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ORIGINAL ARTICLE

Effect of Disinfectants on Glucose Monitors

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Abstract

Background:

Monitoring blood glucose levels is an integral part of routine diabetes management. To minimize the risk of transmission of bloodborne pathogens during monitoring, the Centers for Disease Control and Prevention (CDC) recommends that glucose meters be disinfected after each use whenever they are used to test multiple patients. The objective of this study is to assess the compatibility of some common disinfectants with certain blood glucose meter systems.

Methods:

We tested six disinfectants for adverse impact on meter performance or the exterior meter surfaces. The disinfectants tested were 0.525% sodium hypochlorite, 20% 2-propanol and 10% ethanol, 17.2% isopropanol, 55% isopropanol, 70% isopropanol, and hydrogen peroxide. To assess meter performance, we tested OneTouch® Ultra® blood glucose monitoring systems with control solution before and after application of either water or disinfectant. To assess the effect on exterior meter surfaces, we performed a soaking test to simulate long-term exposure to disinfectant.

Results:

Paired *t*-test results showed that the control solution data associated with disinfectant and with water application were not significantly different for each meter type. However, most of the meter types were adversely affected by hydrogen peroxide and/or by the higher concentrations of alcohol-based disinfectants.

Conclusions:

Although none of the six disinfectants affected meter performance, hydrogen peroxide and isopropanol >20% adversely affected the exterior surfaces of the tested meters. When complying with CDC instructions for meter disinfection, users should use caution and choose disinfectants that have been validated by the meter manufacturer.

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Abbreviations: (AMBG) assisted monitoring of blood glucose, (CDC) Centers for Disease Control and Prevention, (FDA) Food and Drug Administration, (HBV) hepatitis B virus, (MSDS) material safety data sheet

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Introduction

Monitoring blood glucose levels is an integral part of routine diabetes management.[1] Typically, capillary blood glucose is sampled via finger stick and measured using a glucometer.

In settings where blood glucose monitoring is performed by a caregiver for one or more patients, termed "assisted monitoring of blood glucose" (AMBG), the risk of transmission of bloodborne pathogens between patients is high when the glucose monitoring equipment is shared.[2]

Despite numerous notifications and written guidance by the Centers for Disease Control and Prevention (CDC) and state health departments regarding procedures to minimize exposure to bloodborne pathogens during diabetes care,[3,4] there have been a significant number of hepatitis B virus (HBV) outbreaks, most frequently in residents of nursing homes and assisted living facilities, where AMBG is commonly practiced.[5–7] Hepatitis B virus is very infectious and can remain viable in occult blood on environmental surfaces for at least 7 days[8–10]; therefore, it may be transmitted between patients more easily than the more fragile human immunodeficiency virus or hepatitis C virus.

Unsafe practices such as using the same finger stick device on multiple patients, sharing glucometers without cleaning and disinfection between uses, failure to wear gloves and to perform hand hygiene by caregivers, failure to adhere to other infection control practices, and lack of compliance with the Occupational Safety and Health Administration Bloodborne Pathogens Standard have been associated with these outbreaks.[2,9,11–12]

In September 2010, in response to the continuing critical public safety risk concerning the risk of transmission of disease from shared use of finger stick devices and point-of-care blood testing devices, the U.S. Food and Drug Administration (FDA) modified its regulatory review for blood glucose monitoring systems and required that manufacturers of such systems provide adequate labeling and instructions for use in AMBG and single-patient use settings.[13] One of several new FDA requirements includes providing validated cleaning and disinfecting procedures for blood glucose monitoring systems. This article focuses on this aspect and documents our early experience on this issue and is not intended to describe the testing that is currently required by the FDA for glucose meter manufacturers. This article also does not represent LifeScan's most recent disinfection testing procedures.

Methods

We tested the OneTouch® Ultra®, Ultra®2, and UltraMini® blood glucose monitoring systems, all of which use OneTouch® Ultra® test strips (LifeScan, Inc., Milpitas CA), for their compatibility with six disinfectants. **Table 1** provides details regarding the tested disinfectants: 0.525% sodium hypochlorite (Gluco-Chlor wipes, Medtrol, Niles, IL), 20% 2-propanol and 10% ethanol (Incidin® Foam, Ecolab GmbH & Co.OHG, Dusseldorf, Germany), 17.2% isopropanol (Caviwipes™, Metrex Research Corp, Orange, CA), 55% isopropanol (Sani-Cloth®, PDI, Orangeburg, NY), 70% isopropanol (RelyOn™, DuPont, Wilmington, DE), and hydrogen peroxide (Oxivir TB™, JohnsonDiversey, Oakville, Ontario, Canada). These disinfectants were

Table 1.
Disinfectants Tested in This Study

Disinfectant	Active ingredient	Manufacturer	EPA registration number
Gluco-Chlor Wipes	0.525% Sodium hypochlorite	Medtrol	69687-1
Incidin Foam	20% 2-Propanol and 10% ethanol	Ecolab GmbH & Co.	N/A
Caviwipes	17.2% Isopropanol	Metrex Research Corp	46781-8
Sani-Cloth Germicidal Wipes[a]	55.0% Isopropanol	PDI	9480-4
RelyOn Disinfectant Wipes	70% Isopropanol	DuPont	60142-3-71654
OxivirTB	0.1–1.5% Hydrogen peroxide	Johnson Diversey	70627-56

EPA, Environmental Protection Agency; N/A, not available.
[a] Sani-Cloth Germicidal Wipes are now called Super Sani-Cloth® Germicidal Disposable Wipes.

selected because they are in widespread use in North America (note: 20% 2-propanol and 10% ethanol is used in Europe). We followed the safe handling practices, as described in the Material Safety Data Sheet (MSDS), and tested each of the disinfectants per manufacturer's instructions for use (e.g., application of the disinfectant and contact time) when we assessed each disinfectant for its effect on glucose meter performance. To assess the impact of each disinfectant on exterior meter surfaces (i.e., exterior plastic surfaces, casings, lenses, buttons, and labels), we performed a materials compatibility test using a prolonged surface contact time. This prolonged exposure allowed us to simulate multiple disinfectant applications and provided the time necessary for fluid surface contact in order to assess disinfectant–surface interaction and degradation (if any) of the meter materials.

Exterior Surface Testing

To test the exterior surface compatibility with each disinfectant, three meters of each type were wrapped in towels soaked with each disinfectant and sealed in plastic bags to help retain moisture. After the 18 h soaking period was completed, each meter was visually compared to the meter soaked in water (control) for the same duration. The result would be pass/fail based upon a visual exterior surface comparison for each meter type. Acceptance criteria for exterior testing were that the exposed surfaces of the meter would not show (1) significant visual degradation of the plastic or rubber parts, (2) gross discoloration of the painted surfaces, and/or (3) permanent stickiness after the 18 h soaking test.

Note: The 18 h test combined a closed environment with excess fluid concentration and so there was (1) potential for fluid ingress into the meter via the test strip port connector and/or battery compartment and (2) potential for vapor penetration into the integrated circuit boards that was above and beyond what would occur during normal disinfectant use. Therefore, possible damage to the meter's internal electronic components or parts was not considered in the acceptance criteria for this test.

Performance Testing

Each meter was wiped with water, dried, tested with normal control solution, and the data recorded. Then each meter was wiped with disinfectant that was allowed to remain in contact with the meter according to the disinfectant manufacturer's instructions. Following application of disinfectant, each meter was again tested with normal control solution and the data were recorded. Safe handling practices, as described in the MSDS for each disinfectant, were followed. This process "water/dry—test—disinfectant—test" was repeated for a total of 10 replicates. The acceptance criterion was that the mean difference of the two sets of 10 readings would not be statistically different at the 5% level of significance (i.e., 95% confidence). Ten readings were presumed to be an adequate number of tests based on the expected number of cleanings that might be performed by customers who tested frequently. However, this number might be high or low depending on the clinical use of the meter (e.g., long-term care setting vs outpatient clinic).

Results

Exterior Testing

There were differences between disinfectants for materials compatibility. The data showed that Gluco-Chlor wipes (0.525% sodium hypochlorite) and Incidin Foam (20% 2-propanol and 10% ethanol) did not adversely affect the exterior surfaces, lenses, or labels of any of the meters. Caviwipes (17.2% isopropanol) interacted with the rubber on the up-and-down arrow key of the UltraMini meter, but the disinfectant did not produce any other noticeable issues with the meter exterior surfaces.

However, all meters were found to have exterior materials and/or finishes that were sensitive to >20% alcohol-based and hydrogen peroxide-based disinfectants.

Sani-Cloth Germicidal Wipes (55% isopropanol), RelyOn Disinfectant Wipes (70% isopropanol), and OxivirTB (hydrogen peroxide) caused significant paint peeling, screen failure, rubber arrow key breakdown, and/or paint peeling. Screen failure was observed as spots (or raised dots) or adhesion of the towel material onto the screen such that the screen became unreadable.

Performance Testing

Table 2 shows the results of the performance testing of one tested meter of each type. The control solution results of a water testing closely approximated the results of disinfectant testing, and none of the differences were statistically significant as assessed by paired *t*-test.

Discussion

The ideal disinfectant for medical devices would have the following characteristics (1) safe for use around humans and the macro environment, (2) economical, (3) broad spectrum of antimicrobial activity, (4) surface and device materials compatibility, (5) long shelf life, (6) ease of use,

(7) short contact time without chemical residue, and (8) no off-gassing or volatile organic compounds.[14]

In our study, although 10% bleach and mild alcohol-based products did not cause any damage to the glucose meters, higher concentrations of hydrogen peroxide and alcohol did cause significant damage to the exterior surface plastics and other materials. We did not test the efficacy of each disinfectant. It is recommended that customers adhere to meter manufacturer's instructions regarding device cleaning and use only validated disinfecting agents.

None of the disinfectants affected glucose response. Several studies have reported that a hydrogen peroxide-based disinfectant adversely affected a hospital glucose meter with a glucose oxidase chemical reaction that formed hydrogen peroxide and a chromophore.[15–16] However, exogenous hydrogen peroxide is not expected to affect the Ultra test strip because this test strip is not designed to detect oxidizing agents.

For purposes of this study, we assumed that the disinfectants, most of which were approved by the Environmental Protection Agency, did not require proof of efficacy. Rather, we were interested in the material's compatibility and the functional impact of these disinfectants.

Conclusions

Transmission of bloodborne pathogens during blood glucose monitoring, especially in AMBG, is associated with several factors, most notably the lack of adherence to standard precautions and proper infection control methods. Per the CDC's recommendation of meter disinfection after each use in multiple patient settings,[17] we set out to assess the compatibility of disinfectants on certain blood glucose monitoring systems.

The performance data from our study showed that none of the disinfectants adversely affected meter performance. However, hydrogen peroxide and isopropanol >20% adversely affected the exterior surfaces. When complying with CDC instructions for meter disinfection, users should use caution and choose disinfectants that have been validated by the meter manufacturer.

Table 2.
Control Solution Results for Meter Performance Testing

Disinfectant	Meter	CS mean (control)[a]	CS mean (disinfectant)	*P* value
10% bleach	Ultra	114.5	113.4	0.35
	Ultra2	112.9	114.1	0.18
	UltraMini	112.7	112.6	0.91
20% 2-propanol/10% ethanol	Ultra	Not tested		
	Ultra2	126.5	126.9	0.76
	UltraMini	Not tested		
17% isopropanol	Ultra	107.4	108.6	0.36
	Ultra2	112.4	111.1	0.11
	UltraMini	105.0	106.1	0.14
55% isopropanol	Ultra	113.1	111.7	0.13
	Ultra2	109.0	108.2	0.49
	UltraMini	110.6	110.9	0.77
70% isopropanol	Ultra	107.7	109.3	0.18
	Ultra2	109.3	109.1	0.85
	UltraMini	114.4	115.7	0.20
Hydrogen peroxide	Ultra	110.2	109.1	0.36
	Ultra2	111.9	111.4	0.69
	UltraMini	109.5	109.1	0.77

[a] Normal-level control solution test after wiping with water.

Disclosures:

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