caused by the intended use of the device. Subsequently, 5 test meters were processed according to the manufacturer's disinfection instructions. Two devices served as controls; they were not subjected to the disinfection process instruction.

For disinfection, the test strip holder was separated from the meter. In the next step, the entire outer surface was wiped for ≥2 minutes with a ready-to-use tissue (70 % isopropyl alcohol, 30 % deionized water). The inner part of the BG meter was wiped carefully in order to avoid damage to sensitive parts. After the disinfection procedure, BG meters were expected to reach at least an intermediate level of disinfection. With a view on ASTM E1837-96, an intermediate level of disinfection corresponded to a 6-log reduction of the mixed suspension of vegetative organisms (P. aeruginosa, S. aureus, E. coli, E. aerogenes) and a 3-log reduction of M. terrae[17].

The applied disinfection process was associated with a $\log_{10}$-reduction >6 for both the mixed suspension of test organisms and M. terrae. In general, the combination of the described cleaning procedure and disinfection procedure resulted in clean and safe Accu-Chek Active BG meters.

In-meter dosing and out-of-meter dosing

Regarding the design of BG meters, a distinction may be drawn between in-meter dosing and out-of-meter dosing. In the latter case, the blood drop is applied to the test strip while this is outside the meter, i.e. before inserting the test strip into the port of the meter. Certain BG meters (e.g. Accu-Chek Active) with an out-of-meter dosing option may thereby support the prevention of cross-contamination and can be expected to be beneficial in multi-patient settings. This assumption is supported by a multicenter study among 12 US hospitals, which evaluated the risk of contamination with in-meter and out-of-meter test strip dosing systems in a point-of-care setting[10].

Practical recommendations for adequate hygiene procedures during BG measurements

Individuals performing BG measurements in multi-patient settings must be aware of basic safe practices to protect against infection transmission. These include the following infection control requirements[1]:

- Wearing gloves during the procedure of BG measurement (as well as any other procedure that involves potential exposure to blood or body fluids) and changing gloves between patient contacts are absolutely essential. Performance of hand hygiene (hand washing with soap and water or use of an alcohol-based hand rub) is recommended immediately after removal of gloves and before touching other medical supplies intended for use on other persons[12].
- Lancing devices for single-patient use (e.g. Accu-Chek Softclix, Accu-Chek Multiclix, Bayer Microlet) should never be used in a multi-patient setting[1]. Even if the lancet is changed between patients, there is a significant risk of blood contamination of the inner or outer surfaces of the device. In a professional environment (hospitals, ICUs etc.), only lancing devices for single-use (such as Accu-Chek Safe-T Pro Uno, Accu-Chek Safe-T Pro Plus or BD Microtainer) should be used.
- Even microscopic amounts of blood on lancing devices or BG meters may lead to the transfer of infectious viral particles from healthcare provider's hands

or gloves into a patient's finger-stick wound. Thus, such devices should only be used in multi-patient settings when absolutely necessary, with absolute imperative adherence to cleaning and disinfection protocols. BG meters should be consistently cleaned and disinfected after each use[1].

- Purchasing decisions should take into account if the manufacturer of the respective devices has proven that disinfectants or cleaning solutions do not cloud the face/display of the BG meter and corrode or erode the plastic housing or buttons. If this is the case, the costs for replacing such meters might outweigh the savings achieved by buying a cheaper meter initially easily.
- If the BG meter is to be used in a multi-patient setting, devices with out-of-meter dosing options might provide an additional benefit due to advantages with regards to cleanability and disinfectability.

Conclusion

Blood glucose meters which are applied in multi-patient settings require special attention for prevention of contamination. Hygiene, cleaning and disinfection procedures are therefore of the utmost importance to prevent the transmission of blood borne diseases. It appears to us that the need for adequate handling of such procedures is not clear to all employees in such setting. First studies on cleanability and disinfectability of glucose meters demonstrate a strong potential for reduction in contamination. Therefore, demonstration that BG meters intended for use in multi-patient settings can be handled appropriately several times is important. In the future, while selecting BG meters such factors should be taken more into account.

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