

## Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Technologies

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### Abstract

#### **Background:**

As part of routine diabetes care, capillary blood is typically sampled using a finger-stick device and then tested using a handheld blood glucose meter. In settings where multiple persons require assistance with blood glucose monitoring, opportunities for bloodborne pathogen transmission may exist.

#### **Methods:**

Reports of hepatitis B virus (HBV) infection outbreaks in the United States that have been attributed to blood glucose monitoring practices were reviewed and summarized.

#### **Results:**

Since 1990, state and local health departments investigated 18 HBV infection outbreaks, 15 (83%) in the past 10 years, that were associated with the improper use of blood glucose monitoring equipment. At least 147 persons acquired HBV infection during these outbreaks, 6 (4.1%) of whom died from complications of acute HBV infection. Outbreaks appear to have become more frequent in the past decade, primarily affecting long-term care residents with diabetes. 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 spring-loaded finger-stick devices on multiple persons and the sharing of blood glucose testing meters without cleaning and disinfection between uses.

#### **Conclusion:**

Hepatitis B virus infection outbreaks associated with blood glucose monitoring have occurred with increasing regularity in the United States and may represent a growing but under-recognized problem. Advances in technology, such as the development of blood glucose testing meters that can withstand frequent disinfection and noninvasive glucose monitoring methods, will likely prove useful in improving patient safety.

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**Abbreviations:** (CDC) Centers for Disease Control and Prevention, (HBV) hepatitis B virus, (HCV) hepatitis C virus, (HIV) human immunodeficiency virus, (LTC) long-term care

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## Introduction

Monitoring blood glucose is an essential component of diabetes management, helping patients to maintain glycemic control and preventing both acute and long-term complications.<sup>1-3</sup> Typically, capillary blood is sampled using a finger-stick device and then tested using a handheld blood glucose meter. In general, this equipment is designed to be convenient for individual self-monitoring of blood glucose levels. However, a well-documented,<sup>4-10</sup> yet under-acknowledged risk associated with blood glucose monitoring is the transmission of bloodborne viral pathogens such as hepatitis B virus (HBV)—a serious and potentially life-threatening infection.<sup>11,12</sup> This can occur when blood glucose monitoring equipment is shared, resulting in inadvertent exposure to blood from an infected person.<sup>4-8,13-15</sup> Not surprisingly, the risk for this type of transmission is higher in settings where multiple persons require assistance with blood glucose monitoring. Finger-stick devices, blood glucose testing meters, or even a health care worker's hands may all become vehicles for indirect transmission of viruses if they become contaminated with blood. Since HBV is highly infectious and environmentally stable, even invisible amounts of blood are sufficient to spread infection.<sup>4,16-18</sup>

In the United States, recommendations for preventing the transmission of hepatitis viruses by restricting the use of spring-loaded finger-stick devices for individual use were first developed in 1990.<sup>4</sup> Expanded prevention recommendations, specifically directed toward long-term care (LTC) settings (e.g., nursing homes and assisted-living facilities) were summarized and published in a 2005 Centers for Disease Control and Prevention (CDC) report.<sup>8</sup> Despite these recommendations, outbreaks of HBV infection among LTC residents with diabetes continue to occur.<sup>14,15</sup> This article summarizes relevant outbreak experience in the United States since 1990 to help raise awareness of infection risks involving blood glucose monitoring and to highlight the vital role that diabetes technology can play in preventing unnecessary morbidity and mortality from bloodborne infections.

## Methods

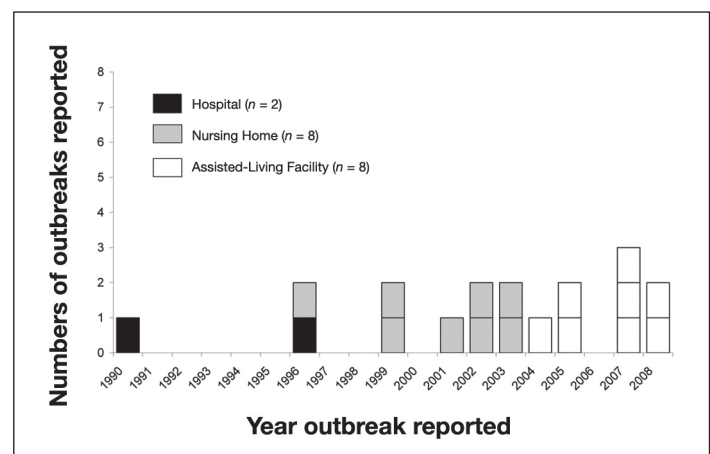
We reviewed published articles and unpublished reports at CDC to identify outbreaks in the United States that involved HBV transmission associated with blood glucose monitoring. Our review extended back to 1990, when the problem was first identified in the United States.<sup>4</sup> For each outbreak we summarized the number of persons

with newly acquired HBV infection, the setting in which the outbreak occurred, and the identified or purported transmission mechanisms.

An outbreak of HBV infection was defined as two or more persons with newly acquired HBV infection epidemiologically linked to the receipt of blood glucose monitoring in a common facility. Since newly acquired HBV infection is often asymptomatic, the investigations usually involved targeted testing of persons in a particular ward or unit or with selected conditions (e.g., diabetes) or exposures (e.g., finger sticks). 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 (newly acquired) infection, or signs and symptoms of acute hepatitis and the absence of competing risk factors (e.g., injection drug use and high-risk sexual behaviors) or a past history of HBV infection.

## Results

Since 1990, 18 outbreaks of HBV infection associated with blood glucose monitoring were identified and investigated in the United States. Each outbreak occurred in a setting where multiple persons were undergoing regular blood glucose monitoring. While the earliest reports involved acute care hospitals, a notable shift occurred toward LTC settings, beginning with skilled nursing homes and, most recently, assisted-living facilities (**Figure 1**).<sup>4-8,13-15</sup>



**Figure 1.** Reported outbreaks of HBV infection associated with blood glucose monitoring in the United States, 1990–2008.

The outbreak investigations were led by state and local health departments, usually with assistance from the CDC. During these investigations, 147 persons (median 7 persons per outbreak, range 2 to 26) were found to represent newly acquired cases of HBV infection. While the initial HBV-infected persons identified in each outbreak typically had classic signs and symptoms of acute viral hepatitis (e.g., jaundice), the majority of infected persons were asymptomatic and were only identified through targeted serologic testing. Most were elderly and did not report the typical risk factors for acquiring HBV infection in the United States (e.g., injection drug use and high-risk sexual behaviors).<sup>6,7,13</sup> Hepatitis B virus infections occurred almost exclusively among persons with diabetes ( $n = 140$ , 95%), but several persons undergoing blood glucose monitoring for other reasons and persons with close contact with infected persons were occasionally identified as having acquired HBV infection. Significant morbidity and mortality was evident<sup>7,8,14</sup> and was occasionally the event that prompted outbreak recognition or reporting to public health authorities. In all, 6 (4.1%) persons were known to have died from acute HBV infection or had acute HBV infection listed as a contributing cause of death on their death certificates. In some of the investigations, the prevalence of chronic and resolved HBV infection was higher than expected among residents undergoing blood glucose monitoring,<sup>5-8</sup> suggesting ongoing transmission prior to outbreak recognition and possible undercounting of the true numbers of outbreak-associated cases. Finally, follow-up testing to determine whether infected persons resolved or went on to develop chronic HBV infection was recommended by investigators, but these results were not systematically collected or reported.

Using combinations of epidemiologic methods (e.g., case-control or cohort studies) and observational assessments of infection control practices, the public health investigations of these outbreaks identified person-to-person spread as the most likely mechanism of HBV transmission. While other diabetes care or patient care procedures (e.g., insulin delivery) were sometimes statistically associated with acute HBV infection status, blood glucose monitoring clearly dominated as a risk factor for infection.<sup>5-8,13</sup> In 12 outbreaks (67%), spring-loaded finger-stick devices were used for multiple persons and were considered to represent the most likely vehicle for transmission. Typically, these finger-stick devices appeared to be the types designed and marketed for individual patient use during self monitoring of blood glucose levels. Overt reuse of the lancet itself was not clearly identified in any investigation. However, disposable endcaps that house the

lancet were reused in some of the outbreak facilities or, in some instances, used and unused endcaps were typically stored together. In all the outbreaks, blood glucose testing meters were shared by multiple persons without cleaning between uses, including five outbreaks in which reusable spring-loaded finger-stick devices were not present (i.e., single-use safety lancets were used exclusively).

A number of investigations also noted deficiencies among staff regarding the wearing or changing of gloves and the performance of appropriate hand hygiene between finger-stick procedures. Likewise the common storage of clean and used equipment and supplies was recognized as a contributing factor in several outbreaks. In every investigation, recommendations for safe practices (e.g., discontinuing the use of shared finger-stick devices and consistent cleaning and disinfection of blood glucose testing meters) were implemented, after which HBV transmission ceased.

## Discussion

This review demonstrates that person-to-person transmission of HBV infection during blood glucose monitoring has been documented repeatedly since 1990. In each outbreak HBV transmission resulted from sharing blood-contaminated equipment. For example, transmission was frequently associated with sharing of spring-loaded finger-stick devices that were intended for individual use. Even when the endcap and lancet on these devices was changed, the barrel may have become contaminated with blood and resulted in exposure of subsequent patients. Similarly blood glucose testing meters were shared in these outbreaks but were not adequately cleaned between uses. A multicenter survey of blood glucose testing meters in routine use in hospital settings showed that 30% had blood detectable on their surfaces, and those with on-meter test-strip dosing format were associated with significantly higher rates of contamination.<sup>19</sup> Blood-contaminated devices provide opportunities for the transfer of infective viruses into the finger-stick wound of a susceptible person when the device is brought in contact with the patient or via contamination of a health care worker's hands.

Despite explicit recommendations for preventing blood-borne pathogen transmission during diabetes care,<sup>4,8</sup> HBV infection outbreaks have continued to occur. Of additional concern is the fact that the frequency of these outbreaks appears to have increased: five were identified and reported from 2006 to 2008. This trend will likely continue in the absence of appropriate prevention measures and technological advances.

One challenge is that equipment designed for personal use might be marketed or selected for use in health care settings despite the availability of safer alternatives. For example, many of the outbreaks we summarized involved multiuse spring-loaded finger-stick devices, despite the widespread availability of disposable safety lancets that permanently retract after a single use. Insulin pens provide another example of the potential for bloodborne pathogen transmission when these devices, designed for individual use, are inappropriately used for multiple patients. Two reports of insulin pens being used on multiple patients in hospitals suggest this is an emerging issue that warrants attention from the diabetes technology community.<sup>20,21</sup> In one incident over 2000 patients had to be notified and advised to undergo testing for HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

The main limitation of this review is that it likely under-represents the burden of bloodborne infections attributed to poor blood glucose monitoring and diabetes care practices. First, most (50–67%) adults newly infected with HBV are asymptomatic,<sup>10</sup> and thus many infections are unrecognized and go undiagnosed.<sup>12</sup> Second, health care is under-recognized as a mode of viral hepatitis transmission in the United States,<sup>22</sup> and the receipt of diabetes care may be overlooked as a risk factor for infection, particularly among elderly LTC residents.<sup>8,18</sup> Third, because outbreak investigations have not prospectively followed the health outcomes of infected persons, the long-term hepatitis B morbidity and mortality among this vulnerable population is not known. Nonetheless, our review did find a striking 4.1% mortality rate among those with outbreak-associated HBV infection, demonstrating the considerable impact of acute hepatitis B disease among older persons. Considering these factors, the outbreaks summarized here likely underestimate the magnitude of the true burden of HBV infections attributable to unsafe diabetes care practices. Another limitation is that the information needed to determine a denominator of the persons potentially exposed during these outbreaks was not uniformly reported, thus the risk of infection could not be estimated. It is essential, however, to remember the expected number of infections transmitted during blood glucose monitoring should be zero, as the receipt of health care should not be a risk factor for acquiring bloodborne pathogens.<sup>22</sup>

Nursing homes and assisted-living facilities have been the primary setting for HBV transmission during diabetes care. These settings are heterogeneous with

respect to their resident populations and levels of health care, nursing care, and physician input.<sup>23</sup> One common characteristic is that residents of these facilities are typically elderly and require assistance with management of chronic medical conditions. For example, approximately one-fourth of nursing home residents have diabetes, and the typical facility performs hundreds of glucose monitoring procedures each week.<sup>24,25</sup> Compared to acute care hospitals, these facilities have less well-trained staff, fewer resources, and less infection-control training and oversight.<sup>23,26–28</sup> Yet hospital patients may also face increasing risks in association with increasing reliance on blood glucose monitoring.<sup>29</sup> Given these ongoing challenges, prevention efforts will need to go beyond staff education, training, and oversight to include more of a focus on design and safety-engineered equipment.

Diabetes technology advancements can aid the effort to prevent bloodborne pathogen transmission among persons receiving diabetes care. The potential impact of appropriate technologies is exemplified by development and adoption of engineering controls (e.g., safety devices) to reduce occupational needlestick injuries and bloodborne virus infections among health care personnel.<sup>30,31</sup> Advances in diabetes technology to provide safer devices or to eliminate the need for percutaneous finger-stick procedures is much needed. Possible examples include further development of finger-stick devices and insulin pens that prevent use for multiple persons and blood glucose testing meters designed specifically for institutional use that feature off-meter test-strip dosing to reduce contamination potential and that can withstand frequent cleaning and disinfection. In addition, diabetes technologies such as noninvasive glucose monitoring methods hold further promise that the need for finger-stick procedures may be substantially reduced or eliminated altogether.

Prevention efforts derived from advances in diabetes technology that can provide safer blood glucose monitoring equipment and noninvasive glucose monitoring technologies are likely to have broad utility and a far-reaching impact. The problem of person-to-person HBV transmission among diabetes patients in LTC settings described here is not unique to the United States. Hepatitis B virus infection outbreaks of this nature have also been described and documented in France,<sup>32</sup> Canada,<sup>33</sup> the United Kingdom,<sup>34</sup> Germany,<sup>35</sup> Poland,<sup>36</sup> the Netherlands,<sup>37</sup> Belgium,<sup>38</sup> and Japan.<sup>39</sup> In addition to HBV, the spread of other bloodborne pathogens such as HCV and HIV may also be possible when blood glucose monitoring equipment or insulin pens are used for more than one person.<sup>9</sup> Indeed, HCV infections



attributed to sharing blood glucose monitoring practices have already been described in France.<sup>40</sup>

The development and adoption of new diabetes technology is of particular importance and urgency, as persons aged 75 years and older are the fastest growing age cohort in the United States, and this population is expected to increase significantly over the next decade.<sup>41</sup> Concurrently the prevalence of persons with diabetes<sup>42</sup> and chronic HBV, HCV, and HIV infections will increase among residents of LTC settings.<sup>9,43</sup>

In summary, persons in hospitals, LTC, and other health care settings—or in group settings such as shelters, schools, and correctional facilities—may face an increased risk for infection from bloodborne pathogens such as HBV when blood glucose monitoring or other diabetes care equipment is improperly handled or shared. Through lack of awareness or failure to follow prevention recommendations, HBV infections associated with poor blood glucose monitoring practices among persons in LTC settings will likely continue to occur—and additional prevention strategies are needed. The diabetes technology community should be cognizant of the risk for bloodborne pathogen transmission when designing devices. Through the development and marketing of safety-engineered equipment, the diabetes technology community can play a significant part in eliminating unnecessary risks and reducing the disease burden from hepatitis viruses.

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