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ORIGINAL ARTICLE

"Never Events": Hepatitis B Outbreaks and Patient Notifications Resulting from Unsafe Practices during Assisted Monitoring of Blood Glucose, 2009–2010

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Abstract

Introduction:

Despite sustained public health efforts to publicize the risk of hepatitis B virus (HBV) infection outbreaks during assisted monitoring of blood glucose (AMBG), outbreaks continue to occur. Here, we highlight several outbreaks and patient notifications due to AMBG, discuss prevention initiatives, and highlight gaps that remain.

Methods:

We reviewed available data and information from investigations of health care-associated HBV infection outbreaks and patient notification events associated with AMBG in the United States between 2009 and 2010.

Results:

Four HBV infection outbreaks were reported, all in assisted living facilities. Common infection control breaches included use of reusable finger stick devices, which are intended for personal use, on multiple persons; use of BG meters for more than one person without cleaning and disinfection between each use; and comingling of contaminated and clean equipment and supplies. Twenty-nine (88%) of the 33 residents who acquired acute HBV infection as part of these outbreaks received AMBG. Compared with those who did not, residents undergoing AMBG had significantly increased risk of acquiring acute HBV infection (relative risk: 27.7, 95% confidence interval: 10.3 to 74.4). During two patient notifications, approximately 320 persons were recommended to undergo bloodborne pathogen testing after being placed at risk for exposure to another person's blood when personal-use multilancet finger stick devices were selected for use on multiple persons.

Conclusions:

Misperception on the risk for bloodborne pathogen transmission and confusion regarding selection and appropriate use of BG monitoring devices for AMBG remain a problem. In addition to public health outreach and infection control recommendations, clear labeling, packaging, instructions for device use, and appropriate device marketing will assist in infection prevention efforts.

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Abbreviations: (AMBG) assisted monitoring of blood glucose, (BG) blood glucose, (CDC) Centers for Disease Control and Prevention, (CI) confidence interval, (CMS) Centers for Medicare and Medicaid Services, (FDA) Food and Drug Administration, (HBV) hepatitis B virus, (HCV) hepatitis C virus, (HIV) human immunodeficiency virus, (RR) relative risk, (SMBG) self-monitoring of blood glucose

Keywords: blood glucose monitoring, hepatitis B, infection, patient safety, prevention

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Introduction

Self-monitoring of blood glucose (SMBG), in which individuals perform all steps of testing for themselves, is a mainstay for management and prevention of diabetes-related complications and is commonly practiced. Estimates from a nationally representative survey indicated that 66% of persons diagnosed with diabetes perform SMBG at least once daily.[1] An alternative to SMBG is assisted monitoring of blood glucose (AMBG), defined as BG monitoring that is performed for one or more persons with diabetes by either a health care provider or other caregiver.[2] Assisted monitoring of BG can supplement SMBG, for example, when provided in hospitals, physicians' offices, or schools. Or, it may supplant SMBG altogether. A prime example is residents of nursing homes or assisted living facilities (also known as residential care homes) who, due to physical or mental health limitations, are no long able to perform SMBG.

While fundamentally similar to SMBG, the provision of AMBG services, typically performed serially for multiple persons, must incorporate additional safety measures to effectively prevent the spread of infections among AMBG recipients. There exists a long history of hepatitis B virus (HBV) infection outbreaks in the United States and elsewhere due to poor infection control practices while delivering AMBG to multiple persons.[3–8] Outbreak investigations have clearly illustrated that opportunities for bloodborne pathogen transmission exist when equipment used for AMBG is not dedicated for individual patient use (i.e., finger stick devices) or not cleaned and disinfected between each use (i.e., BG meters). Despite sustained efforts to publicize this risk and recommended prevention practices,[4,9–10] HBV infection outbreaks continue to occur in settings where AMBG is provided, therefore, additional partners in the prevention effort are needed.

In this article, we review several HBV infection outbreaks and patient notification events reported in the United States during the delivery of AMBG, discuss prevention initiatives, and highlight gaps that remain.

Methods

We reviewed published articles (PubMed search), conference abstracts, and outbreak investigation reports made available by state or local investigators to the Centers for Disease Control and Prevention (CDC) of confirmed HBV infection outbreaks associated with the delivery of AMBG in the United States between 2009 and 2010, the 2 years that follow a published review of this type.[8] For the same 2-year time period, we also reviewed media reports (using Google Alerts) of patient notification events due to potential exposure to another person's blood during receipt of AMBG.

An outbreak of HBV infection was defined as ≥2 persons with newly acquired HBV infection epidemiologically linked to the receipt of AMBG performed by a common provider or in a common facility or setting. In each investigation, persons were determined to have had outbreak-associated HBV infection on the basis of evidence that included epidemiologic investigation findings, documented positive hepatitis B serology that was consistent with acute (recently acquired) infection,[11] presence of signs and symptoms of acute hepatitis or clinical diagnosis, and absence of a past history of HBV infection or competing risk factors (e.g., injection drug use, high risk sexual behaviors). Furthermore, epidemiologic studies to identify significant risk factors for infection were performed by investigators on the cohort of persons with acute HBV infection or who were susceptible to HBV infection (i.e., persons with chronic HBV infection or immunity to HBV infection were excluded).

For each outbreak we summarize the setting in which it occurred, describe the specific practices investigators identified that contributed to infection transmission, the number of persons tested, the number found to have acute HBV infection stratified by receipt of AMBG, and report the relative risk (RR) and 95% confidence interval (CI) as a measure of association between receipt of AMBG and acute HBV infection status.

Patient notification events were communications (via letter or press release) that advised bloodborne pathogen testing to a group of patients because of an identified breach in infection control practices[12–13] that occurred during the performance of AMBG. There was no evidence of disease transmission prior to the patient notification. For each patient notification, we summarized the infection control breach that was reported, the setting in which it occurred, and the number of persons who were placed at risk for exposure to another person's blood and recommended to undergo testing for bloodborne pathogens. The number of patients tested and their results were not publicly available and are therefore not included.

Results

Outbreak Summary

During 2009 and 2010, four HBV infection outbreaks associated with AMBG were investigated and reported.[14–17] All four occurred in assisted living facilities where multiple residents were receiving AMBG. Overall, testing for bloodborne viruses was performed for 279 consenting residents; 33 (11.8%) were diagnosed with acute HBV infection and 9 (3.2%) additional residents were diagnosed with chronic HBV infection. Epidemiologic cohort studies (including only residents with acute HBV infection and those susceptible to HBV infection) performed as part of each investigation identified that receiving finger sticks for BG monitoring was the leading risk factor associated with acute HBV infection status (**Table 1**). While insulin administration was found to be a significant risk factor for acute HBV infection in one investigation,[17] in general, other potential risk factors that were assessed, including receipt of other medical procedures (e.g., podiatry or dental care), sexual activity, or having a roommate with HBV infection, were not found to be significantly associated with acute HBV infection status. For the four studies combined, the acute HBV infection attack rate among residents receiving AMBG was 67% (29/43 residents) compared to just 2.4% (4/164 residents) for those not receiving AMBG (RR: 27.7, 95% CI: 10.3 to 74.4). Among those not receiving AMBG, at least two acute HBV infections were thought to be secondary transmission due to sexual contact with another HBV-infected resident. In one outbreak,[14] all 8 residents undergoing AMBG and diagnosed with acute HBV infection were hospitalized, and 6 (75% case fatality rate) died from hepatitis-related complications.

Personnel directly employed by the facility were performing AMBG for residents[14–16] in three of the outbreaks. In the other outbreak,[17] AMBG services were provided to residents by nursing personnel from a home health agency. As part of the public health investigation, review of local disease surveillance data identified an additional case of acute HBV infection in a resident receiving AMBG at a second assisted living facility.[17] Further investigation revealed the second assisted living facility was operated by the same owner as the first, and AMBG services were provided by the same home health agency.

Single-use, autodisabling finger stick devices were not used to perform AMBG in any of the facilities where outbreaks occurred. No evidence of lancet reuse was identified by public health officials, however, in two investigations,[14,16] the same reusable finger stick device was determined (by investigator observation or self-report by personnel in the facility) to have been used for multiple residents. In another investigation,[17] shared use of reusable finger stick devices was not identified. However, potentially contaminated finger stick devices and glucose meters were stored together with clean supplies, resulting in opportunities for cross-contamination. Investigators identified visible blood on several glucose meters and on a reusable finger stick device. In two investigations,[14,16] BG meters

Table 1.
Analysis of Data from Epidemiologic Studies Conducted among Residents of Assisted Living Facilities during HBV Infection Outbreak Investigations Found to Be Associated with AMBG—United States, 2009–2010

State (reference)[a]	Total number of residents tested	Residents included in epidemiologic study[b]				RR (95% CI)
		Receiving AMBG		Not receiving AMBG		
		Tested	Acute HBV infection (%)	Tested	Acute HBV infection (%)	
NC (14)	61	15	8 (53%); 6 died	25	0 (0%)	27.6 (1.7–446.7)
VA (15)	44	5	3 (60%)	26	1 (4%)	15.6 (2.0–121.3)
VA (16)	126	13	12 (92%)	75	2 (3%)	34.6 (8.7–137)
FL (17)	48	10	6 (60%)	38	1 (3%)	22.8 (3.0–168.3)

[a] NC = North Carolina; VA = Virginia; FL = Florida
[b] Includes only residents with acute HBV infection and those susceptible to HBV.

were being used for multiple persons without performing cleaning and disinfection of device surfaces between each finger stick procedure.

In one investigation, investigators failed to identify a clear breach in recommended infected control practices when performing AMBG.[15] Reusable finger stick devices were in use but personnel denied having used them on more than one person and stated that BG meters were not routinely shared. It was reported that the facility had an extra meter for use when residents ran out of test strips, which was used for multiple persons. Epidemiologic data from this investigation did strongly suggest an association (**Table 1**) between development of infection and receipt of finger sticks. Of note, around the time of this outbreak, a facility staff member was diagnosed with acute HBV infection, prompting testing of facility personnel and identification of an additional staff member with acute HBV infection. Both were involved in providing AMBG and had not received hepatitis B vaccine. Investigators identified that after performing AMBG, personnel manually removed the used, exposed lancet from the finger stick device and disposed of it in a sharps container, thus placing themselves at risk for exposure via a sharps injury.

Patient Notification Summary

During 2009 and 2010, two patient notification events resulting from unsafe practices during AMBG were identified. Both events were linked to multipatient use of a finger stick device that was intended and approved only for single-patient use. In both instances, these devices were of a design that utilized preloaded cartridges containing multiple lancets. One patient notification was initiated among patients who had undergone AMBG at a community health center after personnel noted that the lancet had not retracted correctly and could have been reused on another patient.[18] This type of personal-use finger stick device (i.e., neither intended nor approved for use on more than one person), had incorrectly been selected for use at this health care facility and used on multiple patients for more than 6 months before the patient notification was initiated. In total, 283 patients received AMBG at least once with this device and, due to their risk of exposure to another person's blood, were recommended to undergo testing for HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

The second patient notification event, involving a similar device inappropriately selected for multiple person use, occurred among persons who underwent free diabetes screening provided by physician assistant students at a health fair.[19,20] During the delivery of AMBG at the fair, students realized they had failed to advance the lancet while using the finger stick device for multiple persons, prompting concerns about the potential for bloodborne pathogen transmission. Names and records of persons who received AMBG had not been kept but it was estimated that approximately 60 persons had undergone testing with this device. Public health authorities used a local media campaign to notify persons who had undergone AMBG at this fair of the increased risk of exposure to the blood of others and the recommendation to undergo testing for HBV, HCV, and HIV infection.

Discussion

During 2009 and 2010, unsafe practices during AMBG resulted in at least four HBV infection outbreaks and two patient notification events in the United States. This is despite clear guidance from the CDC[4,9–10] and numerous publications outlining the risks and recommendations for infection prevention. The summary of outbreak data from epidemiologic studies performed during these public health investigations showed that persons receiving AMBG were at increased risk of becoming newly infected with acute HBV infection relative to those who did not receive AMBG. Furthermore, in one outbreak, 6 persons died from the resulting hepatitis complications.[14] Hepatitis B virus infection outbreaks due to infection control breaches and equipment misuse during the delivery of AMBG have been identified with increasing frequency over the past few decades.[3–10] Increasing prevalence and diagnosis of diabetes among the aging U.S. population[21,22] along with increasing reliance on AMBG services indicate that there will be a growing at-risk population. There is a need for renewed and improved prevention efforts.

There are several limitations to this review. First, we included only published outbreaks and reported patient notification events; the number of unreported outbreaks and patient notification events are not known. However, detection and investigation of health care-associated viral hepatitis outbreaks is haphazard: a large proportion (50–70%) of adults with acute HBV infection are asymptomatic;[8,11] underdiagnosis and underreporting of acute HBV infections is common;[23] and investigations can be lengthy and resource-intense. Therefore, the numbers presented here are certainly underestimates. Second, a specific infection control breach during AMBG was not clearly identified in one outbreak facility.[15] Practices and conditions present at the time of transmission may have changed prior to the investigation (performed months later), and staff naturally perform to their best when

under observation by public health officials. Nevertheless, both having diabetes and receipt of AMBG were the only significant risk factor identified for acquiring acute HBV infection. Third, estimates of attack rates and risk of infection due to AMBG may not be accurate as persons present in the facility at the time of transmission may not have been present at the time of investigation. Finally, compared to the number of persons diagnosed with diabetes, the number of persons affected during these outbreaks and patient notification events may appear small. However, these outbreaks and patient notification events are entirely preventable. As with wrong-site surgery, infection control errors such as the use of a finger stick device for more than one person during AMBG should be considered as "never events."

Unfortunately, deficient practices during delivery of AMBG are not only identified during outbreak investigations. Surveys conducted in 166 facilities (including nursing homes, assisted living facilities, and ambulatory surgical centers) found that between 7 and 21% of facilities reused finger stick devices for multiple patients.[24–26] Furthermore, 32 to 73% of surveyed facilities were sharing BG meters without cleaning and disinfection between each use. Following a series of five HBV infection outbreaks in 3 years due to AMBG in the United Kingdom,[6] a series of informal surveys conducted observed that incorrect use of finger stick devices was widespread in a range of health care settings. Patient safety can be maintained through adherence to the recommended infection control practices such as cleaning and disinfection of shared BG meters, appropriate use of gloves, and adherence to hand hygiene. However, critical to this process is appropriate device selection such as the use of single use, autodisabling lancing devices for AMBG that provides safety to the AMBG recipient and the provider.

Misperception regarding the potential for bloodborne pathogen transmission and confusion in the selection of devices appropriate for performing AMBG are common themes among the summarized outbreaks and patient notification events. For example, in both patient notification events, it was only after a malfunction of the finger stick device that personnel considered the need for patient notification. However, the reusable finger stick devices should never have been used for more than one person in the first place. Even with a new lancet for each patient and without device malfunction, blood contamination of the inner or outer surfaces of the finger stick device poses a substantial risk to patients.[8] Investigators from the United Kingdom similarly concluded that confusion regarding the correct use of BG monitoring equipment was a contributing factor to HBV transmission.[6] They reported that models intended for self-use (i.e., SMBG) and professional use (i.e., AMBG) were very difficult to distinguish from one another and that the manufacturer's information that accompanies devices was often unclear. Ultimately, the accountability for providing safe care rests with the facilities and personnel who are providing AMBG. However, these findings highlight the unique role for the diabetes technology industry in national prevention efforts. The creation of clear labeling, packaging, instructions for device use, and marketing of devices intended for personal and professional use will help to inform AMBG providers and reduce common misperceptions and confusion regarding appropriate and safe device selection and use.[27]

Since the earlier review of this type,[8] several prevention activities to assure compliance with safe practices during AMBG have been initiated at the federal level. In May 2010, the CDC hosted a meeting bringing together federal and industry partners to discuss strategies and opportunities for prevention in this area.[28] Following this meeting, the CDC and the Food and Drug Administration (FDA) released clinical alerts reminding personnel that finger stick devices must never be used for more than one person.[27,29] The CDC also updated its Web-based materials summarizing recommended practices and responses to frequently asked questions.[30,31] In addition, the FDA released guidance for manufacturers on recommended labeling of blood lancet devices[32] and alerted manufacturers to the revised process for evaluating and approving BG monitoring devices to better address infection prevention needs. Changes included the need for manufacturers to provide clear labeling of single-patient use devices and validated instructions for cleaning and disinfecting meters.

Surveyors for the Centers for Medicare and Medicaid Services (CMS) are also paying increased attention to infection control practices related to AMBG during facility inspections. In ambulatory surgical centers, surveyors are using an infection control audit tool that specifically targets handling of BG monitoring equipment. Furthermore, the CMS has issued updated guidance to nursing home surveyors, referencing materials from the CDC and the FDA that describe appropriate citation of identified breaches in infection control during AMBG.[33] However, the reach of the CMS does not extend to the arena of assisted living except in a limited manner (e.g., through regulation of CMS-certified home health agencies) since assisted living facilities are regulated and licensed at the state level. Certainly, the same standard of care for

providing AMBG should be required in assisted living facilities but individual states will have to act to establish such equitable standards.

Outbreak activity and patient notification events indicate patients are continuing to be placed at unacceptable risk for acquiring bloodborne viral infections during receipt of AMBG. Renewed prevention efforts are needed. Confusion regarding the selection and use of finger stick devices and BG meters intended for either SMBG or AMBG persists. Attention to improving the labeling, packaging, instructions for device use, and device marketing from diabetes technology and manufacturing industry partners will be helpful to better assist providers with the selection and use of devices that are safe and appropriate for AMBG.

Disclosures:

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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