

## “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.

*J Diabetes Sci Technol* 2011;5(6):1396-1402

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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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